PreferredOne®
UPDATE *A Newsletter for PreferredOne Providers & Practitioners*
FEBRUARY 2007

The Role of the Consumer in Health Care

John Frederick, MD, Chief Medical Officer

As 2007 begins, we are growing our business primarily with small employer groups, which are the most challenged in being able to offer health care benefits to their employees. We ended 2006 being able to maintain our enrollment in a very competitive health care market by offering consumer-focused health plans to the small employer groups. Now many large employer groups are following their lead as noted by the recent actions of the financially strapped auto industry. With the majority of our membership in the consumer-directed health plans (CDHP), we are investing much energy in educating members and providers about the real cost of health care services. These efforts will be crucial to the long-term success of PreferredOne

A member in a CDHP, offered by their employer, typically will have a deductible of $3000 to $5000. (Preventative services are frequently exempted from the deductible.) These individuals are very interested and concerned about the costs and quality of the health care services they receive. This "value" information is hard to find in the health care marketplace. Many members will look to their primary physicians for advice. Generally physicians have a bias in naming the "best value" hospital, surgeon, or pharmaceutical. Is there good data to support these conclusions? Actually, this information is becoming more readily available to the consumer.

PreferredOne has conducted market research and has found that members in the consumer- directed health plans will choose their providers for many services based solely on cost. They may assume that the quality is comparable. The cost difference need not be great for patients to choose a different provider of services even over their physician's recommendation. It is important that physicians are aware of their patients' concerns and take the time to understand these issues. PreferredOne is making this information available on our website not only for members but also for providers. This information will be updated in the coming months to reflect the updates in costs of services, contracted rates, and efficiencies of providers. You may access this information on the PreferredOne providers' website at www.PreferredOne.com or by contacting your Provider Relations Representative for access information.

PreferredOne will work aggressively in 2007 to get this cost information to the members to help them make wise decisions. We will proactively approach members who are at risk of needing certain services and give them specific cost information about providers. We will also identify providers of certain services as "preferred" based on their cost, quality, safety, and efficiency. *Page 2...*

In This Issue:

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Many members will have strong financial incentive to use this information because of the design of their health plan benefits. If any of the PreferredOne network providers would like to discuss these issues, share their thoughts, or find ways to show more value to our members, I would be open for the discussion. Please give me a call at 763-847-3051.

One of the areas offering a great opportunity for consumer education is that of CT, MRI, and PET imaging. As you know, some of the local plans are instituting a consultation process prior to ordering a scan for a patient. PreferredOne's approach to the overuse or misuse of good technology is to identify certain imaging providers as "preferred." This is based on their cost, quality, and safety. The first radiology group identified as preferred is the Center for Diagnostic Imaging. We have determined that our members will get more value by having their imaging done at one of the twelve CDI sites. Your patients may request CDI services, and we would hope that you would advise PreferredOne members of CDI's preferred status. These radiologists would also be expected to screen to get the right scan for the patient's needs. We will be identifying other preferred providers of imaging and other services throughout 2007. We feel this approach to the imaging concerns is less intrusive on the provider and will be more effective in the long-term to get the best overall result for our members.

National Provider Identifier (NPI)

NPI Notification

PreferredOne is continuing its preparations to comply with the NPI implementation deadline of May 23, 2007. All providers are required to notify PreferredOne of their Type 1 (individual) and Type 2 (facility) NPIs. Notification can be done using a number of methods:

- XML or Excel version of the ENUF (Electronic NPI Upload File) file
- Provider/Organization NPI Submission Form
- MN Uniform Demographic Change Form
- MN Uniform Credentialing Application

To learn more about the listed methods, please visit www.PreferredOne.com and go to "For Providers".

Please note: PreferredOne will not load provider NPIs from claim submissions. You must use one of the methods listed above.

If you have questions about notifying PreferredOne of your NPI, please contact us at NPI@PreferredOne.com.

Claim Submission

We will be utilizing a "dual ID" strategy which requires the continued use of the PreferredOne-assigned ID (legacy ID), but which allows the provider to begin sending their NPI on claim submissions. We are currently accepting claims with both legacy IDs and NPIs.

Please note: If the place of service is different than the Billing Provider, we will require a Type 2 (facility) NPI on all claim submissions. If you have any questions about the NPI as it relates to claim submissions, please contact Ed Stroot at 763-847-3323, or ed.stroot@preferredone.com.

Electronic Remittance Advice

PreferredOne has the capability to send the HIPAA-mandated 835 transaction (Electronic Remittance Advice) for PCHP and PAS claims (PPO claims are not paid by PreferredOne, and therefore are not included). We currently have EDI connections with the following clearinghouses for the 835 transaction:

- McKesson
- Claimlynx

Other clearinghouses will be added in the future.

Electronic Funds Transfer (EFT) is also available for providers who receive the 835.

If you would like to receive the 835 transaction, please contact your clearinghouse, or you may contact your PreferredOne Provider Relations Representative.

Paper Claim Submission

CMS-1500

The new CMS-1500 Health Insurance Claim Form (08-05 version) has been available for use since October 1, 2006. PreferredOne is accepting the new form. The old form can continue to be submitted until April 2, 2007 at which time it will be discontinued. For more information about the new CMS-1500 (08-05) claim form and to obtain an Instruction Manual, please visit www.nucc.org.

UB-04

PreferredOne will begin accepting the new form on March 1, 2007. We will continue to accept the old (UB-92) form until May 23, 2007. For more information about the new UB-04 claim form, please visit www.nubc.org.

Coding Update

2007 New Codes Added

As communicated in the October 2006 PreferredOne Update, PreferredOne added the new 2007 CPT/HCPCS codes to the fee schedules effective 1/1/2007. However, due to a system constraint, the new fees for the new HCPCS codes for drugs will not be loaded until April 1, 2007. PreferredOne will accept the new drug codes effective 1/1/2007 and pay at the default rates until April 1, 2007. The reimbursement for the new drug codes will be based on PreferredOne standard methodology, using AWP as listed by RJ Health as of December 2006.

The affected codes are: C9232, C9233, C9234, C9235, J0129, J0348, J0364, J0594, J0894, J1324, J1458, J1562, J1740, J2170, J2248, J2248, J2315, J3243, J3473, J7187, J7311, J7319, J7345, J7346, J8650, J9261.

More Coding Updates

PreferredOne has received some claims for 2006 date of service with the 2007 CPT codes. These claims have to be returned for correction, as we cannot process 2006 claims with new 2007 CPT codes.

The following new codes will need prior authorization (not inclusive of all CPT codes):

- 0141T-0143T – Pancreatic islet cell transplantation's
- 0144T-0151T – CT Heart
- 0155T-0158T – Gastric Stimulation
- 0166T-0167T – VSD closure
- 0168T – Rhinophototherapy
- 15830-15847 – Abdominoplasty
- 37210 – Uterine fibroid embolization
- 43647-43648 – Gastric Neurostimulator
- 43881-43882 – Gastric Neurostimulator
- 77371-77372 – Stereotactic radiation treatment
- 91111 – Capsule endoscopy, esophagus
- 19105 – Cryosurgical ablation of fibroadenoma
- 32998 – Ablation of pulmonary tumors
- 83698 – Lp-PLA2
- 95012 – Nitric oxide gas determination
- 96904 – Whole body photography

The following new codes will be considered investigational (not inclusive of all CPT codes):

- 0160T-01611T – Transcranial magnetic stimulation
- 0162T – Gastric neurostimulation
- 0163T – 0165T – Disc arthroplasty
- 22526-22527 – Electrothermal annuloplasty
- 22857-22865 – Disc arthroplasty

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Genetic Counseling

Code 96040 – Medical Genetics counseling – per CPT this code is to be used by trained genetic counselors and is not to be used by physicians. Physicians are to use the appropriate level of E&M codes. PreferredOne has not credentialed genetic counselors in the past, but we are considering this for the near future so that the genetic counselors can submit their claims with their own provider number rather than the supervising MD as we currently require. Please be aware that not all employer groups allow genetic counseling as a benefit.

Anti-Coagulation

Codes 99363 and 99364 – Anticoagulation management – have extensive instruction in CPT regarding frequency of submission. Additional information can also be found in the AMA's 2007 CPT Code Changes book. These codes are for physician use and are not to be used for anticoagulation management by another source (e.g., outpatient pharmacist or nurse anticoagulation clinics).

Common Plantar Warts

Appropriate codes are 17110 and 17111.

HCPCS Changes for January, March and April 2007

Please see the attached spreadsheet (Exhibit A) for the first quarter 2007 changes, deletions and additions after the publication of HCPCS 2007.

3D Rendering Radiology Services

PreferredOne considers all 3D rendering services part of the base CT, MRI or ultrasound service. No additional reimbursement will be made for either the TC or 26 components of CPT 76376 and 76377. Only the base CT, MRI or ultrasound (TC & 26) service will be reimbursed. When the 3D rendering is reported, the remit will reflect provider responsibility for CPT 76376 and 76377 (Exhibit B).

World Insurance

There has been some confusion among Providers regarding policy and group numbers for patients with World Insurance through the PreferredOne PPO Network. World Insurance uses PreferredOne for their individual PPO product. When you submit a claim use the insurance policy number which starts with four zeros in the individual identification field as well as in the group or policy number field. Do not use anything with CA when you submit a claim. This is the product number the person has purchased with World Insurance and is not a form of individual patient identification. If you have any questions or concerns, please contact your Provider Relations Representative.

Medical Management Update

Medical Policy

PreferredOne Medical/Pharmacy Policies and Criteria are available on the PreferredOne website to members and to providers without prior registration. The website address is http://www.PreferredOne.com. Click on Health Resources in the upper left-hand corner and choose the Medical Policy Menu option.

At the Behavioral Health Quality Subcommittee meeting there was continued discussion about criteria used by Preferred One and their delegated entity for behavioral health reviews, Behavioral Healthcare Providers (BHP). It was determined the criteria sets were equitable and each entity will continue to use their own criteria sets. PreferredOne will continue to share with BHP changes made to their criteria sets in order to ensure that equity is maintained.

The Health Services Management (HSM) Quality Management Committee approved three new clinical policy bulletins: CPB-006 Active Care – Therapeutic Exercise , CPB-007 Acute and Chronic Pain, and CPB-008 Multiple Passive Therapies (Exhibits C, D, & E). One policy CPB-005 Electrical Stimulation was retired since it is now addressed in CPB-003 Passive Treatment Therapies. *Page 5...*

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New in the pharmacy area are five criteria sets: PC/A003 Advair Step Therapy, PC/C003 Topical Corticosteroid Step Therapy, PC/H001 HMG-CoA Reductase Inhibitor (HMG) Step Therapy, PC/L003 Lyrica Step Therapy and PC/N002 Nasal Steroids Step Therapy Program (Exhibits F, G, H, I, & J). One pharmacy policy was renamed to PP/C002 Cost Benefit Program, it was originally named PP/C002 Combination Drugs (Exhibit K). Two pharmacy polices were retired: PP/L001 Long-Acting Medications (policy is now addressed in PP/C002 Cost Benefit Program) and PP/U001 Urgent Pharmacy Situations (this policy was already addressed in MP/C003 Criteria Management and Application).

New in the medical/surgical area are six criteria sets: MC/E010 Oncotype DX, MC/F018 Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis, MC/F017 Hip Resurfacing, MC/L004 Coronary Computed Tomography (CT) Angiography, MC/L005 Virtual Colonoscopy, and MC/L006 Wireless Capsule Endoscopy (Exhibits L, M, N, O, P, & Q). There are also two new medical policies: MP/S009 Screening Tests for Patient Specific Situations and MP/S010 Stereotactic Radiosurgery (Exhibits R & S).

The Medical/Surgical Quality Management Subcommittee addressed the following investigational list items:

Effective November 28, 2006

Additions to List:

- Electrothermal Arthroscopic Capsulorrhaphy for all orthopedic Indications
- Platelet Injections for Lateral Epicondylitis

Retired from List:

- Flexitouch Lymphedema System
- Oncotype DX

Effective January 23, 2007

Additions to List:

- Balloon Sinuplasty
- Electrothermal Thoracic Bioimpedance

Retired from List:

- Carionet/Mobile Cardiac Telemetry

The latest Medical, Pharmacy and Chiropractic Policy and Criteria indexes indicating new and revised documents approved at recent meetings of the PreferredOne Quality Management Subcommittee are attached. Please add these documents (Exhibit T, U, & V) to the Utilization Management section of your Office Procedures Manual and always refer to the online policies for the most current version.

If you wish to have paper copies or you have questions feel free to contact the Medical Policy Department at (763) 847-3386 or online at pkreber@preferredone.com.

Affirmative Statement About Incentives

PreferredOne does not specifically reward practitioners or other individuals for issuing denials of coverage or service care. Financial incentives for utilization management decision-makers do not encourage decisions that result in under-utilization. Utilization management decision making is based only on appropriateness of care and service and existence of coverage.

Institute for Clinical Systems Improvement (ICSI)

Health Care Guidelines:

- Adult Low Back Pain
- Domestic Violence
- Routine Prenatal Care
- Initial Management of Abnormal Cervical Cytology (Pap Smear) and HPV Testing
- Menopause and Hormone Therapy (HT): Collaborative Decision-Making and Management
- Preventive Services for Adults
- Preventive services for Children and Adolescents

Prior Authorization of Radiological Procedures

Improvements and new developments in technology have offered many opportunities in medical imaging. Unfortunately the advances in technology also come with an increase in medical costs. A balance needs to be found to allow patients access to tests that are appropriate, but also to prevent over utilization of tests. New criteria or policies have recently been developed to outline when PreferredOne considers certain radiology procedures medically necessary. Medical Policies and Criteria are available on the PreferredOne website to members and to providers without prior registration. The website address is http://www.PreferredOne.com. Click on Health Resources in the upper left-hand corner and choose the Medical Policy Menu option.

The following procedures require prior authorization:

- Coronary Artery Calcium Scoring (see Medical Criteria MC/L002 Coronary Artery Calcium Scoring Without Contrast)
- CT Angiography (see Medical Criteria MC/L004 Coronary CT Angiography)
- Positron Emission Tomography (PET) Scans (see Medical Criteria MC/L001 Positron Emission tomography (PET) Scans)
- Stereotactic Radiosurgery (see Medical Policy MP/S010
- Virtual Colonoscopy (see Medical Criteria MC/L005 Virtual Colonoscopy)
- Wireless Capsule Endoscopy (see Medical Criteria MC/L006 Wireless Capsule Endoscopy)

See also separate article on 3D Interpretation of Imaging in Coding section of this provider newsletter.

Disease Management Update

Accordant

Participation in the Accordant Rare Disease Management Program continues to grow within the PreferredOne membership and 2006 ended with a total enrollment of 460 members. In July of 2006 Crohn's Disease was added as one of the managed programs which contributed to the increase in PreferredOne participation. The majority of the members enrolled in all the diseases managed by Accordant are fully engaged in the program meaning they are actively sharing information with their Accordant specialty nurse and receiving and responding to periodic phone calls and communications.

The diseases managed by Accordant for PreferredOne members are:

- Rheumatoid Arthritis
- Multiple Sclerosis
- Parkinson's Disease
- Lupus
- Myasthenia Gravis
- Sickle Cell Disease
- Cystic Fibrosis
- Hemophilia
- Scleroderma
- Polymyositis
- Crohn's Disease
- Chronic Inflammatory Polyradiculoneuropathy, Demyelinating (CIPD)
- ALS
- Dermatomyositis
- Gaucher Disease

Members are identified through claims data and receive an invitation into the program by an Accordant Enrollment Specialist. Please encourage your PreferredOne members diagnosed with one of these diseases to be open to participating in a worthwhile program.

PreferredOne Healthy Mom & Baby Program

Expectant PreferredOne members have been receiving an invitation to participate in the PreferredOne Healthy Mom and Baby Program since February 2006. Members are identified by claims data and are enrolled by invitation and also self-referral into the program. *Page 7...*

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PreferredOne has contracted with Matria Health Care to administer the program and provide support, information, and initial case management for participating members.

Currently there are:

- 435 active participants
- 76 members have completed the program and received a $25 Target gift card as a thank you from PreferredOne for participating
- 80 members are being and /or have been case managed for conditions such as:
  - gestational diabetes
  - hypertension
  - history of miscarriage
  - history of premature labor
  - diagnosis of a birth defect

The benefits of the program include a 24/7 maternity nurse line, integration of member information with the member's provider and PreferredOne case management, and continual member education by phone, print and web.

Members may call 1-866-721-2229 to enroll.

LifeMasters

Our disease management program for diabetes, CAD, COPD, asthma and CHF is up and running as of October, 2006. We have contracted with LifeMasters Self Supported Care to administer the program. The program is being made available to the total PreferredOne Community Health Plan (PCHP) membership and several PreferredOne Administrative Services (PAS) groups. Members are identified by claims data and receive a letter and phone call from a LifeMasters Enrollment Specialist inviting them to participate. Enrolled members are assigned a LifeMasters nurse who will contact them periodically to inquire about their health status, answer questions and encourage and support them to keep up with their medications and physician visits. The nurse will also alert the member's health care provider and PreferredOne case management of any areas of concern regarding the member's condition.

Membership in the program is currently at 569 participants with the majority enrolled in the CAD and CHF programs.

We are expecting more PAS employer groups to enroll in the LifeMasters program in 2007 and will see an increase in program participation by the end of the year.

Pharmacy Update

2007 PreferredOne Formulary

PreferredOne utilizes the Express-Scripts National Preferred formulary for its members that have Express-Scripts as their Pharmacy Benefit Manager (PBM). This formulary undergoes a complete review annually with all changes taking effect in January of each year. Attached please find the 2007 Express-Scripts National Preferred Formulary (Exhibit W).

Please note that the following medications are also on the 2007 PreferredOne formulary:

- Geodon
- Lipitor
- Xalatan

Pharmacy Website Update

Providers without login access to the PreferredOne website can now view pharmacy benefit information that impacts PreferredOne members.

The PreferredOne Pharmacy Department has added a new link to the PreferredOne web page for providers. Within the "Pharmacy Resources - Drug Formulary" box you can access the following information:

- **2007 Express Scripts National Preferred Formulary** - (This information applies only to those members with Express Scripts as their Pharmacy Benefit Manager)
- **Medication Request Forms –** Contains updated Infertility and Erectile Dysfunction Medication Request Forms
- **Pharmacy Policy & Criteria** *Page 8...*

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- **Guide for providers interested in learning about our on-line Medication Request Form**

Providers are able to request hard copies of this information by contacting the pharmacy department from the email link at the top of the pharmacy information page on the website. That address is pharmacy@preferredone.com.

Medication Request Forms Now Available Online

Medication Request Forms for PreferredOne HMO and TPA members can now be completed and submitted through an on-line process. This new option will not be available for PPO members as pharmacy claims for this population group are not reviewed by PreferredOne.

Accessing the form is as easy as logging into the PreferredOne provider page at www.PreferredOne.com.

Below are the steps you, or anyone from your office staff, need to follow for locating and submitting the on-line form. Please note that each provider office has a "parent login holder" who has the option of logging in for you or setting up a new sub-login/password unique to you. If you are not clear on who your office parent login holder is, or wish to have your own login and password, you can go to www.PreferredOne.com, select Online Resource Center, choose "For Provider" then "Register." Within 5 business days you will receive login and password information.

- Log into the PreferredOne provider site with your user ID and password
- From the main menu window, select "Medication Authorization" from within the green box labeled PCHP/PAS Products
- Search for the appropriate member by entering their member ID and/or name. A list of member names will populate the screen, and the appropriate member can be selected
- As soon as a member has been selected, the Medication Request form will open. The patient's demographic and plan information will be populated for you
- Complete the required fields and submit for authorization
- Submitted requests that include an email address will receive a return acknowledgment that PreferredOne has the request and will act upon it within the standard 48-hour turnaround time.

We at PreferredOne are excited about this new on-line option available to our providers. It is our expectation that utilizing this process will save time for the provider, the member, and PreferredOne.

Pharmacy Information Available Upon Request

A paper copy of any pharmacy information that is posted on the PreferredOne Provider website is available upon request by contacting the Pharmacy Department online at pharmacy@preferredone.com.

Quality Management Update

Smoking Cessation Program

PreferredOne offers the Free and Clear Quit Plan for Life Tobacco Cessation Program to all PreferredOne Community Health Plan (PCHP) and several PreferredOne Administrative Services (PAS) groups. Each participating member is contacted by a Free & Clear health professional via one-to-one phone counseling whom coaches and supports the member to quit their tobacco habit. This is a 12-month program that PreferredOne members self refer into by calling 1-800-292-2336.

Summary of 2006 Free & Clear PreferredOne Participation

- Total enrollments for calendar year 2006: 44 / PCHP and PAS members of which 57% were female.

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- Member's health professional was the primary way that PreferredOne members heard about the program in 2006
- 11 the of enrolled members were dosed/recommended for the NRT Patch in 2006

The standard Free & Clear program that PreferredOne members have access to consists of:

- Six outbound calls delivered over a 12-month period.
- Printed self-paced quitting materials- the FREE & CLEAR Quit Kit.
- Evaluation and dosing recommendations for nicotine replacement therapy (NRT) or Zyban.
- Unlimited use of a toll-free, inbound support line.

Free & Clear's 12-month quit rates consistently range from 25 to 30 percent.

We would like to thank the providers who have referred our members to the tobacco cessation program offered through PreferredOne. Please continue to do so and let us know how we may help you in supporting your PreferredOne patients who would like to quit smoking.

Medical Record Documentation Policy

PreferredOne requires member medical records to be maintained in a manner that is detailed, current and complete to promote safe and effective care, and stored in manner that is organized and secure to maintain the confidentiality of the member's health history and allow access. Attached you will find the Quality Management policy for medical record documentation guidelines (Exhibit X). Both the state and NCQA require health plans to assess and measure compliance with developed medical record documentation guidelines. Compliance with these standards will be assessed in conjunction with HEDIS medical record data abstraction in 2007. Baseline results will be examined to determine clinic adherence to the documentation standards. Clinics not meeting PreferredOne's documentation standards will be reassessed the following year. Please review these guidelines and your clinic operations to ensure your medical record-keeping system is compliant.

Clinical Practice Guidelines

PreferredOne is a sponsor of the Institute for Clinical Systems Improvement (ICSI) and promotes clinical practice guidelines to increase the knowledge of both our members and contracted providers about best practices for safe, effective, and appropriate care. Although PreferredOne endorses all of ICSI's guidelines, it has chosen to adopt several of them and monitor their performance within our network (Exhibit Y). Additionally, to address behavioral health conditions, we have partnered with Behavioral Healthcare Providers (BHP) to adopt two of their developed treatment guidelines.

The guidelines that PreferredOne has adopted include ICSI's clinical guidelines for Coronary Artery Disease (Exhibit Z) and Asthma (Exhibit AA), and BHP's treatment guidelines for Depression and ADHD (which have previously been distributed to all BHP provider sites). The performance of these guidelines by our network practitioners and BHP's network practitioners will be monitored using HEDIS measurement data, PreferredOne's disease management vendor's data, and BHP's annual evaluation. In addition, all of the ICSI guidelines that we have adopted can be found on ICSI's website at www.icsi.org. If you'd like to request a paper copy of any of the guidelines, please call 763-847-3562 or email Quality@PreferredOne.com.

Patient Safety - Adverse Health Events

The state of Minnesota has an established collaborative effort that addresses patient safety efforts at hospitals. As a Minnesota health plan, PreferredOne is a member of the Minnesota Alliance for Patient Safety (MAPS), a supporting organization of the Minnesota Department of Health (MDH) Adverse Event Reporting Law. In 2003, Minnesota became the first state in the nation to institute a mandatory adverse health event reporting system that included all 27 "never events" identified by the National Quality Forum (NQF) and a *Page 10...*

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public report that identified adverse events by facility. The Adverse Health Events Reporting Law provides consumers with information on how well hospitals and outpatient surgical centers are doing at preventing adverse events.

Examples of the 27 types of incidents that are tracked and publicly reported include wrong-site surgery, retention of a foreign object in a patient after surgery, and death or serious disability associated with medication error. The law requires that hospitals disclose when any of these 27 events occur and requires MDH to publish annual reports of the events by facility, along with an analysis of the events, the corrections implemented by facilities and any recommendations for improvement in Minnesota.

The third annual report on Adverse Health Events in Minnesota has recently been released. PreferredOne has established a link from its website to MDH's website where our members and practitioners can view the report. (Please see www.PreferredOne.com, click on Health Resources, then Healthcare Quality, then hospital to view MDH's site related to the Adverse Health Events in Minnesota.)

Minnesota Immunization Information Connection (MIIC)

The Minnesota Immunization Information Connection (MIIC) is network of regional immunization services, health care providers, public health agencies, health plans, and schools working together to prevent disease and improve immunization levels. These services combine high quality immunization delivery with public health assessment and outreach to help ensure children and adults are protected against vaccine-preventable diseases.

These regional services use a confidential, computerized information system that contains shared immunization records. This information system - also known as an immunization registry - provides clinics, schools, and parents with secure, accurate, and up-to-date immunization data, no matter where the shots were given. MIIC users can generate reminder cards when shots are coming due or are past due. And they greatly simplify the work of schools in enforcing the school immunization law.

What are the Benefits of MIIC?

- Consolidates immunizations a person has received into a single record, no matter where they received the shots.
- Provides an accurate, official copy of a child's immunization history for day care, school, camp enrollment, or for personal records.
- Helps ensure a child's immunizations are up to date.
- Provides reminders when an immunization is due.
- Provides recalls when an immunization has been missed.
- Helps ensure timely immunization for children whose families move or switch health care providers.
- Prevents unnecessary (duplicative) immunization.

(Information from the Minnesota Department of Health)

We are encouraging all health care practitioners to participate in MICC and submit immunization information to the registry to support our efforts in ensuring our members are getting the immunizations they need. **For more information, or to become a member of MICC please visit www.health.state.mn.us/divs/idepc/immunize/registry/index.html**.

Exhibit A

2007 First Quarter - Coding Changes, Deletions & Additions				
HCPCS Code	**Description**	**Action**	**Effective Date**	**Comments**
S0167	Injection apomorphine HCL, 1 mg	Discontinued	3/31/2007	Use J0634
S0820	Computerized corneal topography, unilateral	Discontinued	3/31/2007	Use CPT 92025
S1025	Inhaled nitric oxide for resp failure in neonate; per diem.	Discontinued	3/31/2007	This is a hospital charge for inpatient neonatal. Included in DRG for UB not for use with HCPCS code or CMS 1500.
S2213	Implantation of gastric electrical stimulation device.	Discontinued	3/31/2007	**Req Prior Auth for PrefOne**. Use CPT 43647, 43648, 43881 - 43882, 64590, 0155T, 0156T
S2250	Uterine artery embolization for uterine fibrioids.	Discontinued	3/31/2207	**Requires Prior Authorization**. Use CPT 37210
S0180	Etonogestrel contraceptive implant system, including, implant and suplies (dropping "S" from implants to reflect the single implant.)	Revise text	4/1/2007	Based on members benefits
S0270	Physician mangament of patient home care, standard montly case rate per 30 days.	ADD	4/1/2007	Not part of any P1 contract
S0271	Physician management of patient home care, hospice standard monhtly case rate per 30 days.	ADD	4/1/2007	Not part of any P1 contract
S0272	Physician management of patient home care, episodic care monthly case rate (Per 30 days).			Not part of any P1 contract
S0273	Physician visit at member's home, outside of a capitation arrangement.	ADD	4/1/2007	Not part of any P1 contract
S0274	Nurse practitioner visit at members home outside of a capitation arrangement.	ADD	4/1/2007	Not part of any P1 contract
S3618	Free beta HCG Chorionic gonadotropin. Used for first quarter screening for Down's syndrome with fetal nuchal translucency.	ADD	4/1/2007	Must be used in conjunction with 76813/ 76814. Based on members genetic benefits.
T1503	Medication administration other than oral.	ADD	4/1/2007	This is a code that Medicaid needed for administration of drugs other than oral or injectable.
G0377	Administration of vaccine for Part D drugs.	ADD	1/1/2007	For Medicare usage. Paid if necessary if P1 is secondary payor.
Q4083	Hyaluronan or derivative, Supartz, intra articular injection, per dose.	ADD	1/1/2007	
Q4084	Hyaluronan or derivative, Synvisc, intra articular injection, per dose.	ADD	1/1/2007	
Q4085	Hyaluronan or derivitive, Euflexxa, intra articular injection, per dose.	ADD	1/1/2007	
Q4086	Hyaluronan, or derivative, Orthovisc, intra articular injection, per dose.	ADD	1/1/2007	
J7319	Hyaluronan (sodium hyaluronate) or derivative, intra articular injection, per injection (use this code for hylan G F 20, Hyalgan, Hylan, Provisc, Euflexxa, Supartz, Synvisc.	Medicare changed their coverage to non covered, but the code was not deleted.		Can either use J7319, or use the new Q codes for the specific drug

Exhibit B

PreferredOne®

Department of Origin: Coding Reimbursement	**Approved by:**	**Date approved:** 1/24/2007
Department(s) Affected: Network Management, Claims, Customer Service, Sales and Finance	**Effective Date:** 1/24/2007	
Policy Description: 3 D Rendering of Radiology Services	**Replaces Effective Policy Dated:**	
Reference #: P-34	**Page:** 1 of 1	

PRODUCT APPLICATION:

☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

PURPOSE: PreferredOnes guidelines for bundling of the CPT codes for 3D rendering of Radiology services

POLICY: PreferredOne will be bundling the CPT codes for the 3D rendering into the codes for the Radiology services billed.

1. PreferredOne considers all 3D rendering services to be part of the base CT, MRI or ultrasound service.

2. No additional reimbursement will be made for either the TC or the 26 components of the CPT codes 76376 and 76377

3. Only the base CT, MRI and ultrasound (TC and 26) services will be reimbursed.

4. When the 3D rendering is reported the remit will reflect provider responsibility for CPT 76376 and 76377.

DOCUMENT HISTORY:

Created Date: 1/24/2007
Reviewed Date:
Revised Date:

Exhibit C

HSM DEPARTMENTAL POLICY AND PROCEDURE

DEPARTMENT: Clinical Management **Policy #:** CPB-006
SUBJECT: Active Care – Therapeutic Exercise **Date of Origin:** 09/06/06
QM Approval: 09/06/06
Date of Last Review: 09/06/06, 12/13/06 **Initials of Reviewer:** RB

SCOPE: Clinical Management, Coding, Customer Service, Claims and Contracting.

PURPOSE: To provide treatment guidelines related to the use of exercise therapy in a chiropractic clinical setting.

POLICY: Exercise such as flexibility, range of motion, strengthening and conditioning and posture, movement, and balance activities is appropriate for treatment of common uncomplicated musculoskeletal conditions. There is sufficient scientific evidence supporting superior outcomes when this treatment is used in combination with spinal manipulation and/or mobilization for uncomplicated non-specific neck and low back pain compared to manipulation and/or mobilization alone.

HSM supports the use of these procedures.

Definitions:
This policy refers to the following CPT code definitions (copyright AMA, 2006):
97110 - Therapeutic Exercise (strength and endurance, range of motion and flexibility)
97112 - Neuromuscular reeducation (movement, balance, coordination, kinesthetic sense, posture and or proprioception).
97530 – Therapeutic Activities (dynamic activities to improve functional performance).
97535 – Self-care/home management training (ADL training and compensatory training).
97150 – Group Therapy (constant attendance of group but not one-on-one patient contact).

Procedure:
1. Guidelines:

- According to the Centers for Medicare and Medicaid Services rules published in Transmittal AB-00-14 each procedure must have direct (one-on-one) patient contact. One 15-minute unit is defined as a minimum of 8 minutes to a maximum of 23 minutes and excludes pre and post delivery services.
- The patient record should note the length of time, plan of care, rationale and a description of the exercises provided for each procedure.
- Exercise therapy should be included for all documented functional deficits in activities of daily living as a method to improve health outcomes. HSM will recommend payment of services when clinically indicated.

    - Functional deficit is defined as a limitation of action, task or activity that normally can be performed in an efficient, expected or competent manner.
- Current evidence related to the use of active care supports improved outcomes. HSM includes active care as a quality monitoring indicator measured and reported to the provider. Providers who under or over-utilize these procedures may receive additional educational training or be subjected to additional operational requirements.
    - Services should be billed according to applicable CPT, AMA and Medicare guidelines.
        - Therapeutic Exercise (97110) may be used when the patient has documented loss of range of motion, flexibility, endurance or strength.
        - Neuromuscular Reeducation (97112) may be used when the patient has documented loss of balance, coordination, proprioception, or posture deficiency with standing and/or sitting.
        - Therapeutic Activities (97530) may be used when the patient has documented loss of functional performance.
        - Self-care/home management training (97535) may be used when the patient has documented functional deficit with activities of daily living (ADL's) or required instruction on assistive technology or adaptive equipment.

2. Exclusions:
    - Although the use of active care procedures may be clinically indicated reimbursement is determined by the patients chiropractic benefit.
    - 97150 (Group Therapy) CPT code is not on the HSM fee schedule and is included for definition and clarity purposes only.

3. References

Guidelines

1. Airaksinen O, Brox JI, Cerderlund CG, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. European guidelines for the management of chronic non-specific low back pain. European commission, research directorate general, 2004. (Amended June 2005) www.backpaineurope.org (accessed August 23, 2006)
2. Australian acute musculoskeletal pain guidelines group. Evidence-based management of acute musculoskeletal pain. 2004. http://www7.health.gov.au/nhmrc/publications/_files/cp95.pdf (accessed August 23rd, 2006)

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6. Hoving JL, Gross AR, Gasner D, Kay T, Kennedy C, Hondras MA, et al. A critical appraisal of review articles on the effectiveness of conservative treatment of neck pain. Spine 2001;26(2):196-205.
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Randomized Clinical Trials

8. Geisser ME, Wiggert EA, Haig AJ, Colwell MO. A randomized, controlled trial of manual therapy and specific adjuvant exercise for chronic low back pain. Clin J Pain 2005;21:463-470.
9. UK BEAM trial team. United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care. BMJ 2004; 329:1377-81.
10. Niemisto L, Lahtinen-Suopanki T, Rissnen P, Lingren K, Sarna S, Hurri H. A randomized trial of combined manipulation, stabilizing exercises, and physical consultation compared to physician consultation alone for chronic low back pain. Spine 2003;28:2185-2191.
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12. Bronfort G, Evan R, Nelson B, Aker PD, Goldsmith CH, Vernon H. A randomized clinical trial of exercise and spinal manipulation for patients with chronic neck pain. Spine 2001;26(7):788-99.
13. Erhard RE, Delitto A, Cibulka MT. Relative effectiveness of an extension program and a combined program of manipulation and flexion and extension exercises in patients with acute low back syndrome. Phys Ther 1994;74:1093-100.

Exhibit D

HSM DEPARTMENTAL POLICY AND PROCEDURE

DEPARTMENT:	Clinical Management	**Policy #:**	CPB-007
SUBJECT:	Acute and Chronic Pain	**Date of Origin:**	9/06/06
		QM Approval:	9/06/06
Date of Last Review:	09/06/06, 12/13/06	**Initials of Reviewer:**	RB

Scope: Clinical Management, Coding, Customer Service, Claims and Contracting.

Subject: Define acute, sub-acute and chronic musculoskeletal conditions.

Purpose: To provide a clear definition of acute, sub-acute and chronic pain based upon current research and pain-related literature.

Policy: Health plans often define their chiropractic benefit as medically necessary and appropriate treatment related to acute musculoskeletal conditions. A literature-based definition for each phase of pain is necessary to clearly delineate potential benefit inclusions and limitations.

Definitions: HSM has adopted the European guidelines definition of acute, sub-acute and chronic pain.

Pain is defined as an unpleasant sensory experience associated with actual or potential tissue damage, or described in terms of such damage.

Functional Deficit is defined as a limitation of action, task or activity that normally can be performed in an efficient, expected or competent manner.

Acute pain is defined as the duration of an episode persisting for up to but less than 6 weeks. Pain that comes on quickly, can be severe, but lasts a relatively short time. Acute is also defined as present or experienced to a severe, extreme or intense degree.

Sub-acute pain is defined as an episode persisting between 6 weeks and up to but less than 12 weeks. Sub-acute is defined as present to a moderate degree.

Chronic pain is defined as an episode persisting for 12 weeks or more.

Episode is defined as the onset of pain (beginning) through the end (resolution or maximum therapeutic benefit) of pain. A new episode of pain is defined as the onset of pain after a symptom-free period of 90 days, but not an exacerbation of chronic pain.

References:

- Airaksinen O, Brox JI, Cerderlund CG, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. European guidelines for the management of chronic non-specific low back pain. European commission, research directorate general, 2004. (Amended June 2005) www.backpaineurope.org (accessed August 23, 2006)
- Institute for Clinical Systems Improvement. Health Care Guidelines. Adult Low Back Pain. Last Update September 2005. Retrieved August 23rd, 2006 from www. ICSI.org.
- Websters New World Medical Dictionary 2nd edition (January, 2003) Wiley Publishing, Inc.; ISBN: 0-7645-2461-5.
- Assendelft WJJ, Morton SC, Yu Emily L, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low-back pain. The Cochrane Database of Systematic Reviews 2004, Issue 1. Art No.:CD000447.

Exhibit E

HSM DEPARTMENTAL POLICY AND PROCEDURE

DEPARTMENT:	Clinical Management	**Policy #:**	CPB-008
SUBJECT:	Multiple Passive Therapies	**Date of Origin:**	09/06/06
		QM Approval:	09/06/06
Date of Last Review:	9/06/06, 12/13/06	**Initials of Reviewer:**	RB

Scope: Clinical Management, Coding, Customer Service, Claims and Contracting.

Purpose: To provide a statement regarding the efficacy and appropriateness related to multiple passive therapies for the treatment of musculoskeletal conditions within the scope of chiropractic practice.

Policy: HSM does not support the use of multiple passive therapies for the treatment of musculoskeletal pain within the scope of chiropractic practice.

Definitions:

- Passive therapy is defined as the use of and/or billing of two or more physical medicine modalities each visit or during the same session to the same region.
- Most passive modalities have similar physiological effects related to pain control and reduction of inflammation.
- The use of modalities with duplicative physiological effects is unnecessary and inappropriate.
- Multiple passive therapies have not been shown to improve or accelerate patient health outcomes.
- Passive therapies should be applied during the acute pain phase. Please refer to our passive therapy clinical policy bulletin for additional information.
- The use of hot or cold packs is not appropriate beyond the initial 3 visits. See our Clinical Policy Bulletin on hot and cold packs for more information.
- The purpose of passive therapy use is to promote pain reduction, improve function and quickly transition the patient to self-care and active care engagement.
- The following is a list of procedures considered to be passive modalities:
    1. Thermal and light therapy – Hot/cold (97010), diathermy (97024), microwave (97020) infrared (97026), ultraviolet (97028), ultrasound (97035), paraffin bath (97018) and whirlpool (97022).
    2. Electrical therapy – High volt, low volt, interferential current, TENS (97014 and 97032).
    3. Mechanical – mechanically assisted and often a sustained pull of the spine or limb such as traction (97012).
    4. Therapeutic massage therapy and myofascial therapy (97124 and 97140).

Exclusions:

1. The use of chiropractic manipulation (98940-98943) is not considered a duplication of service or physiological effect when used in conjunction with passive physical medicine modalities during the acute and sub-acute pain phase.

References:

1. Airaksinen O, Brox JI, Cerderlund CG, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. European guidelines for the management of chronic non-specific low back pain. European commission, research directorate general, 2004. (Amended June 2005) www.backpaineurope.org (accessed August 23, 2006)
2. Institute for Clinical Systems Improvement. Health Care Guidelines. Adult Low Back Pain. Last Update September 2005. (accessed August 23rd, 2006 from www. ICSI.org.)
3. French SD, Cameron M ,Walker BF, Reggars JW, Esterman AJ. Superficial heat and cold for low back pain. Cochrane Database of Systematic Reviews 2006, Issue 1, Art. No.:CD004750.
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5. Clarke JA, van Tulder MW, Bloomberg SEI, de Vet HCW, van der Heijden GJMG, Bronfort G. Traction for low back pain with or without sciatica. The Cochrane Database of Systematic Reviews 2005, Issue 5, Art. No.:CD003010.pub3.
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Exhibit F

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Advair Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/A003	**Page:** 1 of 4	

PRODUCT APPLICATION:

- ☒ PreferredOne Community Health Plan (PCHP)
- ☒ PreferredOne Administrative Services, Inc. (PAS)
- ☐ PreferredOne (PPO)
- ☒ PreferredOne Insurance Company (PIC)

Coverage is subject to the terms of an enrollee's pharmacy benefit plan and formulary. To the extent there is any inconsistency between this criteria set/policy and the terms of an enrollee's pharmacy benefit plan and /or formulary, the enrollee's pharmacy benefit plan and formulary govern.

This criteria set applies only to PAS enrollees when the employer group has adopted the applicable drug trend management program(s).

PURPOSE:

The intent of this criteria set is to ensure appropriate use of Advair Diskus or Advair HFA and to prevent the use of Advair in conditions where there is no evidence to support the use.

DEFINITIONS:

Step Therapy:

Step therapy requires the use of the more cost-effective drug when there is no literature to support the therapeutic benefit of one drug over another. The first step in a step therapy process, utilizing the most cost effective drug is called the first-line therapy. If first-line therapies are ineffective for a person, the next required step known as "second-line therapies" are tried, then "third-line therapies" etc. as required.

Automated Step Therapy:

Step therapy programs are generally automated within the pharmacy claims adjudication system. The pharmacy claims system reviews the patient's medication history prior to dispensing at the pharmacy. If the automated requirements are met, the pharmacy claim will automatically process through the claims processing system.

BACKGROUND:

This criteria set is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.

Advair Diskus, an inhalation device containing the inhaled corticosteroid (ICS) fluticasone propionate and the long-acting beta-agonist (LABA) salmeterol, is indicated for the long-term maintenance treatment of asthma in patients ≥ 4 years of age and for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis. Advair HFA is indicated for the long-term twice-daily maintenance treatment of asthma in patient's 12 years of age and older. Both components of Advair are available as single entity products (fluticasone inhalation aerosol (Flovent HFA) and salmeterol inhalation powder (Serevent Diskus) or salmeterol inhalation aerosol (Serevent). According to product labeling, Serevent is indicated in patients with asthma who require regular treatment with an inhaled short-acting beta-agonist and is not indicated for patients whose asthma can be managed by occasional use of an inhaled short-acting beta agonist. LABAs are recommended as control medications for chronic therapy and should not be used to treat acute symptoms; LABAs used concomitantly with ICSs should be used for long-term control of symptoms. In contrast, short-acting beta-

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Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	Effective Date: 11/15/06	
Pharmacy Criteria Document: Advair Step Therapy	Replaces Effective Policy Dated: N/A	
Reference #: PC/A003	Page: 2 of 4	

agonists are indicated for the treatment of intermittent episodes of bronchospasm and are the therapy of choice for the treatment of acute symptoms such as cough, chest tightness, and wheezing.

Drugs Affected:

Generic Name	Generics Available	Brand Name
fluticasone propionate and salmeterol inhalation powder	N	Advair Diskus
fluticasone propionate and salmeterol inhalation aerosol	N	Advair HFA

GUIDELINES:
Medical Necessity Criteria and Step Therapy Requirements - I and III; or II and III and none of IV:

I. The patient has been started and stabilized on Advair during the previous 130 days (i.e. grandfathering) the patient will be allowed to continue on the medication.

II. If a patient has not responded to, is intolerant to, or a poor candidate for one corticosteroid (Table 1,2 &3) and one beta-agonist (Table 3) then Advair will be approved.

III. Indications where coverage of Advair is recommended – one of the following A-D;

A. Long-term maintenance treatment of asthma/reactive airway disease

B. Advair Diskus is indicated for the maintenance treatment of airflow obstruction in patients with COPD associated with chronic bronchitis.

C. Control of chronic cough in stable patients with chronic bronchitis

D. Maintenance treatment of emphysema

IV. Exclusions where coverage of Advair Diskus or Advair HFA is not recommended – none of following A-K:

A. Treatment of symptoms associated with a current rhinovirus infection/cough associated with a current episode of the common cold

B. Treatment of chronic cough due to gastroesophageal reflux disease (GERD)

C. Treatment of symptoms due to an acute respiratory infection (e.g., acute bronchitis, sinusitis, pneumonia)

D. Treatment of a chronic cough due to non-asthmatic eosinophilic bronchitis (NAEB)

E. Treatment of chronic cough due to bronchiolitis

F. Treatment of chronic cough due to bronchiectasis

G. Whooping cough/pertussis

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Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	Effective Date: 11/15/06	
Pharmacy Criteria Document: Advair Step Therapy	Replaces Effective Policy Dated: N/A	
Reference #: PC/A003	Page: 3 of 4	

H. ACE inhibitor-induced cough

I. Psychogenic cough/habit cough/tic cough

J. Any other indications

K. Already stabilized on single inhalers (convenience issues)

Table 1: Nasal Corticosteroids

Generic Name	Generics Available	Brand Name
beclomethasone dipropionate	N	Beconase® Inhaler, Beconase AQ Spray, Vancenase® Inhaler, Vancenase Pockethaler, Vancenase AQ
budesonide	N	Rhinocort®, Rhinocort® AQ nasal spray
flunisolide	Y	Nasalide®, Nasarel® spray, generics
fluticasone propionate	N	Flonase® nasal spray
mometasone furoate	N	Nasonex® nasal spray
triamcinolone acetonide	N	Nasacort® AQ nasal spray, Nasacort nasal inhaler, Tri-Nasal® nasal spray

Table 2: Corticosteroid Inhalers (Inhaled Corticosteroids)

Generic Name	Generics Available	Brand Name
beclomethasone	N	Vanceril, Vanceril DS, Qvar
fluticasone	N	Flovent, Flovent Rotadisk
budesonide	N	Pulmicort, Pulmicort Respules
triamcinolone	N	Azmacort
flunisolide	N	Aerobid, Aerobid-M

Table 3: Beta-Agonist Inhalers

Generic Name	Generics Available	Brand Name
albuterol	Y	Proventil, Ventolin, Proventil HFA, generics
pirbuterol	N	Maxair, Maxair Autohaler
salmeterol	N	Serevent, Serevent Diskus
formoterol	N	Foradil
metaproterenol	N	Alupent
bitolterol	N	Tornalate

Table 4: Beta-Agonist Orals

Generic Name	Generics Available	Brand Name
albuterol	Y	Proventil, generics
albuterol Ext-Rel	N	Proventil Repetabs, Volmax
terbutaline	Y	Brethine, generics

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Advair Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/A003	**Page:** 4 of 4	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Pharmacy Policy PP/S001 Step Therapy

REFERENCES:

1. Express Scripts Prior Authorization Policy. Fluticasone propionate and salmeterol inhalation powder (Advair Diskus® - GlaxoSmithKline), fluticasone propionate and salmeterol inhalation aerosol (Advair®HFA). 6/28/06.
2. National Guideline Clearinghouse. National Asthma Education and Prevention Program expert Panel report: guidelines for the diagnosis and management of asthma update on selected topics – 2002. J Allergy Clin Immunol 2002 Nov;110(5 pt 2):S141-219.
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DOCUMENT HISTORY:

Created Date: 11/15/06
Reviewed Date:
Revised Date: 01/02/07

Exhibit G

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Topical Corticosteroids Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/C003	**Page:** 1 of 7	

PRODUCT APPLICATION:

- ☒ PreferredOne Community Health Plan (PCHP)
- ☒ PreferredOne Administrative Services, Inc. (PAS)
- ☐ PreferredOne (PPO)
- ☒ PreferredOne Insurance Company (PIC)

Coverage is subject to the terms of an enrollee's pharmacy benefit plan and formulary. To the extent there is any inconsistency between this criteria set/policy and the terms of an enrollee's pharmacy benefit plan and /or formulary, the enrollee's pharmacy benefit plan and formulary govern.

This policy applies only to PAS enrollees when the employer group has adopted the applicable drug trend management program(s).

PURPOSE:

The intent of this policy is to require the use of two generic step one topical corticosteroids before the use of a brand name step two topical corticosteroid (Table 2).

DEFINITIONS:

Step Therapy:

Step therapy requires the use of the more cost-effective drug when there is no literature to support the therapeutic benefit of one drug over another. The first step in a step therapy process, utilizing the most cost-effective drug is called the first-line therapy. If first-line therapies are ineffective for a person, the next required step known as "second-line therapies" are tried, then "third-line therapies" etc. as required.

Automated Step Therapy:

Step therapy programs are generally automated within the pharmacy claims adjudication system. The pharmacy claims system reviews the patient's medication history prior to dispensing at the pharmacy. If the automated requirements are met, the pharmacy claim will automatically process through the claims processing system.

BACKGROUND:

This criteria set is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.

When requesting a drug other than a first line drug in step therapy, the ordering physician must supply additional clinical information documenting why the specific medication is required for the patient, or published professional literature supporting the increased therapeutic benefit or safety of the second, third (etc.) line drug.

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Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Topical Corticosteroids Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/C003	**Page:** 2 of 7	

Drugs Affected:

Generic Name	Generics Available	Brand Name
alclometasone	N	Aclovate
amcinonide	N	Cyclocort®
betamethasone dipropionate	N	Diprolene®
betamethasone dipropionate	Y	Diprosone®
betamethasone valerate	Y	Valisone®
clobetasol propionate	N	Clobex®
clobetasol propionate	Y	Temovate®
clocortolone pivalate	N	Cloderm®
desonide	Y	Desowen®
desoximetasone	Y	Topicort®
dexamethasone	N	Decadron Phosphate®
diflorasone diacetate	N	Pscoron®, Psorcon E®
fluocinolone acetonide	Y	Synalar®
fluocinonide	Y	Lidex®
fluocinonide	N	Vanos®
flurandrenolide	N	Cordran®
fluticasone propionate	N	Cutivate®
halcinonide	N	Halog®
halobetasol propionate	N	Ultravate®
hydrocortisone	Y	Hytone®
hydrocortisone butyrate	N	Locoid® Lipocream
hydrocortisone buteprate	N	Pandel®
hydrocortisone valerate	Y	Westcort®
prednicarbate	N	Dermatop®
mometasone furoate	N	Elocon®
triamcinolone acetonide	Y	Aristocort® /Kenalog®

PreferredOne®

Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	Effective Date: 11/15/06	
Pharmacy Criteria Document: Topical Corticosteroids Step Therapy	Replaces Effective Policy Dated: N/A	
Reference #: PC/C003	Page: 3 of 7	

POLICY:
Certain enrollee's may be required to follow a Step Therapy program for certain drug classes.

GUIDELINES:
Step Therapy Requirements:

I. The patient has been started and stabilized on a second line branded topical corticosteroid (Table 2) during the previous 130 days (i.e. grandfathering) the patient will be allowed to continue on the medication.

II. If a patient has not responded to, is intolerant to, or a poor candidate for two generic prescription strength topical corticosteroid products (Table 1) for the current condition, authorization for a brand prescription strength topical corticosteroid (Table 2) may be allowed.

Table 1: PreferredOne First Line Step Therapy Drugs* (Revised 01/19/07)

FIRST LINE TOPICAL CORTICOSTEROIDS	
alclometasone	fluocinolone acetonide
amcinonide	fluocinonide
betamethasone dipropionate	fluticasone propionate
betamethasone dipropionate, augmented	halobetasol propionate
betamethasone valerate	hydrocortisone
clobetasol propionate	hydrocortisone butyrate
desonide	hydrocortisone valerate
desoximetasone	mometasone furoate
diflorasone diacetate	triamcinolone acetonide

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 2: PreferredOne Second Line Step Therapy Drugs* (Revised 01/19/07)

SECOND LINE TOPICAL CORTICOSTEROIDS	
Aclovate®	Hytone®
Apexicon E® emollient cream	Kenalog®
Aristocort®	Lidex®
Clobex®	Locoid® Lipocream
Cloderm®	Pandel®
Cordran®	Psorcon E®
Cordran® SP	Temovate®
Cutivate®	Texacort®
Cyclocort®	Topicort®
Dermatop®	Synalar®
Desowen®	Ultravate®
Diprolene®	Valisone®
Diprosone®	Vanos®
Elocon®	Westcort®
Halog®	

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Topical Corticosteroids Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/C003	**Page:** 4 of 7	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Pharmacy Policy PP/S001 Step Therapy

REFERENCES:

1. Express Scripts Step Therapy Policy: Topical Corticosteroids Step therapy Program. 03/29/06.
2. Abramovits W, Perlmutter A. Steroids versus other immune modulators in the management of allergic dermatoses. Curr Opin Allergy Clin Immunol. 2006 Oct;6(5):345-54.
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DOCUMENT HISTORY:

Created Date: 11/15/06
Reviewed Date:
Revised Date:

PreferredOne®

Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	Effective Date: 11/15/06	
Pharmacy Criteria Document: Topical Corticosteroids Step Therapy	Replaces Effective Policy Dated: N/A	
Reference #: PC/C003	Page: 5 of 7	

Appendix A

Generic Topical Corticosteroid Potency Table

Generic Name	Generics Available	Brand Name	Patentcy
aclometasone 0.05% ointment	N	Aclovate®	Low
aclometasone 0.05% cream	N	Aclovate®	Low
amcinonide 0.1% cream	N	Cyclocort®	High
amcinonide 0.1% lotion	N	Cyclocort®	High
amcinonide 0.1% ointment	N	Cyclocort®	High
betamethasone dipropionate 0.05% lotion	Y	Diprosone®	Medium
betamethasone dipropionate 0.05% cream	Y	Diprosone®	High
betamethasone dipropionate 0.05% gel	Y	Diprosone®	High
betamethasone dipropionate, augmented 0.05% cream	N	Diprolene®	High
betamethasone dipropionate, augmented 0.05% gel	N	Diprolene®	*
betamethasone dipropionate, augmented 0.05% ointment	N	Diprolene®	Very High
Betamethasone dipropionate, augmented 0.05% lotion	N	Diprolene®	Very High
betamethasone valerate 0.1% cream	Y	Beta-Val®/Valisone®	Medium
betamethasone valerate 0.1% lotion	Y	Beta-Val®/Valisone®	*
betamethasone valerate 0.1% ointment	Y	Beta-Val®/Valisone®	High
clobetasol propionate 0.05% topical lotion	N	Coblex ®	*
clobetasol propionate 0.05% spray	N	Coblex®	*
clobetasol propionate 0.05% cream	Y	Temovate®	Very High
clobetasol propionate 0.05% emollient cream	Y	Temovate®	*
clobetasol propionate 0.05% gel	Y	Temovate®	*
clobetasol propionate 0.05% ointment	Y	Temovate®	Very High
clobetasol propionate 0.05% solution	Y	Temovate®	*
Clocortolone pivalate 0.1% cream	N	Cloderm®	Medium
desonide 0.05% cream	Y	Desowen®	Low
desonide 0.05% lotion	Y	Desowen®	Low
desonide 0.05% ointment	Y	Desowen®	Low
desoximetasone 0.05% cream	Y	Topicort®	Medium
desoximetasone 0.05% gel	Y	Topicort®	Medium

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Topical Corticosteroids Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/C003	**Page:** 6 of 7	

desoximetasone 0.25% cream	Y	Topicort®	High
desoximetasone 0.25% ointment	Y	Topicort®	High
dexamethasone	N	Decadron Phosphate ®	Low
diflorasone diacetate 0.05% cream	N	Psorcon®	High
diflorasone diacetate 0.05% ointment	N	Psorcon®	Very High
diflorasone diacetate 0.05% emollient cream	N	Pscoron E®	High
Diflorasone diacetate 0.05% emollient ointment	N	Pscoron E®	High
fluocinolone acetonide 0.01% cream	Y	Synalar®	Low
fluocinolone acetonide 0.025% cream	Y	Synalar®	Medium
fluocinolone acetonide 0.025% ointment	Y	Synalar®	Medium
flucinonide 0.05% cream	Y	Lidex®	High
fluocinonide 0.05% emollient cream	Y	Lidex®	High
fluocinonide 0.05% gel	Y	Lidex®	High
fluocinonide 0.05% ointment	Y	Lidex®	High
fluocinonide 0.05% solution	Y	Lidex®	High
flurandrenolide 0.05% ointment	N	Cordran®	Medium
fluticasone propionate 0.005% ointment	N	Cutivate®	Medium
fluticasone propionate 0.05% cream	N	Cutivate®	Medium
halcinonide 0.1% cream	N	Halog®	High
halcinonide 0.1% ointment	N	Halog®	High
halobetasol propionate 0.05% cream	N	Ultravate®	Very High
halobetasol propionate 0.05% ointment	N	Ultravate®	Very High
hydrocortisone 0.5% cream	Y	Hytone®	Low
hydrocortisone 1% cream	Y	Hytone®	Low
hydrocortisone 1% ointment	Y	Hytone®	Low
hydrocortisone 2.5% cream	Y	Hytone®	Low
hydrocortisone 2.5% ointment	Y	Hytone®	Low
Hydrocortisone buteprate 0.1% cream	N	Pandel®	*
hydrocortisone butyrate 0.1% cream	N	Locoid®	Medium
hydrocortisone butyrate 0.1% ointment	N	Locoid®	Medium
hydrocortisone butyrate 0.1% solution	N	Locoid®	Medium

PreferredOne®

Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Topical Corticosteroids Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/C003	**Page:** 7 of 7	

hydrocortisone valerate 0.2% ointment	Y	Westcort®	Medium
mometasone furoate 0.1% cream	N	Elocon®	Medium
mometasone furoate 0.1% lotion	N	Elocon®	Medium
mometasone furoate 0.1% ointment	N	Elocon®	Medium
prednicarbate 0.1% emollient cream	N	Dermatop®	*
prednicarbate 0.1% ointment	N	Dermatop®	*
triamcinolone acetonide 0.025% cream	Y	Aristocort®/Kenalog®	Medium
triamcinolone acetonide 0.025% ointment	Y	Aristocort®/Kenalog®	Medium
triamcinolone acetonide 0.05% ointment	Y	Aristocort®/Kenalog®	High
triamcinolone acetonide 0.1% cream	Y	Aristocort®/Kenalog®	Medium
triamcinolone acetonide 0.1% ointment	Y	Aristocort®/Kenalog®	Medium
triamcinolone acetonide 0.5% cream	Y	Aristocort®/Kenalog®	Medium
triamcinolone acetonide 0.5% ointment	Y	Aristocort®/Kenalog®	High

*Potency not available

Exhibit H

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Policy and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: HMG-CoA Reductase Inhibitor (HMG) Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/H001	**Page:** 1 of 4	

PRODUCT APPLICATION:

- ☒ PreferredOne Community Health Plan (PCHP)
- ☒ PreferredOne Administrative Services, Inc. (PAS)
- ☐ PreferredOne (PPO)
- ☒ PreferredOne Insurance Company (PIC)

Coverage is subject to the terms of an enrollee's pharmacy benefit plan and formulary. To the extent there is any inconsistency between this criteria set/policy and the terms of an enrollee's pharmacy benefit plan and /or formulary, the enrollee's pharmacy benefit plan and formulary govern.

This criteria set applies only to PAS enrollees when the employer group has adopted the applicable drug trend management program(s).

PURPOSE:

The intent of this criteria set is to require the use of first-line HMGs, over the second-line HMGs.

DEFINITIONS:

Step Therapy:

Step therapy requires the use of the more cost-effective drug when there is no literature to support the therapeutic benefit of one drug over another. The first step in a step therapy process, utilizing the most cost effective drug is called the first-line therapy. If first-line therapies are ineffective for a person, the next required step known as "second-line therapies" are tried, then "third-line therapies" etc. as required.

Automated Step Therapy:

Step therapy programs are generally automated within the pharmacy claims adjudication system. The pharmacy claims system reviews the patient's medication history prior to dispensing at the pharmacy. If the automated requirements are met, the pharmacy claim will automatically process through the claims processing system.

BACKGROUND:

This criteria set is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.

If there are drug-drug interaction issues with these products, exceptions will be made on an individual case by case basis.

When requesting a drug other than a first line drug in step therapy, the ordering physician must supply additional clinical information documenting why the specific medication is required for the patient, or published professional literature supporting the increased therapeutic benefit or safety of the second, third (etc.) line drug.

The HMGs FDA-approved for use in children include lovastatin (Mevacor), simvastatin, pravastatin and Lipitor.

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Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Policy and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: HMG-CoA Reductase Inhibitor (HMG) Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/H001	**Page:** 2 of 4	

Drugs Affected:

Generic Name	Generics available	Brand Name
atrovastatin	N	Lipitor
atorvastatin/amlodipine	N	Caduet
ezetimibe/simvastatin	N	Vytorin
fluvastatin	N	Lescol
fluvastatin extended-release	N	Lescol XL
lovastatin	Y	Mevacor
lovastatin extended-release	N	Altoprev
niacin extended-release/lovastatin	N	Advicor
pravastatin	Y	Pravachol
rosuvastatin	N	Crestor
simvastatin	Y	Zocor

GUIDELINES:
Step Therapy Requirements for HMG-Co A Reductase Inhibitors:

I. The patient has been started and stabilized on a second line medication (Table 2) during the previous 130 days (i.e. grandfathering) the patient will be allowed to continue on the medication.

II. If a patient has not responded to, is intolerant to, or a poor candidate for two first line HMGs (Table 1) a second line HMG (Table 2) will be approved.

Table 1: PreferredOne First Line Step Therapy Drugs*

FIRST LINE HMGs
lovastatin – generic version of Mevacor®
pravastatin – generic version of Pravachol®
simvastatin – generic version of Zocor®
Lipitor®

Revised 10/16/06

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 2: PreferredOne Second Line Step Therapy Drugs*

SECOND LINE HMGs
Advicor®
Altoprev™
Crestor®
Lescol®
Lescol XL®
Mevacor®
Pravachol®
Vytorin®
Zocor®

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Policy and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: HMG-CoA Reductase Inhibitor (HMG) Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/H001	**Page:** 3 of 4	

Revised 10/16/06

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

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Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Policy and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: HMG-CoA Reductase Inhibitor (HMG) Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/H001	**Page:** 4 of 4	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/S009 Medical Step Therapy
Pharmacy Policy PP/D002 Dosing Optimization
Pharmacy Policy PP/S 001 Step Therapy
Pharmacy Policy PP/Q001 Quantity Limits

REFERENCES:

1. Express Scripts Step Therapy Policy. HMG-CoA Reductase Inhibitor (HMG) Step Therapy Program – Enhanced. 08/17/05.
2. Ballantyne CM, Abate N, Yuan Z, King TR, Palmisano J. dose-comparison study of the combination of ezetimibe and simvastatin (Vytorin) versus atorvastatin in patients with hypercholesterolemia: the Vytorin Versus Atorvastatin (VYVA) study. Am Heart J. 2005 Mar;149(3):464-73.
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DOCUMENT HISTORY:

Created Date: 11/15/06
Reviewed Date:
Revised Date: 01/02/07

Exhibit I

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Lyrica Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/L003	**Page:** 1 of 4	

PRODUCT APPLICATION:

☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☐ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Coverage is subject to the terms of an enrollee's pharmacy benefit plan and formulary. To the extent there is any inconsistency between this criteria set/policy and the terms of an enrollee's pharmacy benefit plan and /or formulary, the enrollee's pharmacy benefit plan and formulary govern.

This criteria set applies only to PAS enrollees when the employer group has adopted the applicable drug trend management program(s).

PURPOSE:

The intent of this criteria set is to require the use of generic Neurontin before the use of brand name Lyrica.

DEFINITIONS:

Step Therapy:

Step therapy requires the use of the more cost-effective drug when there is no literature to support the therapeutic benefit of one drug over another. The first step in a step therapy process, utilizing the most cost-effective drug is called the first-line therapy. If first-line therapies are ineffective for a person, the next required step known as "second-line therapies" are tried, then "third-line therapies" etc. as required.

BACKGROUND:

When requesting a drug other than a first line drug in step therapy, the ordering physician must supply additional clinical information documenting why the specific medication is required for the patient, or published professional literature supporting the increased therapeutic benefit or safety of the second, third (etc.) line drug.

Drugs Affected:

Generic Name	Generics available	Brand Name
pregabalin	N	Lyrica
gabapentin	Y	Neurontin

GUIDELINES:

Step Therapy Requirements:
One of the following - I - IV:

I. The patient has been started and stabilized on Lyrica during the previous 130 days (i.e. grandfathering) the patient will be allowed to continue on Lyrica.

II. The patient has not responded to, is intolerant to, or a poor candidate for gabapentin for the treatment of partial onset seizures or post herpatic neuralgia (PHN), Lyrica will be allowed.

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Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	Effective Date: 11/15/06	
Pharmacy Criteria Document: Lyrica Step Therapy	Replaces Effective Policy Dated: N/A	
Reference #: PC/L003	Page: 2 of 4	

III. Lyrica will be allowed if being prescribed for the management of pain associated with diabetic peripheral neuropathy (DPN).

Note: Pregabalin is FDA approved for the management of pain associated with DPN while gabapentin is not.

IV. Lyrica will be allowed if being prescribed for the treatment of generalized anxiety disorder (GAD) and the patient has not responded to, is intolerant to, or a poor candidate for two of the following A - D:

A. A tricyclic antidepressant (TCA) (Table 1)

B. A selective serotonin reuptake inhibitor (SSRI) (Table 2)

C. A serotonin and norepinephrine reuptake inhibitor (SNRI) (Table 3)

D. Buspirone

Table 1: Tricyclic Antidepressants*

Generic Name	Generics available	Brand Name
amitriptyline	Y	Elavil
amitriptyline	Y	Endep
doxepin	Y	Doxipin
imipramine	Y	Tofranil
nortriptyline	Y	Aventyl
nortriptyline	Y	Pamelor

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 2: Selective Serotonin Reuptake Inhibitors*

Generic Name	Generics available	Brand Name
citalopram	Y	Celexa
escitalopram	N	Lexapro
fluvoxamine	Y	Luvox
paroxetine HCL	N	Paxil CR
paroxetine	Y	Paxil
paroxetine mesylate	N	Pexeva
fluoxetine	Y	Prozac
fluoxetine	N	Prozac Weekly
fluoxetine	N	Sarafem
sertraline	Y	Zoloft

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 3: Serotonin and Norepinephrine Reuptake Inhibitors*

Generic Name	Generics available	Brand Name
duloxetine	N	Cymbalta
venlafaxine ER	N	Effexor XR

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

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Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Lyrica Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/L003	**Page:** 3 of 4	

Table 4: PreferredOne First Line Step Therapy Drugs*

First Line Medications
gabapentin- generic version of Neurontin

Revised 06/30/06

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 5**:** PreferredOne Second Line Step Therapy Drugs*

Second Line Medications
Lyrica®

Revised 06/30/06

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Lyrica Step Therapy	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/L003	**Page:** 4 of 4	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Pharmacy Policy PP/S001 Step Therapy

REFERENCES:

1. Backonja M, Beydoun A, Edwards KR, Schwartz SL, Fonseca V, Hes M, laMoreaux L, Garofalo E. Gabapentin for the symptomatic treatment of painful neuropathy in patients with diabetes mellitus: a randomized controlled trial. JAMA. 198 Dec 2;280(21):1831-6.
2. Express Scripts Step Therapy Policy: Lyrica Step Therapy Program. 12/07/05.
3. Gidal BE. New and emerging treatment options for neuropathic pain. Am J Manag care. 2006 Jun;12(9 Suppl):s269-78.
4. Gilron I, Flatters SJ. Gabapentin and pregabalin for the treatment of neuropathic pain: a review of laboratory and clinical evidence. Pain Res Manag. 2006 Summer;11 Suppl A:16A-29A.
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6. Lauer D, Holzel L, Hornyak M. generalized anxiety disorder with comorbidity: treatment wit pregabalin. Nervenarzt. 2006 Jun 20.

DOCUMENT HISTORY:

Created Date: 11/15/06
Reviewed Date:
Revised Date:

Exhibit J

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Nasal Steroids Step Therapy Program	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/N002	**Page:** 1 of 4	

PRODUCT APPLICATION:

- ☒ PreferredOne Community Health Plan (PCHP)
- ☒ PreferredOne Administrative Services, Inc. (PAS)
- ☐ PreferredOne (PPO)
- ☒ PreferredOne Insurance Company (PIC)

Coverage is subject to the terms of an enrollee's pharmacy benefit plan and formulary. To the extent there is any inconsistency between this criteria set/policy and the terms of an enrollee's pharmacy benefit plan and /or formulary, the enrollee's pharmacy benefit plan and formulary govern.

This policy applies only to PAS enrollees when the employer group has adopted the applicable drug trend management program(s).

PURPOSE:

The intent of this policy is to require the use of a generic nasal steroids before the use of a branded nasal steroid.

DEFINITIONS:

Step Therapy:

Step therapy requires the use of the more cost-effective drug when there is no literature to support the therapeutic benefit of one drug over another. The first step in a step therapy process, utilizing the most cost effective drug is called the first-line therapy. If first-line therapies are ineffective for a person, the next required step known as "second-line therapies" are tried, then "third-line therapies" etc. as required.

Automated Step Therapy:

Step therapy programs are generally automated within the pharmacy claims adjudication system. The pharmacy claims system reviews the patient's medication history prior to dispensing at the pharmacy. If the automated requirements are met, the pharmacy claim will automatically process through the claims processing system.

Perennial Allergic Rhinitis (PAR):

Occurs year-round and can result from sensitivity to pet hair, mold on wallpaper, houseplants, carpeting, and upholstery. Some studies suggest that air pollution such as automobile engine emissions can aggravate allergic rhinitis. Although bacteria is not the cause of allergic rhinitis, one medical study found a significant number of the bacteria Staphylococcus aureus in the nasal passages of patients with year-round allergic rhinitis, concluding that the allergic condition may lead to higher bacterial levels, thereby creating a condition that worsens the allergies.

Seasonal Allergic Rhinitis (SAR):

Also known as hayfever occurs in late summer or spring. Hypersensitivity to ragweed, not hay, is the primary cause of seasonal allergic rhinitis in 75 percent of all Americans who suffer from this seasonal disorder. People with sensitivity to tree pollen have symptoms in late March or early April; an allergic reaction to mold spores occurs in October and November as a consequence of falling leaves.

PreferredOne®

Department of Origin: Pharmacy	Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Nasal Steroids Step Therapy Program	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/N002	**Page:** 2 of 4	

BACKGROUND:
This criteria set is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.

When requesting a drug other than a first line drug in step therapy, the ordering physician must supply additional clinical information documenting why the specific medication is required for the patient, or published professional literature supporting the increased therapeutic benefit or safety of the second, third (etc.) line drug.

Table 1 Drugs Affected:
Nasal Steroids

Generic Name	Generics available	Brand Name
budesonide nasal spray	N	Rhinocort Aqua
fluticasone nasal spray	Y	Flonase
beclomethasone nasal spray	N	Beconase AQ
triamcinolone nasal spray	N	Nasacort AQ
flunisolide nasal spray	Y	Nasarel
mometasone nasal spray	N	Nasonex

POLICY:
Certain enrollee's may be required to follow a Step Therapy program for certain drug classes.

GUIDELINES:
Step Therapy Requirements:

I. The patient has been started and stabilized on a second line medication (Table 2) during the previous 130 days (i.e. grandfathering) the patient will be allowed to continue on the medication.

II. If a patient has not responded to, is intolerant to, or a poor candidate for one first line nasal steroid (Table 1) a second line nasal steroid (Table 2) will be approved.

III. Exceptions

A. Budesonide (Rhinocort Aqua) may be used before a first step nasal steroid (Table 2) if the patient is pregnant.

Note: All of the nasal steroid formulations are pregnancy category C except for budesonide (Rhinocort Aqua) which is pregnancy category B.

B. Mometasone (Nasonex) may be used before a step two nasal steroid (Table 2) if the patient is less than 4 years of age.

Note: Nasonex is the only nasal steroid indicated in children less than 4 years of age.

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Nasal Steroids Step Therapy Program	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/N002	**Page:** 3 of 4	

Table 1: PreferredOne First Line Step Therapy Drugs*

FIRST LINE NASAL STEROIDS
fluticasone – generic version of Flonase®
flunisolide – generic version of Nasarel®

Revised 09/06/06

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 2: PreferredOne Second Line Step Therapy Drugs*

SECOND LINE NASAL STEROIDS
Beconase AQ®
Flonase®
Nasacort AQ®
Nasarel®
Nasonex®
Rhinocort® Aqua™

Revised 09/06/06

*Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

Table 3:
FDA-Approved Indications

Drug	FDA-Approved Indications						
	SAR	*PAR*	Non-allergic (vasomotor) rhinitis	Treatment of nasal polyps	Treatment of nasal polyp recurrence following surgical removal	Prophylaxis of SAR nasal symptoms	Age
Beconase AQ®	X	X	X		X		Greater than or equal to 6 yrs
Flonase®	X	X	X				Greater than or equal to 4 yrs
Nasacort AQ®	X	X					Greater than or equal to 6 yrs
Nasarel®	X	X					Greater than or equal to 6 yrs
Nasonex®	X *Greater than or equal to 2 yr	X *Greater than or equal to 2 yr				X *Greater than or equal to 2 yr	See specific indications
Rhinocort Aqua®	X	X					Greater than or equal to 6 yrs

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Criteria Document: Nasal Steroids Step Therapy Program	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/N002	**Page:** 4 of 4	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Pharmacy Policy PP/S001 Step Therapy
Pharmacy Policy PP/Q001 Quantity Limits

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DOCUMENT HISTORY:

Created Date: 11/15/06
Reviewed Date:
Revised Date: 01/02/07

Exhibit K

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Chief Medical Officer	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Policy Document: Cost Benefit Program	**Replaces Effective Policy Dated:** 08/17/05	
Reference #: PP/C002	**Page:** 1 of 2	

PRODUCT APPLICATION:
- ☒ PreferredOne Community Health Plan (PCHP)
- ☒ PreferredOne Administrative Services, Inc. (PAS)
- ☐ PreferredOne (PPO)
- ☒ PreferredOne Insurance Company (PIC)

Coverage is subject to the terms of an enrollee's pharmacy benefit plan and formulary. To the extent there is any inconsistency between this criteria set/policy and the terms of an enrollee's pharmacy benefit plan and /or formulary, the enrollee's pharmacy benefit plan and formulary govern.

PURPOSE:
To provide coverage guidelines for medications when the use of that medication is not cost effective or shown to be superior to comparable medications.

BACKGROUND:
Drugs Affected:

Excluded Drug Name		Generic Available	Alternative Drug		Generics Available for Drug Components
Generic Name	Brand Name		Generic Name	Brand Name	
alendronate/ vitamin D	Fosamax plus D	N	alendronate	Fosamax	N
atorvastatin/ amlodipine	Caduet	N	amlodipine	Norvasc	
			atorvastatin	Lipitor	
doxycycline	Oracea	N	doxycycline	Vibramycin	Y
isorsorbide dinitrate/ hyralazine	BiDil	N	isosorbide dinitrate	Isordil	Y
			hydralazine	Apresoline	Y
minocycline	Solodyn	N	minocycline	Minocin	Y
pravastatin/ buffered aspirin	Pravigard PAC	N	pravastatin	Pravachol	Y
risidronate/ calcium	Actonel with Calcium	N	risidronate	Actonel	Y
zolpidem controlled -release	Ambien CR	N	zolpidem	Ambien	N*

* Will be available generically April 2007

PROCEDURE:
Initiation of *cost benefit program* exemption request:

I. The drugs that are affected by *cost benefit program* are dependent on the Plan and Pharmacy Benefit Manager. Enrollees can find out what drugs and/or drug classes fall into *cost benefit program* requirements by calling the Customer Service telephone number listed on the enrollee's insurance card

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Chief Medical Officer	**Date approved:** 11/15/06
Department(s) Affected: Medical Management and Pharmacy	**Effective Date:** 11/15/06	
Pharmacy Policy Document: Cost Benefit Program	**Replaces Effective Policy Dated:** 08/17/05	
Reference #: PP/C002	**Page:** 2 of 2	

II. The enrollee's prescribing provider must submit a written request for an exception from Cost Benefit Program on behalf of the enrollee with clinical information supporting the request. This can be initiated by completing the Medication Request Form or by calling the Customer Service Department telephone number listed on the enrollee's insurance card to obtain a medication request form.

III. Requests for exception for cost benefit program will be reviewed on a case by case basis by a nurse reviewer and if necessary a physician reviewer.

IV. If the *cost benefit program* override is approved using the following guidelines, PreferredOne will enter an override in the PBM processing system to allow processing of the prescription, and a letter will be sent to the provider and enrollee notifying them of the approval of the override.

V. If the *cost benefit program* override is not approved using the following guidelines, PreferredOne will notify the practitioner of the denial and appeal rights by phone and letter. PreferredOne will notify the enrollee of the denial and appeal rights by letter.

POLICY:
PreferredOne requires the use of the most cost-effective medication when equivalent medications are available.

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/S009 Medical Step Therapy
Pharmacy Criteria PC/H001 HMG Step Therapy

DOCUMENT HISTORY:

Created Date: 11/04
Reviewed Date:
Revised Date: 08/17/05, 11/15/06

Exhibit L

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Oncotype DX Test	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/E010	**Page:** 1 of 3	

PRODUCT APPLICATION:

☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This Criteria Set applies to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

PURPOSE:

The intent of this criteria set is to ensure services are medically necessary.

BACKGROUND:

This criteria set is based on expert consensus opinion and/or available reliable evidence.

The Oncotype DX assay is a patented multiple gene assay that provides a quantitative assessment of the likelihood of distant breast cancer recurrence, and also assesses the benefit from certain types of chemotherapy.

GUIDELINES:

Must have I – IV, and none of V:

I. Test is ordered by an oncologist

II. Recently diagnosed estrogen-receptor positive breast tumor; and

III. Nodes are negative for metastatic disease (positive tests by immunohistochemisty testing only would be treated as negative nodes); and

IV. No evidence of distant metastatic cancer; and

V. Test result will influence the member's chemotherapeutic management (patient must be able to tolerate and must be willing to undergo chemotherapy).

VI. Exclusions – none of the following A-E:

A. Invasive tumor under 0.5 cm in size (smaller tumors have little data at this time)

B. Invasive tumor over 4.0 cm in size (larger tumors have little data at this time)

C. Carcinoma in situ

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Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Oncotype DX Test	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/E010	**Page:** 2 of 3	

D. Inflammatory breast cancer

E. Preoperative treatment decisions

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Oncotype DX Test	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/E010	**Page:** 3 of 3	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/C009 Medical Step Therapy
Medical Policy MP/G001 Genetic Testing

REFERENCES:

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DOCUMENT HISTORY:

Created Date: 01/23/07
Reviewed Date:
Revised Date:

Exhibit M

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F018	**Page:** 1 of 3	

PRODUCT APPLICATION:
☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This Criteria Set applies to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

PURPOSE:
The intent of this criteria set is to ensure services are medically necessary.

BACKGROUND:
This criteria set is based on expert consensus opinion and/or available reliable evidence.

GUIDELINES:
Extracorporeal shock wave therapy for plantar fasciitis - both of the following I & II:

I. Symptoms have been present for at least four months

II. Failure of conservative treatment including both of the following A & B:

A. Patient directed treatment for at least six weeks– all of the following 1 - 6:

1. Stretching of calf muscles
2. Home cryotherapy
3. Over the counter heel cushions or shoe inserts
4. Padding or strapping of foot
5. Limiting activity
6. Over the counter anti-inflammatory medications

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F018	**Page:** 2 of 3	

B. Physician directed treatment for at least 3 months – all of the following 1 - 3:

1. Immobilization of foot – one of the following a – c:
   a. casting of foot
   b. night splints
   c. prescription orthotics

2. Prescription anti-inflammatory medications

3. Corticosteroid injections

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F018	**Page:** 3 of 3	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/C009 Medical Step Therapy

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DOCUMENT HISTORY:

Created Date: 01/23/07
Reviewed Date:
Revised Date:

Exhibit N

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Hip Resurfacing	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F017	**Page:** 1 of 3	

PRODUCT APPLICATION:
- ☒ PreferredOne Community Health Plan (PCHP)
- ☒ PreferredOne Administrative Services, Inc. (PAS)
- ☒ PreferredOne (PPO)
- ☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This Criteria Set applies to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

PURPOSE:
The intent of this criteria set is to ensure services are medically necessary.

BACKGROUND:
This criteria set is based on expert consensus opinion and/or available reliable evidence.

Hip resurfacing is an alternative to total hip replacement, and can be categorized as partial hip resurfacing or total hip resurfacing. Total hip resurfacing replaces the damaged surfaces of the femoral head and acetabulum with a cobalt/chromium surface (only the surface of the femoral head is removed to implant the femoral head resurfacing component). Partial hip resurfacing consists of implanting a femoral shell over the femoral head.

Hip resurfacing is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip replacement due to an increased possibility of requiring future hip joint revision.

Total hip resurfacing in a patient 50 years of age and older is considered investigational (see investigational list).

Hip resurfacing must be done at a center that is experienced in hip resurfacing procedures.

GUIDELINES:
One of the following I or II:

I. Partial hip resurfacing – all of the following (A-C):

A. Device is FDA approved

B. Used for an FDA approved indication – one of the following (1–6)

1. Osteoarthritis

2. Rheumatoid arthritis

3. Congenital hip dysplasia

4. Post traumatic arthritis

5. Avascular necrosis

6. Slipped capital femoral epiphysis

C. Acetabular replacement is not required or desirable

II. Total hip resurfacing – all of the following (A-C):

A. Patient is under the age of 50

B. Device is FDA approved

C. Used for one of the following indications (1 or 2):

1. Non-inflammatory arthritis (degenerative joint disease) – one of the following (a–c):
   a. osteoarthritis,
   b. traumatic arthritis,
   c. dysplasia/developmental dislocation of the hip (ddh)

2. Inflammatory arthritis such as rheumatoid arthritis.

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Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Medical Management	**Effective Date:** 01/23/07	
Policy Description: Hip Resurfacing	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F017	**Page:** 3 of 3	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/I001 Investigational/Experimental
Medical Policy MP/C009 Medical Step Therapy

REFERENCES:

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DOCUMENT HISTORY:

Created Date: 01/23/07
Reviewed Date:
Revised Date:

Exhibit O

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 11/28/06
Department(s) Affected: Medical Management	**Effective Date:** 11/28/06	
Policy Description: Coronary Computed Tomography (CT) Angiography	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L004	**Page:** 1 of 4	

PRODUCT APPLICATION:
☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This Criteria Set applies to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

PURPOSE:
The intent of this criteria set is to ensure services are medically necessary.

DEFINITIONS:
Chest Pain Syndrome:
Any constellation of symptoms that the physician feels may represent a complaint consistent with obstructive coronary artery disease (CAD). Examples of such symptoms include, but are not exclusive to: chest pain, chest tightness, burning, dyspnea, shoulder pain, and jaw pain.

Computed Tomography Angiography (CTA):
Non invasive images the coronary arteries as an alternative to standard coronary angiograms in detecting and monitoring the status of coronary artery disease. Both electron-beam computed tomography (EBCT) and helical computed tomography, including multislice CT (MSCT) can be used.

Coronary Heart Disease (CHD) Risk:
* Low Risk is defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CHD risk less than 10%
* Moderate/Intermediate risk is defined by the age-specific risk level that is average or above average. In general, moderate risk will correlate with a 10-year absolute CHD risk between 10% and 20%.
* High risk is defined as the presence of diabetes mellitus or the 10-year absolute CHD risk of greater than 20%.

BACKGROUND:
This criteria set is based on expert consensus opinion and/or available reliable evidence.

Electron-beam CT (EBCT) uses a gun instead of a standard X-ray tube that allows high speed scanning. Helical or Spiral CT scanning rotates a standard X-ray tube around a patient producing images gathered in a continuous spiral rather than individual slices. Multidetector or Multislice (MDCT, MSCT) uses CT machines equipped with an array of multiple X-ray detectors that simultaneously image multiple sections at a rapid speed. Currently MSCT/MDCT can have 4, 8, 16, 32, or 64 detectors. The higher number of detectors the thinner the slices and the quicker the images can be obtained. The facility providing the service must use equipment and personnel that meet minimum standards of capability for the intended application.

PreferredOne®

Department of Origin: Medical Management	Approved by: Medical-Surgical Quality Management Subcommittee	Date approved: 11/28/06
Department(s) Affected: Medical Management	**Effective Date:** 11/28/06	
Policy Description: Coronary Computed Tomography (CT) Angiography	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L004	**Page:** 2 of 4	

Table 1: Pre-Test Probability of CAD by Age, Gender, and Symptoms*

Age (yrs)	Gender	*Typical/Definite Angina Pectoris**	*Atypical/Probable Angina Pectoris**	*Non-Anginal Chest Pain**	Asymptomatic
30-39	Men	Intermediate	Intermediate	Low	Very Low
	Women	Intermediate	Very Low	Very Low	Very Low
40-49	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Low	Very Low	Very Low
50-59	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Intermediate	Low	Very Low
60-69	Men	High	Intermediate	Intermediate	Low
	Women	High	Intermediate	Intermediate	Low

ACC/AHA 2002 Guideline Update for Exercise Testing

*Angina Symptoms: As defined by the ACC/AHA 2002 Guideline Update on Exercise Testing:

- Typical Angina (Definite): 1) Susternal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) is relieved by rest and/or nitroglycerin.
- Atypical Anginal (Probable): Chest pain or discomfort that lacks one of the characteristics of definite or typical angina.
- Non-Anginal chest Pain: Chest pain or discomfort that meets one or none of the typical anginal characteristics.

GUIDELINES:
Coronary CT angiography is considered medically necessary for the following indications:

I. Detection or coronary artery disease (CAD) – one of the following A - C:

A. Evaluation of *chest pain syndrome* – 1 and either 2 or 3:

1. Intermediate pre-test probability (Table 1) of CAD

2. ECG uninterpretable or unable to exercise

3. Uninterpretable or equivocal stress test (exercise, perfusion, or stress echo)

B. Evaluation of suspected coronary artery anomalies

C. Evaluation of acute chest pain: both of the following 1 & 2:

1. Intermediate pre-test probability of CAD (Table 1)

2. No ECG changes and serial enzymes negative

II. Evaluation of structure and function – one of the following A - D:

A. Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 11/28/06
Department(s) Affected: Medical Management	**Effective Date:** 11/28/06	
Policy Description: Coronary Computed Tomography (CT) Angiography	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L004	**Page:** 3 of 4	

B. Evaluation of coronary arteries in patients with new onset of heart failure to assess etiology

C. Evaluation of suspected aortic dissection or thoracic aortic aneurysm

D. Evaluation of suspected pulmonary embolism

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 11/28/06
Department(s) Affected: Medical Management	**Effective Date:** 11/28/06	
Policy Description: Coronary Computed Tomography (CT) Angiography	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L004	**Page:** 4 of 4	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/C009 Medical Step Therapy

REFERENCES:

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DOCUMENT HISTORY:

Created Date: 11/28/06
Reviewed Date:
Revised Date:

Exhibit P

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Coding, Claims, Customer Service, Medical Management	**Effective Date:** 01/23/07	
Policy Description: Virtual Colonoscopy	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L005	**Page:** 1 of 2	

PRODUCT APPLICATION:

☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This Criteria Set applies to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

PURPOSE:

The intent of this criteria set is to ensure services are medically necessary.

DEFINITIONS:

Virtual Colonoscopy:
Also know as three-dimensional computed tomographic (CT) colography, or CT colography is a diagnostic test using helical computed tomography (CT) scanning and computer generated images to produce high-resolution two and tree dimensional images of the colon and rectum.

BACKGROUND:

This criteria set is based on expert consensus opinion and/or available reliable evidence.

Use of virtual colonoscopy for any other indication besides what is listed in this criterion including routine colorectal cancer screening is considered investigational (see Investigational List)

Virtual colonoscopy must be done at a center that is experienced in the procedure.

GUIDELINES:

One of the following I or II:

I. Incomplete screening or diagnostic colonoscopy – one of the following A or B:

A. Inability to complete or undergo a traditional colonoscopy due to an obstruction

B. Results of traditional colonoscopy are questionable, or further study is needed

II. In anticoagulated patients who cannot safely discontinue anticoagulation therapy

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Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Coding, Claims, Customer Service, Medical Management	**Effective Date:** 01/23/07	
Policy Description: Virtual Colonoscopy	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L005	**Page:** 2 of 2	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/C009 Medical Step Therapy
Medical Policy MP/S006 Screening Tests Normal Risk Populations
Medical Policy MP/S009 Screening Tests for High Risk Populations

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DOCUMENT HISTORY:

Created Date: 01/23/07
Reviewed Date:
Revised Date:

Exhibit Q

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Coding, Claims, Customer Service, Medical Management	**Effective Date:** 01/23/07	
Policy Description: Wireless Capsule Endoscopy	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L006	**Page:** 1 of 2	

PRODUCT APPLICATION:

☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This Criteria Set applies to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

PURPOSE:

The intent of this criteria set is to ensure services are medically necessary.

BACKGROUND:

This criteria set is based on expert consensus opinion and/or available reliable evidence.

Wireless capsule endoscopy utilizes the use of a small capsule containing a disposable light source, miniature color video camera, battery, antenna and a data transmitter. The patient swallows the capsule and images taken by the camera contained within the capsule are relayed to the data transmitter. The data transmitter is connected to a computer workstation where the images are downloaded, reviewed, and interpreted by the physician.

Use of wireless capsule endoscopy for any other indication besides what is listed in this criterion including use as a screening test is considered investigational (see Investigational List)

GUIDELINES:

Both of the following I and II:

I. Diagnosis of occult gastrointestinal (GI) bleeding the site of which has not previously been identified or initial diagnosis of suspected Crohn's disease; and

II. Standard endoscopic exams such as upper GI endoscopy, colonoscopy, or radiologic procedures such as small bowel follow through (SBFT) are inconclusive.

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Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 01/23/07
Department(s) Affected: Coding, Claims, Customer Service, Medical Management	**Effective Date:** 01/23/07	
Policy Description: Wireless Capsule Endoscopy	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/L006	**Page:** 2 of 2	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/C009 Medical Step Therapy
Medical Policy MP/S006 Screening Tests Normal Risk Populations
Medical Policy MP/S009 Screening Tests for High Risk Populations

REFERENCES:

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DOCUMENT HISTORY:

Created Date: 01/23/07
Reviewed Date:
Revised Date:

Exhibit R

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Chief Medical Officer	**Date approved:** 01/09/07
Department(s) Affected: Claims, Coding, Customer Service, Medical Management and Policy	**Effective Date:** 01/09/07	
Document Description: Screening Tests for Patient Specific Situations (High Risk)	**Replaces Effective Policy Dated:** N/A	
Reference #: MP/S009	**Page:** 1 of 3	

PRODUCT APPLICATION:

☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☐ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This policy applies to PAS enrollees only when the employer group has elected to provide benefits for the service/procedure/device. Check benefits in SPD/COC. If benefits not specifically addressed in the SPD/COC verify with the appropriate account manager the availability of benefits.

PURPOSE:

To provide *medically necessary* coverage guidelines for patient specific tests when benefits are available.

DEFINITIONS:

Patient Specific Test:
Test done for a high-risk population group for specific medical conditions/diagnosis because of medical symptoms or due to a family history of the specific condition.

Screening:
The application of a test to detect a potential disease or condition (or risk factor) in a person who has no documented signs or symptoms of the condition at the time the test is done. Screening is differentiated from diagnosis by whether the person has documented signs or symptoms of the targeted condition.

POLICY:

Patient specific tests are considered medically necessary if the test is ordered by a physician and is necessary to confirm the diagnosis of a specific disease, or direct treatment of a specific disease.

Payment for medically necessary tests are at two different benefit levels. Tests may be paid at the screening/preventative level or at the diagnostic/treatment level. Tests done to confirm a diagnosis or direct treatment because of patient symptoms, personal history of a disease/condition or due to a specific occurrence such as an illness, exposure, or an injury will be covered at the diagnostic/treatment benefit level. Tests done on asymptomatic patients because they are considered at high risk for a diagnosis due to family history would be covered at a screening/preventative benefit level.

GUIDELINES:

I. Characteristics of covered tests - all the following are required A-H:

A. The test must be ordered by a physician, physician assistant or nurse practitioner

B. The cost, accuracy, and acceptability of the screening test are adequate for the population to be screened

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Department of Origin: Medical Management	Approved by: Chief Medical Officer	Date approved: 01/09/07
Department(s) Affected: Claims, Coding, Customer Service, Medical Management and Policy	Effective Date: 01/09/07	
Document Description: Screening Tests for Patient Specific Situations (High Risk)	Replaces Effective Policy Dated: N/A	
Reference #: MP/S009	Page: 2 of 3	

C. The burden of the target disease warrants action

D. Early diagnosis must be scientifically proven to lead to improved clinical outcomes.

E. Patients screened must be willing to consider subsequent appropriate treatment options.

F. The screening test must be accepted practice in the medical community.

G. The test must be supported in the scientific literature to be effective and safe.

H. The test must be ordered for enrollees who have documented family history and/or are considered at appropriate risk for the target disease or be ordered as a screening test to determine whether an enrollee may be a carrier of the specific disease when the enrollee is at high risk for the specific disease as confirmed by a physician, and the outcome of the test would determine and/or impact the enrollee's medical treatment

II. Appropriate tests include but are not limited to:

A. Annual screening tests for women determined to be at high risk for ovarian cancer – must have both of the following 1 and 2:

1. Women at risk for ovarian cancer are defined as having a family history of any one of the following:
   a. One or more first or second degree relatives with ovarian cancer
   b. Cluster of women relatives with breast cancer
   c. Nonpolyposis colorectal cancer
   d. Positive BRCA1 or BRCA2 mutations
   e. Personal history of breast cancer

2. Testing includes any or all of the following:
   a. CA-125 serum tumor marker testing
   b. Transvaginal ultrasound
   c. Pelvic examination
   f. Other proven ovarian cancer screening tests

B. Screening for abdominal aortic aneurysm – must meet all of the following 1 - 3:

1. The test must be performed in a setting with adequate quality assurance (i.e., in an accredited facility with credentialed technologists)

2. Must be a male between age of 65 and 75

3. Must be a smoker or have a history of smoking

C. Patients with history of prostate cancer and treatment being followed for recurrence by PAS

D. Patients with history of colon cancer and treatment being followed for recurrence by CEA

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Department of Origin: Medical Management	**Approved by:** Chief Medical Officer	**Date approved:** 01/09/07
Department(s) Affected: Claims, Coding, Customer Service, Medical Management and Policy	**Effective Date:** 01/09/07	
Document Description: Screening Tests for Patient Specific Situations (High Risk)	**Replaces Effective Policy Dated:** N/A	
Reference #: MP/S009	**Page:** 3 of 3	

EXCLUSIONS/LIMITATIONS (not limited to):
Refer to enrollee's Certificate of Coverage or Summary Plan Description.

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/C009 Medical Step Therapy

REFERENCES:

1. American College of Medical Genetics/American Society of Human Genetics Working Group on ApoE and Alzheimer Disease, American College of Medical Genetics, Bethesda, MD. Consensus statement: Statement on Use of Apolipoprotein E Testing for Alzheimer Disease. (JAMA. 1995;274:1627-1629). Available April 15, 2005: http://www.acmg.net/resources/policies/pol-001.asp
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DOCUMENT HISTORY:

Created Date: 01/09/07
Reviewed Date:
Revised Date:

Exhibit S

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Chief Medical Officer	**Date approved:** 12/12/06
Department(s) Affected: Medical Management	**Effective Date:** 12/12/06	
Policy Description: Stereotactic Radiosurgery (Cyberknife, Gamma Knife, Linear Accelerator)	**Replaces Effective Policy Dated:** N/A	
Reference #: MP/S010	**Page:** 1 of 3	

PRODUCT APPLICATION:
☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

Please refer to the enrollee's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the enrollee's benefit plan or certificate of coverage, the terms of the enrollee's benefit plan document will govern.

This policy applies to PAS enrollees only when the employer group has elected to provide benefits for the service/procedure/device. Check benefits in SPD/COC. If benefits not specifically addressed in the SPD/COC verify with the appropriate account manager the availability of benefits.

The policy applies to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

PURPOSE:
The intent of this policy is to provide coverage guidelines for stereotactic radiosurgery.

DEFINITIONS:
Fractoinated Stereotactic Radiosurgery:
Multiple sessions of stereotactic radiosurgery over several days.

Radiosurgery:
A radiation therapy procedure that uses special equipment to position the patient and precisely deliver a large radiation dose to a tumor and not to normal tissue. This procedure does not use surgery. This procedure is also called gamma knife surgery, radiation surgery, stereotactic external-beam radiation, stereotactic radiation therapy, stereotactic radiosurgery, and stereotaxic radiosurgery.

BACKGROUND:
Three different instruments provide the different forms of steriotactic radiation. The Gamma knife uses 201 separate coblat-60 sources arranged in a steel shell whose beams intersect on a target. Linear acelerators adapted for stereotactic use consist of a single beam of x-rays rotated to produce multiple intersecting beams. Proton beam radiosurgery consists of 3 to 5 fixed beams of protons, neutrons or helium ions. Steriotactic radiosurgery was orginally done with a stationary frame. The frame must be placed prior to pretreatment imaging and kept in place throughout treatment planning and treatment. The frame also limits choices for entry since fixing the frame to bony segments near extracranial sites is difficult. To overcome these obstacles, frameless stereotactic techniques have been devised and include several that involve infrared tracking systems for navigation. Infrared systems recognize the position of the operative field by simultaneous movement of light-emitting diodes attached to a head-holder or the patient and can be used with a removable frame or with implanted fiducials. Additionally, a variety of medical robotic systems, including the CyberKnife®, the NeuroMate™, and the Mehrkoordinaten Manipulator systems, have been designed to allow frameless image-guided stereotactic intervention by combining images from preoperative computed tomography (CT) or magnetic resonance imaging (MRI) with intraoperative target localization strategies.

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Department of Origin: Medical Management	**Approved by:** Chief Medical Officer	**Date approved:** 12/12/06
Department(s) Affected: Medical Management	**Effective Date:** 12/12/06	
Policy Description: Stereotactic Radiosurgery (Cyberknife, Gamma Knife, Linear Accelerator)	**Replaces Effective Policy Dated:** N/A	
Reference #: MP/S010	**Page:** 2 of 3	

POLICY:
Stereotactic radiosurgery will be covered for the diagnoses listed in the following guidelines. Requests for sterotactic radiosurgery for other diagnoses than those listed in this policy will require review on a case by case basis.

Agreement of two internal case reviewers will be needed for additional diagnoses to be added to this list.

GUIDELINES:
Stereotactic radiosurgery using an FDA approved device will be allowed for the following conditions:

I. Arteriovenous malformations

II. Aneurysms

III. Acoustic neuromas

IV. Pituitary adenomas (Cushing's disease or acromegaly)

V. Glioma

VI. Meningiomas (non-resectable, residual or recurrent)

VII. Solitary or multiple brain metastases (initial treatment or treatment of recurrence for patients having good performance status and no active systemic disease)

VIII. Trigeminal neuralgia refractory to medical management

IX. Inoperable primary malignancies of the central nervous system

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Department of Origin: Medical Management	**Approved by:** Chief Medical Officer	**Date approved:** 12/12/06
Department(s) Affected: Medical Management	**Effective Date:** 12/12/06	
Policy Description: Stereotactic Radiosurgery (Cyberknife, Gamma Knife, Linear Accelerator)	**Replaces Effective Policy Dated:** N/A	
Reference #: MP/S010	**Page:** 3 of 3	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/C009 Medical Step Therapy

REFERENCES:

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DOCUMENT HISTORY:

Created Date: 12/12/06
Reviewed Date:
Revised Date:

Exhibit T

Medical Policy Table of Contents

Reference #	Description
C001	**Court Ordered Mental Health & Substance Related Disorders Services**
C002	**Cosmetic Procedures** ***Revised***
C003	**Criteria Management and Application**
C008	**Oncology Clinical Trials, Covered / Non-covered Services** ***Revised***
C009	**Medical Step Therapy**
D002	**Diabetic Supplies**
D004	**Durable Medical Equipment, Supplies, Orthotics and Prosthetics**
D007	**Disability Determinations: Proof of Incapacity Requirements**
D008	**Dressing Supplies**
E004	**Enteral Nutrition Therapy**
F006	**FluMist**
G001	**Genetic Testing** ***Revised***
H003	**Home Prothrombin Time Testing Devices**
H004	**Healthcares Services with Demonstrated Lack of Therapeutic Benefit**
H005	**Home Health Care**
I001	**Investigational/Experimental (Formerly MM/B010)**
I002	**Infertility Treatment**
N002	**Nutritional Counseling**
P004	**Private Room**
P007	**Preparatory/Preoperative Blood Donation**
P008	**Medical Policy Documentation and Application**
R002	**Reconstructive Surgery**
S006	**Screening Tests for Normal Risk Populations** ***Revised***
S008	**Scar Revision**
S009	**Screening Tests for Patient Specific Situations (High Risk)** ***New***
S010	**Stereotactic Radiosurgery (Cyberknife, Gamma Knife, Linear Accelerator)** ***New***
T002	**Transition of Care for Continuity and Safety** ***Revised***
T004	**Therapeutic Overnight Pass**
T005	**Transfers to a Lower Level of Care for Rehabilitation from an Acute Care Facility**
W001	**Physician Directed Weight Loss Programs**

Revised 01/09/07

Medical criteria accessible through this site serve as a guide for evaluating the medical necessity of services. They are intended to promote objectivity and consistency in the medical necessity decision-making process and are necessarily general in approach. They do not constitute or serve as a substitute for the exercise of independent medical judgment in enrollee specific matters and do not constitute or serve as a substitute for medical treatment or advice. Therefore, medical discretion must be exercised in their application. Benefits are available to enrollees only for covered services specified in the enrollee's benefit plan document. Please call the Customer Service telephone number listed on the back of the enrollee's identification card for the applicable pre-certification or prior authorization requirements of the enrollee's plan. The criteria apply to PPO enrollees only when the employer group has contracted with PreferredOne for Medical Management services.

Medical Criteria Table of Contents

J001	Vascular	**Treatment of Varicose Veins**
L001	Diagnostic	**Positron Emission Tomography (PET) Scan** ***Revised***
L002	Diagnostic	**Coronary Artery Calcium Scoring Without Contrast**
L003	Diagnostic	**3D Interpretation Imaging (MRIs and CTs)**
L004	Diagnostic	**Coronary CT Angiography** ***New***
L005	Diagnostic	**Virtual Colonoscopy** ***New***
L006	Diagnostic	**Wireless Capsule Endoscopy** ***New***
M001	BH/Substance Related Disorders	**Inpatient Treatment for Mental Disorders**
M002	BH/Substance Related Disorders	**Electroconvulsive Treatment (ECT): Inpatient Treatment** ***Revised***
M004	BH/Substance Related Disorders	**Day Treatment Program-Mental Health Disorder** ***Revised***
M005	BH/Substance Related Disorders	**Eating Disorders-Level of Care Criteria**
M006	BH/Substance Related Disorders	**Partial Hospitalization Program (PHP)-Mental Health Disorder**
M007	BH/Substance Related Disorders	**Residential Treatment** ***Revised***
M008	BH/Substance Related Disorders	**Outpatient Psychotherapy**
M009	BH/Substance Related Disorders	**Outpatient Chronic Pain Program Criteria**
M010	BH/Substance Related Disorders	**Substance Related Disorders: Inpatient Primary Treatment**
M014	BH/Substance Related Disorders	**Detoxification: Inpatient Treatment**
M019	BH/Substance Related Disorders	**Pathological Gambling: Outpatient Treatment** ***Revised***
M020	BH/Substance Related Disorders	**Autism Spectrum Disorders Treatment** ***Revised***
N001	Rehabilitation	**Acute Inpatient Rehabilitation**
N002	Rehabilitation	**Skilled Nursing Facilities**
N003	Rehabilitation	**Occupational and Physical Therapy: Outpatient Setting**
N004	Rehabilitation	**Speech Therapy: Outpatient** ***New***
T001	Transplant	**Bone Marrow Transplantation/Stem Cell Harvest (Autologous and Fetal Cord Blood)** ***Revised***
T002	Transplant	**Kidney/Pancreas Transplantation** ***Revised***

T003	Transplant	**Heart Transplantation**
T004	Transplant	**Liver Transplantation** ***Revised***
T005	Transplant	**Lung Transplantation**
T006	Transplant	**Intestinal Transplant**

Revised 01/23/07

Exhibit U

Pharmacy Policy Table of Contents

Reference #	Description
C001	**Coordination of Benefits** *Revised*
C002	**Cost Benefit Program** *New*
D001	**Drugs with Potential Adverse Effects or Interactions** *Revised*
D002	**Dosing Optimizing Programs** *Revised*
F001	**Formulary and Co-Pay Drug Overrides** *Revised*
N001	**National Formulary Exceptions** *Revised*
O001	**Off-Label Drug Use** *Revised*
P001	**Prior Authorization of Medications Ordered by a Specialist** *Revised*
Q001	**Quantity Limits per Prescription per Copayment** *Revised*
S001	**Step Therapy** *Revised*

Revised 11/15/06

Pharmacy Criteria Table of Contents

Reference #	Category	Description
A001	Pharmacy	ACE Inhibitors Step Therapy
A002	Pharmacy	Oral Antifungal Treatment *Revised*
A003	Pharmacy	Advair Step Therapy *New*
B003	Pharmacy	Botulinum Toxin
B004	Pharmacy	Biologics for Arthritic Conditions: Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), and Orencia (abatacept) *Revised*
B005	Pharmacy	Biologics for Psoriasis: Amevive (alefacept) Enbrel (etanercept), Humira (adalimumab) and Raptiva (efalizumab)
B006	Pharmacy	Biologics (Remicade) for Crohn's Disease and Ulcerative Colitis
B007	Pharmacy	Biologics (Enbrel & Remicade) for Ankylosing Spondylitis
C002	Pharmacy	Cyclooxygenase-2 (COX-2) Inhibitors (Celebrex)
C003	Pharmacy	Topical Corticosteroids Step Therapy *New*
D001	Pharmacy	Diabetic Adjunct Agents (Byetta and Symlin)
D002	Pharmacy	Dihydropyridine Calcium Channel Blocker (DHP CCB) Step Therapy *Revised*
G001	Pharmacy	Growth Hormone Therapy *Revised*
H001	Pharmacy	HMG - CoA Reductase Inhibitor *New*
I001	Pharmacy	Topical Immunomodulators
L002	Pharmacy	Leukotriene Pathway Inhibitors Step Therapy *Revised*
L003	Pharmacy	Lyrica Step Therapy *New*
N001	Pharmacy	Branded Nonsteroidal Anti-Inflammatory Drug (NSAID) Step Therapy
N002	Pharmacy	Nasal Steroids Step Therapy *New*
P001	Pharmacy	Proton Pump Inhibitor (PPI) Step Therapy *Revised*
R002	Pharmacy	RSV Prohylaxis - American Academy of Peds
S002	Pharmacy	Selective Serotonin Reuptake Inhibitors (SSRIs) Step Therapy
W001	Pharmacy	Weight Loss Medications *Revised*
X001	Pharmacy	Xolair (omalizumab) *Revised*

Revised 11/15/06

Exhibit V

Chiropractic Policy Table of Contents

Revised 01/24/07

EXPRESS SCRIPTS®

2007 Express Scripts National Preferred Formulary

The following is a list of the most commonly prescribed drugs. It represents an abbreviated version of the drug list (formulary) that is at the core of your prescription-drug benefit plan. The list is not all-inclusive and does not guarantee coverage. In addition to using this list, you are encouraged to ask your doctor to prescribe generic drugs whenever appropriate.

PLEASE NOTE: The symbol * next to a drug signifies that it is subject to nonformulary status when a generic is available throughout the year. Not all the drugs listed are covered by all prescription-drug benefit programs; check your benefit materials for the specific drugs covered and the copayments for your prescription-drug benefit program. For specific questions about your coverage, please call the phone number printed on your ID card.

A

ABILIFY (excluding Discmelt & solution)
ACCU-CHEK ACTIVE KIT
ACCU-CHEK ACTIVE test strips
ACCU-CHEK ADVANTAGE KIT
ACCU-CHEK ADVANTAGE test strips
ACCU-CHEK AVIVA KIT
ACCU-CHEK AVIVA test strips
ACCU-CHEK COMFORT CURVE test strips
ACCU-CHEK COMPACT KIT
ACCU-CHEK COMPACT test strips
ACCU-CHEK COMPLETE KIT
acetaminophen w/codeine
acetazolamide
ACTIVELLA
ACTONEL with calcium
ACTOPLUS MET
ACTOS
acyclovir
ADDERALL XR*
ADVAIR DISKUS
ADVICOR
AGGRENOX
albuterol
ALLEGRA-D* (excluding 24 hours)
ALOMIDE
ALORA
ALPHAGAN P
ALTACE
aluminum chloride
amantadine
AMBIEN* (excluding CR)
aminophylline
amitriptyline
ammonium lactate
amox tr/potassium clavulanate
amoxicillin
ANALPRAM-HC* (1% cream, 2.5% lotion)
ANDRODERM
ANDROGEL*
antipyrine w/benzocaine
apri
aranelle
ARANESP [INJ]
ARICEPT
ASACOL
ASTELIN
atenolol, -chlorthalidone
AUGMENTIN XR
AVANDAMET
AVANDARYL
AVANDIA
AVELOX
aviane
AVODART
AXID solution only
azathioprine
azithromycin

B

benazepril, /hctz
BENZACLIN
benzonatate
benzoyl peroxide
betamethasone
BETASERON [INJ]
bisoprolol fumarate/hctz
BRAVELLE [INJ]
brimonidine tartrate
bupropion, sr
butalbital/apap/caffeine
BYETTA [INJ]

C

camila
CANASA
captopril, /hctz
carbamazepine
carisoprodol
cefadroxil
cefpodoxime
cefprozil
cefuroxime
CELEBREX
CELLCEPT
cephalexin
cesia
CETROTIDE [INJ]
chloral hydrate
chlorzoxazone
cholestyramine
choline mag trisalicylate
chorionic gonadotropin [INJ]
ciclopirox
cilostazol
cimetidine
CIPRO HC
CIPRODEX
ciprofloxacin
citalopram
clarithromycin
CLIMARA PRO
clindamycin phosphate
clobetasol propionate
clomiphene citrate
clonidine hcl
clotrimazole/betamethasone
clotrimazole troche
COLAZAL*
colestipol
COMBIPATCH
COMBIVENT
CONCERTA*
COREG*
COSOPT
COZAAR
CREON
CRESTOR
cromolyn sodium
cryselle
cyclobenzaprine hcl
cyclosporine, modified
CYMBALTA [SNRI]

D

DEPAKOTE
desmopressin acetate
desonide
desoximetasone
dextroamphetamine sulfate
diclofenac sodium
dicyclomine hcl
DIFFERIN
diflunisal
diltiazem, extended release
DIOVAN, HCT
diphenhydramine
dipyridamole
DITROPAN XL*
doxepin hcl
DUAC
DYNACIRC CR

E

EDEX [INJ]
EFFEXOR XR [SNRI]
ELIDEL
EMADINE*
enalapril, hctz
enpresse
EPIPEN, JR [INJ]
errin
erythromycin
erythromycin/benzoyl perox.
estradiol, tds
ESTRATEST, H.S.
estropipate
etidronate disodium
etodolac
EUFLEXXA [INJ]
EXELON

F

famotidine
felodipine er
fentanyl citrate
fexofenadine
FINACEA
finasteride
FLOMAX
FLOVENT, HFA
fluconazole
fluocinonide
fluorouracil
fluoxetine hcl
fluticasone nasal spray
fluticasone propionate
fluvoxamine maleate
folic acid
FOLLISTIM, AQ [INJ]
FOLTX
FORADIL
FORTEO [INJ]
FOSAMAX, PLUS D
fosinopril, /hctz

G

gabapentin
GANIRELIX ACETATE [INJ]
gemfibrozil
gentamicin sulfate
glimepiride
glipizide, er, xl
glipizide/metformin
glyburide, micronized
glyburide/metformin
GONAL-F, RFF [INJ]
guaifenesin w/pseudoephedrine

H

haloperidol
HUMALOG [INJ]
HUMATROPE [INJ]
HUMIRA [INJ]
HUMULIN [INJ]
hydrochlorothiazide
hydrocodone w/guaifenesin
hydrocodone/acetaminophen
hydrocortisone
hydroxyurea
hyoscyamine sulfate
HYZAAR

I

ibuprofen
imipramine
IMITREX*
indomethacin
INNOPRAN XL
INTAL inh
ipratropium bromide
isotretinoin
itraconazole

J

jolivette
junel, fe

K

kariva
kelnor
ketoconazole

L

labetalol hcl
lactulose
LAMISIL tabs*
lamotrigine
LANTUS Vials Only [INJ]
leena
lessina
leucovorin
leuprolide acetate [INJ]
LEVAQUIN
LEVEMIR Vials Only [INJ]
LEVITRA
levora
levothyroxine sodium
LEVOXYL
LEXAPRO
lisinopril, /hctz
LOTEMAX
LOTREL*
lovastatin
low-ogestrel
LUMIGAN
lutera

M

MAXAIR AUTOHALER
meclizine hcl
medroxyprogesterone acetate
megestrol
meloxicam
MENEST
MENOPUR [INJ]
mercaptopurine
MERIDIA*
METANX
metaproterenol
metformin, er
methocarbamol
methotrexate
methylphenidate hcl
methylprednisolone
metoclopramide hcl
metolazone
metoprolol, hctz
METROGEL*
metronidazole cream
microgestin, fe
mirtazapine, soltab
mometasone
mononessa
morphine sulfate

N

nabumetone
naproxen
NASACORT AQ
NASONEX
necon
neomycin/polymyxin/dexamethasone
neomycin/polymyxin/hc
NEXIUM
NIASPAN
nifedipine er
nitrofurantoin macrocrystal
nizatidine
nora-be
nortrel
NOVAREL [INJ]
NOVOFINE 30
NOVOLIN [INJ]
NOVOLOG [INJ]
NUTROPIN, AQ (excluding Depot) [INJ]
nystatin
nystatin w/triamcinolone

O

ofloxacin
ogestrel
OMACOR
omeprazole
OMNICEF*
ONETOUCH BASIC SYSTEM
ONETOUCH FASTTAKE
ONETOUCH INDUO
ONETOUCH PROFILE SYSTEM
ONETOUCH II / Basic / Profile test strips
ONETOUCH SURESTEP test strips
ONETOUCH SURESTEP SYSTEM
ONETOUCH ULTRA test strips
ONETOUCH ULTRA SMART SYSTEM
ONETOUCH ULTRA SYSTEM
ONETOUCH ULTRA2 SYSTEM
ONETOUCH ULTRAMINI SYSTEM
orphenadrine citrate
ORTHO EVRA
ORTHO TRI-CYCLEN LO*
oxybutynin chloride
oxycodone w/acetaminophen
OXYCONTIN
OXYTROL

P

paroxetine
PATANOL
peg 3350/electrolyte
PEGASYS [INJ]
penicillin v potassium
PENLAC
PENTASA
perphenazine
phentermine hcl
phenytoin sodium, extended

(continued)

THIS DOCUMENT LIST IS EFFECTIVE JAN. 1, 2007 THROUGH DEC. 31, 2007. THIS LIST IS SUBJECT TO CHANGE.

The symbol [G] next to a drug name signifies that a generic is available for at least one or more strengths of the brand-name medication. Most generics are available at the lowest copayment.

You can get more information and updates to this document at our web site at www.express-scripts.com.

PHOSLO
pilocarpine hcl
PLAVIX*
polymyxin b sul/ trimethoprim
portia
PRANDIN
pravastatin
PRECISION SURE DOSE
PRECISION XTRA
prednisolone acetate
prednisolone sodium phosphate
prednisone
PREGNYL [INJ]
PREMARIN
PREMPHASE
PREMPRO
PREVACID
PREVACID NAPRAPAC
previfem
PREVPAC
PROAIR HFA
prochlorperazine
PROCRIT [INJ]
promethazine hcl
promethazine w/codeine
promethazine w/dm
PROMETRIUM
propranolol hcl, w/hctz
PROTOPIC
PROVENTIL HFA
pseudoephedrine w/chlorpheniramine
PULMICORT

Q

quinapril
quinaretic
QVAR

R

ranitidine
REBIF [INJ]
reclipsen
RENAGEL
REPRONEX [INJ]
RESTORIL (7.5mg)
ribasphere
ribavirin
rimantadine
RISPERDAL (excluding M-tabs)

S

SAIZEN [INJ]
salsalate
selenium sulfide
SEREVENT DISKUS
serophene
SEROQUEL
sertraline
simvastatin
SINGULAIR
SKELAXIN*
sodium sulfacetamide/ sulfur
solia
SPIRIVA
sronyx
STARLIX
STRATTERA
SULAR
sulfacetamide sodium
sulfasalazine
SYMLIN [INJ]

T

TAMIFLU
tamoxifen
TAZORAC
TEGRETOL XR
temazepam
theophylline, anhydrous, er
thioguanine
thioridazine hcl
thiothixene
thyroid
TILADE
timolol maleate
tobramycin sulfate
TOPAMAX
TOPROL XL*
trazodone hcl
tretinoin
triamcinolone acetonide
TRICOR
trifluoperazine hcl
trimethobenzamide
trimethoprim
trinessa
tri-previfem
tri-sprintec
trivora
TRUSOPT
TUSSIONEX
TWINJECT [INJ]

U

UNIPHYL
urea
UROXATRAL
URSO, FORTE

V

VALTREX
velivet
venlafaxine
VENTOLIN HFA
verapamil hcl
VERELAN PM
VESICARE
VIGAMOX
VIVELLE, -DOT
VOLTAREN ophthalmic
VYTORIN

W

warfarin
WELCHOL
WELLBUTRIN XL*

X

XENICAL
XOPENEX solution

Y

YASMIN
YAZ

Z

ZADITOR
ZETIA
ZOFRAN, ODT*
ZOMIG, ZMT
zonisamide
zovia
ZYLET
ZYMAR
ZYPREXA (excluding Zydis)

Examples of Nonformulary Medications With Selected Formulary Alternatives

The following is a list of some nonformulary brand-name medications with examples of selected alternatives that are on the formulary.

Column 1 lists examples of nonformulary medications.
Column 2 lists some alternatives that can be prescribed.

Thank you for your compliance.

Nonformulary	Formulary Alternative
ACCOLATE	Singulair
ACEON	Generic Ace Inhibitor, Altace
ACIPHEX	omeprazole, Nexium, Prevacid
ACULAR, LS, PF	Voltaren Ophthalmic
AEROBID,M	Flovent/HFA, Pulmicort, Qvar
ALAMAST	cromolyn sodium, Alomide, Emadine*, Patanol, Zaditor
ALLEGRA	fexofenadine
ALOCRIL	cromolyn sodium, Alomide, Emadine*, Patanol, Zaditor
ALREX	Generic steroids
ALTOPREV	lovastatin, pravastatin, simvastatin, Crestor, Vytorin
AMARYL	glimepiride
AMBIEN CR	Ambien* (non-CR)
AMERGE	Imitrex*, Zomig/ZMT
ANTARA	gemfibrozil, Tricor
ANZEMET	Zofran*
APIDRA	Humalog, Novolog
ASCENSIA	Accu-Chek, OneTouch
ASMANEX	Flovent/HFA, Pulmicort, Qvar
ATACAND	Cozaar, Diovan
ATACAND HCT	Diovan HCT, Hyzaar
AVALIDE	Diovan HCT, Hyzaar
AVAPRO	Cozaar, Diovan
AVITA	tretinoin, Differin
AXERT	Imitrex*, Zomig/ZMT
AZELEX	tretinoin, Differin
AZMACORT	Flovent/HFA, Pulmicort, Qvar
AZOPT	brimonidine tartrate, Alphagan P, Cosopt, Trusopt
BECONASE AQ	fluticasone, Nasacort AQ, Nasonex
BENICAR	Cozaar, Diovan
BENICAR HCT	Diovan HCT, Hyzaar
BENZAMYCIN, PAK	erythromycin/benzoyl peroxide
BETIMOL	betaxolol, timolol, other generics
BIAXIN, XL	clarithromycin
BONIVA tab	Actonel, Fosamax
CADUET	CCB + HMG combination - CCB - felodipine er, nifedipine er, Dynacirc CR, Sular, HMG - simvastatin, Crestor
CARDENE SR	nifedipine extended release, felodipine er, Dynacirc CR, Sular
CARDIZEM LA	diltiazem extended release, Verelan PM
CAVERJECT	Edex, Levitra
CEDAX	amox tr/potassium clavulanate, Augmentin XR, Omnicef*
CEFZIL	cefprozil
CELEXA	citalopram
CENESTIN	Menest, Premarin
CEREFOLIN	Generic vitamin supplement
CIALIS	Levitra
CILOXAN	ciprofloxacin eye drops
CIPRO XR	ciprofloxacin, ofloxacin, Avelox, Levaquin
CLARINEX	fexofenadine
CLARINEX-D	Allegra-D 12 hour*
CLIMARA	estradiol tds, Alora, Vivelle/-Dot
COVERA-HS	verapamil extended release, Verelan PM
CYCLESSA	cesia, velivet
DETROL LA	oxybutynin, Ditropan XL*, Vesicare
DIDRONEL	editronate
DIPENTUM	Asacol, Colazal*, Pentasa
DURAGESIC (excl 12mcg/hr)	fentanyl citrate
DYNACIRC	felodipine er, nifedipine extended release, Dynacirc CR, Sular
EFFEXOR	venlafaxine
ELESTAT	cromolyn sodium, Alomide, Emadine*, Patanol, Zaditor
ENABLEX	oxybutynin, Ditropan XL*, Vesicare
ENJUVIA	Menest, Premarin
EPOGEN	Aranesp, Procrit
ERTACZO	Generic antifungal
ESTRADERM	Generic patches, Alora, Vivelle/-Dot
ESTRASORB	Generic patches, Alora, Vivelle/-Dot
ESTROGEL	Generic patches, Alora, Vivelle/-Dot
FACTIVE	ciprofloxacin, ofloxacin, Avelox, Levaquin
FAMVIR	acyclovir, Valtrex
FemHRT	Activella, Prempro/Premphase
FEMTRACE	Menest, Premarin
FERTINEX	Bravelle, Follistim, AQ, Gonal-F/RFF
FML FORTE	Generic steroids, Lotemax
FOCALIN, XR	methylphenidate, Concerta*
FOSRENOL	Phoslo, Renagel
FREESTYLE	Accu-Chek, OneTouch
FROVA	Imitrex*, Zomig/ZMT
GENOTROPIN	Humatrope, Nutropin/AQ, Saizen
GEODON	Abilify regular tabs, Risperdal (non M-tabs), Seroquel, Zyprexa (non-Zydis)
GLUCOMETER	Accu-Chek, OneTouch
HELIDAC	Prevpac
IOPIDINE	brimonidine tartrate, Alphagan P, Cosopt, Trusopt
ISTALOL	timolol maleate
KETEK, PAK	clarithromycin, erythromycin
KRISTALOSE	lactulose
KYTRIL	Zofran*
LANTUS cartridges	Lantus vials, Levemir vials
LESCOL, XL	lovastatin, pravastatin, simvastatin, Crestor, Vytorin
LEVEMIR flexpen	Lantus vials, Levemir vials
LEXXEL	Lotrel*
LIPITOR	lovastatin, pravastatin, simvastatin, Crestor, Vytorin
LOCOID	hydrocortisone
LOFIBRA	gemfibrozil, Tricor
LOPROX	ciclopirox
LUNESTA	Ambien* (excluding CR)
MAVIK	Generic Ace Inhibitor, Altace
MAXALT,MLT	Imitrex*, Zomig/ZMT
MAXAQUIN	ciprofloxacin, ofloxacin, Avelox, Levaquin
MENOSTAR	Generic patches, Alora, Vivelle/-Dot
METADATE CD	methylphenidate, Concerta*
METAGLIP	glipizide/metformin
MIACALCIN NASAL	fortical, Actonel, Fosamax
MICARDIS	Cozaar, Diovan
MICARDIS HCT	Diovan HCT, Hyzaar
MOBIC	meloxicam
MUSE	Edex, Levitra
NASAREL	fluticasone, Nasacort AQ, Nasonex
NEVANAC	Voltaren Ophthalmic
NORDITROPIN	Humatrope, Nutropin/AQ, Saizen
NORITATE	metronidazole cream
NOROXIN	ciprofloxacin, ofloxacin, Avelox, Levaquin
NORVASC	felodipine er, nifedipine extended release, Dynacirc CR, Sular
NUTROPIN DEPOT	Humatrope, Nutropin/AQ, Saizen
NUVARING	Generics, Ortho-Evra, Ortho Tri-Cyclen Lo*, Yasmin, Yaz
OPTIVAR	cromolyn sodium, Alomide, Emadine*, Patanol, Zaditor
ORAPRED	prednisolone soln
OVIDREL	chorionic gonadotropin, Novarel
PAXIL	paroxetine
PAXIL CR	paroxetine (immediate release), citalopram, fluoxetine (daily), sertraline, Lexapro
PEDIAPRED	prednisolone soln
PEG-INTRON, REDIPEN	Pegasys
PHENYTEK	phenytoin sodium extended release
PLENDIL	felodipine er
PLEXION, TS, SCT	sulfacetamide sodium/sulfur sublimed
PRAMOSONE	lidocaine-hc
PRAVACHOL	pravastatin
PRECISION QID, PCX	Accu-chek, OneTouch
PREFEST	Activella, Prempro/Premphase
PRILOSEC	omeprazole
PROSCAR	finasteride
PROTONIX	omeprazole, Nexium, Prevacid
PROTROPIN	Humatrope, Nutropin/AQ, Saizen
PROZAC WEEKLY	fluoxetine (daily), citalopram, paroxetine, sertraline, Lexapro
QUIXIN	ciprofloxacin, ofloxacin, Vigamox, Zymar
RELENZA	rimantadine, Tamiflu
RELPAX	Imitrex*, Zomig/ZMT
RESTORIL (excluding 7.5mg)	temazepam
RETIN-A, MICRO	tretinoin, Differin
RHINOCORT AQUA	fluticasone, Nasacort AQ, Nasonex
RISPERDAL M-TAB	Risperdal (non M-tabs)
RITALIN LA	methylphenidate, Concerta*
ROZEREM	Ambien* (excluding CR)
RYNATAN	Allegra-D 12-hour*
SANCTURA	oxybutynin, Ditropan XL*, Vesicare
SEASONALE	levora, portia (continuous regimen)
SKELID	Actonel, Fosamax
SOF-TACT	Accu-Chek, OneTouch
SONATA	Ambien* (excluding CR)
SPORANOX caps, kit	itraconazole
SUPRAX	amox tr/potassium clavulanate, Augmentin XR, Omnicef*
SYMBYAX	fluoxetine+Zyprexa (non-Zydis)
SYNTHROID	levothyroxine sodium, Levoxyl
SYNVISC	supartz, Euflexxa
TARKA	verapamil+ACE Inhibitor, Lotrel*
TESTIM	Androderm, Androgel*
TEVETEN	Cozaar, Diovan
TEVETEN HCT	Diovan HCT, Hyzaar
TEV-TROPIN	Humatrope, Nutropin/AQ, Saizen
TOBRADEX	Zylet
TOFRANIL-PM	imipramine tabs
TRAVATAN	Lumigan, Xalatan
TRIGLIDE	gemfibrozil, Tricor
ULTRASE, MT	amylase/lipase/protease
UNIRETIC	benazepril/hctz, enalapril/hctz, fosinopril/hctz, lisinopril/hctz, quinaretic
VANTIN suspension	amox tr/potassium clavulanate, Omnicef*
VANTIN tabs	cefpodoxime
VEXOL	Generic steroids, Lotemax
VIAGRA	Levitra
WELLBUTRIN SR	bupropion sr
XIBROM	Voltaren Ophthalmic
ZEGERID	omeprazole, Nexium, Prevacid
ZITHROMAX	azithromycin
ZOCOR	simvastatin
ZOLOFT	sertraline
ZYPREXA ZYDIS	Zyprexa (non-Zydis)
ZYRTEC	fexofenadine
ZYRTEC-D	Allegra-D 12 hour*

KEY

The symbol [G] next to a drug name indicates that a generic is available for at least one or more strengths of the brand-name medication.
The symbol [INJ] next to a drug name indicates that the drug is available in injectable form only.
The symbol [SNRI] stands for Serotonin-Norepinephrine Reuptake Inhibitor.
For the member: Generic medications contain the same active ingredients as their corresponding brand-name medications, although they may look different in color or shape. They have been FDA-approved under strict standards.
For the physician: Please prescribe preferred products and allow generic substitutions when medically appropriate. Thank you.
Brand-name drugs are listed in CAPITAL letters.
Generic drugs are listed in lower case letters.

THIS DOCUMENT LIST IS EFFECTIVE JAN. 1, 2007 THROUGH DEC. 31, 2007. THIS LIST IS SUBJECT TO CHANGE.

The symbol [G] next to a drug name signifies that a generic is available for at least one or more strengths of the brand-name medication. Most generics are available at the lowest copayment.

You can get more information and updates to this document at our web site at www.express-scripts.com.

Exhibit X

PreferredOne®

Department of Origin: Quality Management	Approved by: Quality Management Committee	Date approved: 10/26/06
Department(s) Affected: Quality Management, Network Management	Effective Date: 10/26/2006	
Procedure Description: Medical Record Documentation Guidelines	Replaces Effective Procedure Dated: 5/22/06	
Reference #: QM/M001	Page: 1 of 2	

PRODUCT APPLICATION:
☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

BACKGROUND:
PreferredOne requires medical records to be maintained in a manner that is complete, current, detailed and organized, and permit effective and confidential patient care and quality review.

The medical record for each PreferredOne member, whether paper or electronic, should be an organized consistent record that accurately communicates information required to render timely, comprehensive medical care.

PROCEDURE:

PreferredOne member health records must be maintained according to all of the following:

I. The medical record must include all the following:

A. All pages of patient record contain patient identifier (name or ID#)

B. All record entries must:

1. Be dated; and

2. Legible to someone other than the author

C. All medical record documentation must include (Core Elements are identified by an asterisk *):

1. Patient specific demographic data (address, home or work telephone numbers and marital status)

2. A completed problem list that indicates significant illnesses and medical conditions for patient seen three or more times in one year*

3. A medication list

4. Medication allergies and other allergies with adverse reactions prominently noted in the record, or documentation or no known allergies (NKA) or no history of adverse reaction appropriately noted*

5. Past medical history is identified and includes a review of serious accidents, surgical procedures and illnesses if the patient has been seen three or more times (for children and adolescents, 18 years and younger, past medical history relates to prenatal care, birth, operations and childhood illnesses) *

6. Current or history of "use" or "non-use" of cigarettes, alcohol and other habitual substances is present when age appropriate

PreferredOne®

Department of Origin: Quality Management	Approved by: Quality Management Committee	Date approved: 10/26/06
Department(s) Affected: Quality Management, Network Management	**Effective Date:** 10/26/2006	
Procedure Description: Medical Record Documentation Guidelines	**Replaces Effective Procedure Dated:** 5/22/06	
Reference #: QM/M001	**Page:** 2 of 2	

7. Encounter forms or notes indicating the specific time for return/follow-up in weeks, months, or "as needed" if the member requires follow-up care or return visits

8. Continuity and coordination of care between the primary care practitioner and consultants as evidenced by consultant's written report or notation of verbal follow-up in the record's notes if consultations are ordered for the member

9. An immunization record/history

10. For ordered tests or studies there is evidence that the practitioner has reviewed the results either by initialing the reports or notation within the record's notes

11. Working diagnoses are consistent with findings*

12. Treatment plans are consistent with diagnoses*

II. Medical records must be stored in a secure area that is inaccessible to unauthorized individuals.

III. Clinic has written policies for:

A. Documented standards for an organized medical record keeping system

B. Confidentiality, release of information and advanced directives

C. Chart availability including between practice sites (if applicable)

IV. Compliance with medical record organization and documentation requirement policies will be monitored as follows:

A. Chart audits will occur in coordination with HEDIS data collection on a yearly basis beginning in 2007. Data collection in 2007 will serve as a baseline for goal setting in 2008 and the policy will be updated accordingly to include performance goals.

B. Organizations not meeting 80 percent of the above record keeping requirements will be notified and a corrective action plan will be requested from the clinic addressing how they will conform to the above guidelines with follow-up measurement performed the following year

REFERENCES:

- 2006 NCQA MCO Standards and Guidelines, QI 13 Standards for Medical Record Documentation
- Minnesota State Statue 4685.1110, Subp. 13

DOCUMENT HISTORY:

Created Date: 5/22/06
Reviewed Date:
Revised Date: 10/26/06

Exhibit Y

PreferredOne®

Department of Origin: Quality Management	**Approved by:** Quality Management Committee	**Date approved:** 10/26/06
Department(s) Affected: Quality Management, Network Management	**Effective Date:** 10/26/06	
Procedure Description: Clinical Practice Guidelines	**Replaces Effective Procedure Dated:** 1/24/06	
Reference #: QM/C003	**Page:** 1 of 2	

PRODUCT APPLICATION:
☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☒ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)

BACKGROUND:
PreferredOne sponsors the Institute for Clinical Systems Improvement (ICSI) and endorses all of their healthcare guidelines. Clinicians from ICSI member medical organizations survey scientific literature and draft health care guidelines based on the best available evidence. These guidelines are subjected to an intensive review process that involves physicians and other health care professionals from ICSI member organizations before they are made available for general use. More than 50 guidelines for the prevention or treatment of specific health conditions have been developed and are updated annually.

Behavioral Health Providers (BHP), a delegated entity of PreferredOne, has also developed and adopted several behavioral health clinical guidelines that PreferredOne approves in their annual work plan each year.

PreferredOne adopts the guidelines listed below for distribution in the contracted networks and performance measurement.

PROCEDURE:

I. PreferredOne adopts the following guidelines and supports implementation within its provider network:

A. ICSI Guidelines
1. Coronary Artery Disease
2. Asthma, Diagnosis and Outpatient Management of

B. BHP Guidelines
1. Assessment Guideline for Depression
2. Guideline for ADHD/ADD Assessment and Treatment

II. Distribution and Update of Guidelines

A. ICSI Guidelines
1. PreferredOne's adopted guidelines are distributed via the provider newsletter to the contracted network and posted on the PreferredOne Web site. Adopted guidelines are always available upon request.
2. Guidelines are reviewed approximately every 18 months following publication to reevaluate scientific literature and to incorporate suggestions provided by medical groups who are members of ICSI. The ICSI workgroup revises the guideline to incorporate the improvements needed to ensure the best possible quality of care. When guidelines are revised PreferredOne will send out the updated guideline(s) to all practitioners via the provider newsletter.
3. On an annual basis, practitioners are notified that all guidelines are available at *www.icsi.org*

B. BHP Guidelines

PreferredOne®

Department of Origin: Quality Management	Approved by: Quality Management Committee	Date approved: 10/26/06
Department(s) Affected: Quality Management, Network Management	**Effective Date:** 10/26/06	
Procedure Description: Clinical Practice Guidelines	**Replaces Effective Procedure Dated:** 1/24/06	
Reference #: QM/C003	**Page:** 2 of 2	

1. BHP distributes their guidelines via their BHP annual newsletter, they include them in a mailing with initial contract, BHP Web site and they are also sent with audit request letters and results (for those who do not meet the standards specified in the guidelines)
2. Guidelines are reviewed annually by BHP's Quality Improvement Committee in conjunction with the chart audit results.

II. Performance Measurement

A. The ICSI guidelines provide the basis for measurement and monitoring of clinical indicators and quality improvement initiatives. The annual measures that will be used to assess performance for each clinical guideline adopted are as follows:

1. Coronary Artery Disease
   a. Beta-blocker treatment after a heart attack (HEDIS technical specifications)
   b. Cholesterol management after acute cardiovascular event (HEDIS technical specifications)
2. Asthma, Diagnosis and Outpatient Management of
   a. Percentage of patients with persistent asthma who are on inhaled corticosteroid medication (HEDIS technical specifications)
   b. Peak flow meter use (Disease Management vendor measure)

C. BHP Guidelines

1. Assessment Guideline for Depression
   a. Percent of comprehensive assessments from a sample population of practitioners treating members with depression (BHP Specifications and Measurement)
   b. Evidence of a medical evaluation (BHP Specifications and Measurement)
2. Guideline for ADHD/ADD Assessment and Treatment
   a. Percent of comprehensive assessments based on community criteria and improvement in children and adolescents with this diagnosis (BHP Specifications and Measurement)
   b. Evidence of a medical evaluation (BHP Specifications and Measurement)

IV. PreferredOne's disease management vendor, LifeMasters has adopted the two ICSI's practice guidelines as the clinical basis for its disease management programs and will ensure program materials are consistent with the practice guidelines.

ATTACHMENTS:

ICSI Program Description

REFERENCES:

2006 NCQA MCO Standards and Guidelines
- QI 8 Clinical Practice Guidelines
- QI 7 Disease Management

DOCUMENT HISTORY:

Created Date: 5/22/06
Reviewed Date:
Revised Date: 10/26/06

Exhibit Z

Health Care Guideline:
Stable Coronary Artery Disease

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Eleventh Edition
April 2006

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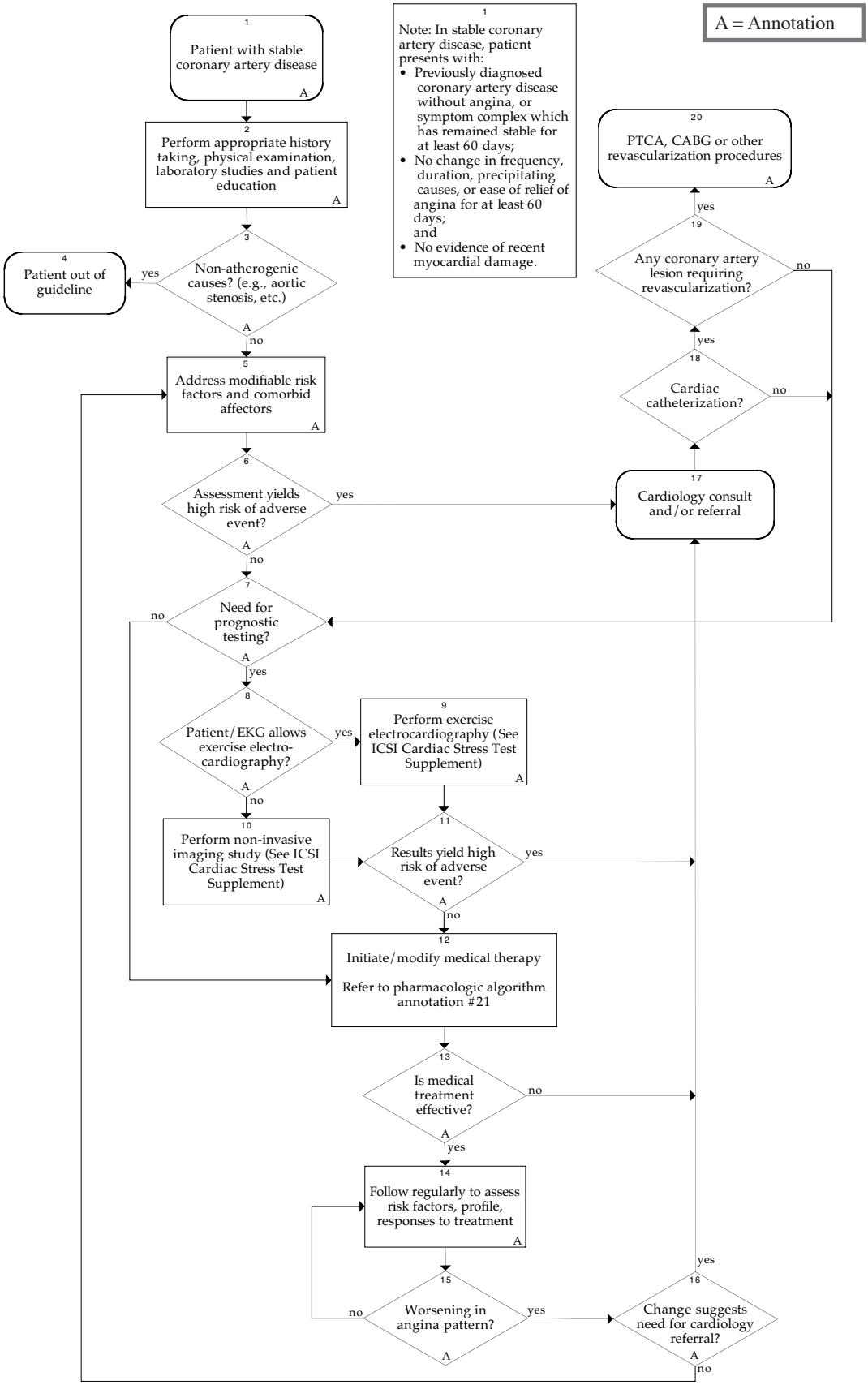

These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.

Pharmacologic Algorithm

A = Annotation

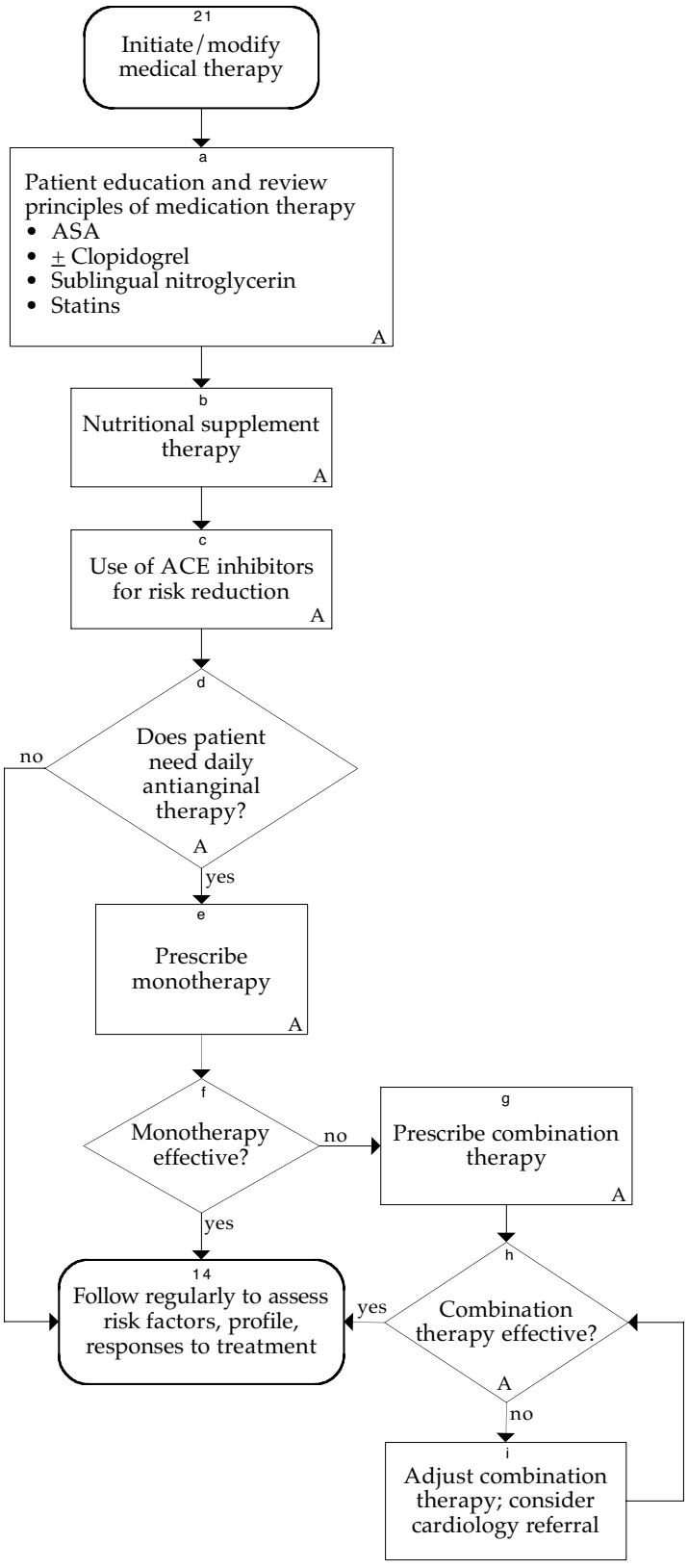

Table of Contents

Foreword

Scope and Target Population

Adults aged 18 and over who meet the stated guideline criteria as identified in Annotation #1, Patient with Stable Coronary Artery Disease.

Clinical Highlights and Recommendations

- Prescribe aspirin in patients with stable coronary artery disease if there are no medical contraindications. *(Annotation #21a)*
- Evaluate and treat the modifiable risk factors, which include smoking, sedentary activity level, stress, hyperlipidemia, obesity, hypertension and diabetes. *(Annotation #5)*
- Patients with chronic stable coronary artery disease should be on statin therapy regardless of their lipid levels unless contraindicated. (*Annotation #5)*
- Perform prognostic testing in patients whose risk determination remains unclear. This may precede or follow an initial course of pharmacologic therapy. *(Annotations #7, 8, 9, 10)*
- Refer the patient for cardiovascular consultation when clinical assessment indicates the patient is at high risk for adverse events, the non-invasive imaging study or EKG indicates the patient is at high risk for an adverse event, or medical treatment is ineffective. *(Annotations #11, 16)*
- For relief of angina, prescribe beta-blockers as first line medication. If beta-blockers are contraindicated, nitrates are the preferred alternative. Calcium channel blockers may be an alternative medication if the patient is unable to take beta-blockers or nitrates. *(Annotation #21e)*

Priority Aims

1. Improve selection and education of patients with stable CAD on the use of aspirin and antianginal drugs.
2. Improve patient understanding of management of stable CAD.
3. Increase the percentage of patients with stable CAD who receive an intervention for modifiable risk factors.
4. Improve assessment of patient's anginal symptoms.
5. Increase the use of ACE inhibitors in all patients with CAD who also have diabetes and/or LVSD, or other cardiovascular diseases.

Related ICSI Scientific Documents

Related Guidelines

- Cardiac Stress Test Supplement
- Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS)
- Heart Failure in Adults
- Hypertension Diagnosis and Treatment
- Lipid Management in Adults
- Management of Type 2 Diabetes Mellitus
- Menopause and Hormonal Therapy: Collaborative Decision-Making and Management
- Tobacco Use Prevention and Cessation for Adults and Mature Adolescents

Technology Assessment Reports

- Biochemical Markers for Cardiovascular Disease Risk (#66, 2003)
- B-type Natriuretic Peptide (BNP) for the Diagnosis and Monitoring of Congestive Heart Failure (#91, 2005)
- Cardiac Rehabilitation (#12, 2002)
- Drug-eluting Stents for the Prevention of Restenosis in Native Coronary Arteries (#78, 2003)
- Electron-Beam and Helical Computed Tomography for Coronary Artery Disease (#34, 2004)
- Intracoronary Brachytherapy to Treat Restenosis after Stent Placement (In-stent Restenosis) (#34, 2002)
- Off-pump Coronary Artery Bypass Grafting (#72, 2003)

Patient and Family Guidelines

- Heart Failure in Adults for Patients and Families
- Hypertension Diagnosis and Treatment for Patients and Families
- Lipid Management in Adults for Patients and Families
- Management of Type 2 Diabetes Mellitus for Patients and Families
- Menopause and Hormonal Therapy: Collaborative Decision-Making and Management for Patients and Families
- Tobacco Use Prevention and Cessation for Adults and Mature Adolescents for Patients and Families

Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

Key conclusions are assigned a conclusion grade: I, II, III, or Grade Not Assignable.

A full explanation of these designators is found in the Supporting Evidence section of the guideline.

Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

Phillip M. Kofron, MD has received honoraria and expense reimbursement from Kos and Pfizer for speaker training. He has a speaker consulting agreement with Pfizer but he has not made presentations or received speaker fees from Kos or Pfizer to date.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at http://www.icsi.org.

Algorithm Annotations

1. Patient with Stable Coronary Artery Disease

This guideline applies to patients with coronary artery disease either with or without angina. Examples include patients with prior myocardial infarctions, prior revascularization (i.e., PTCA, CABG), angiographically proven coronary atherosclerosis, or reliable noninvasive evidence of myocardial ischemia.

A patient presenting with angina must meet the following criteria *(Hurst, 1990; Rutherford, 1992; Shub, 1990)*:

- Symptom complex has remained stable for at least 60 days;
- No significant change in frequency, duration, precipitating causes or ease of relief of angina for at least 60 days; and
- No evidence of recent myocardial damage.

The patient may already have undergone some diagnostic workup as a result of a prior presentation of chest pressure, heaviness, and/or pain with or without radiation of the pain and/or shortness of breath. Initial care of such patients falls under the auspices of the Diagnosis of Chest Pain guideline.

Supporting evidence is of class: R

2. Perform Appropriate History Taking, Physical Examination, Laboratory Studies and Patient Education

Thorough history taking and physical examination including medication and compliance reviews are important to confirm diagnosis, to assist in risk stratification, and to develop a treatment plan (*Rutherford, 1992; Shub, 1990)*. Important points to elicit on history taking are:

- Recognize women may have atypical symptoms of cardiac ischemia. These may include fatigue, SOB without chest pain, nausea and vomiting, back pain, jaw pain, dizziness, and weakness *(Bell, 2000; Harvard Medical School, 2005; Kordella, 2005)*.
- History of previous heart disease
- Possible nonatheromatous causes of angina pectoris (e.g., aortic stenosis)
- Comorbid conditions affecting progression of CAD
- Symptoms of systemic atherosclerosis (i.e., claudication, TIAs and bruits)
- Severity and pattern of symptoms of angina pectoris

The physical examination should include a thorough cardiovascular examination as well as evaluation for evidence of hyperlipidemia, hypertension, peripheral vascular disease, congestive heart failure, anemia, thyroid disease, and renal disease.

Initial laboratory studies should include an electrocardiogram and a fasting lipid profile (total cholesterol, HDL-cholesterol, calculated LDL-cholesterol and triglycerides). Further tests, based on history and physical examination findings, may include chest x-ray, measurement of hemoglobin, and tests for diabetes, thyroid function, and renal function.

An important aspect to treatment of stable coronary artery disease is education to help the patient understand the disease processes, prognosis, treatment options, and signs of worsening cardiac ischemia so that prompt medical assistance is sought when necessary and appropriate. Education may be accomplished in a number of ways among the various medical groups. It may be ongoing, occur in a formal class, and/or

be done at the provider visit. Instruction on the proper use of ASA and sublingual nitroglycerin, as needed, should also be reviewed at this time.

Supporting evidence is of class: R

3. Non-Atherogenic Causes? (e.g., aortic stenosis, etc.)

Aortic stenosis is an important nonatherogenic cause of angina. This and any other nonatherogenic causes are considered to be outside the scope of this clinical guideline *(Shub, 1990)*.

Supporting evidence is of class: R

5. Address Modifiable Risk Factors and Comorbid Affectors

Comorbid conditions that could affect myocardial ischemia may include hypertension, anemia, thyroid disease, hypoxemia and others.

Modifiable risk factors for coronary heart disease need to be evaluated and may include smoking, inadequate physical activity, stress, hyperlipidemia, obesity, hypertension and diabetes mellitus. Intervention involving any risk factor pertinent to the patient is encouraged, and may include education, goal setting, and follow-up as necessary *(Rutherford, 1992; Shub, 1990)*.

Please see Appendix A, "Comorbid Conditions," for treatment recommendations in the presence of comorbid conditions.

Supporting evidence is of class: R

Emerging Risk Factors

An association between homocysteine levels and cardiovascular disease has been demonstrated. The recently published NORVIT trial and HOPE 2 trial found that folate, and vitamins B6 and B12 did not reduce the risk of recurrent cardiovascular events in patients with vascular disease. These supplements cannot be recommended as routine treatment in patients with Stable CAD *(Bønaa, 2006; HOPE 2 Investigators, 2006)*.

In select patients, clinicians may want to consider obtaining a lipoprotein (a) and highly sensitive C-reactive protein (hsCRP) *(Ridker, 2005)*. Highly sensitive CRP and related markers of inflammation may provide useful prognostic information and help guide further therapy for patients with CAD.

Smoking

Cigarette smoking may cause an acute cardiac ischemic event, and may interfere with the efficacy of medications to relieve angina.

Please refer to Tobacco Use Prevention and Cessation for Adults and Mature Adolescents for recommendations regarding smoking cessation.

Sedentary Activity Level

An important aspect of the provider's role is to counsel patients regarding appropriate work, leisure activities, eating habits, and vacation plans. Patients should be encouraged to exercise regularly to obtain cardiovascular benefit and to enhance their quality of life. The American College of Cardiology endorses a minimum schedule of 30-60 minutes of aerobic activity (walking, jogging, etc.) three to four times per week, supplemented by an increase in daily lifestyle activities (walking breaks at work, gardening, etc.) Medically supervised programs are recommended for moderate to high-risk patients. Exercise can be an important adjunct to modification of risk factors such as hypertension, hyperlipidemia and obesity. In addition, it can enhance patients' perception of their quality of life. Strenuous activities should be modified if they produce

severe or prolonged angina; caution is needed to avoid consistent reproduction of ischemic symptoms or situations that may precipitate ischemic complications. Education is critical in achieving these goals. A recent study *(Hambrecht, 2005)* showed less progression of CAD and significantly fewer ischemic events in patients who regularly exercised.

Supporting evidence is of class: A

Stress

Psychophysiologic stress is a notable feature of the relationship between myocardial ischemia and the patient's daily environment. Depressive symptoms are common in Stable CAD patients, with prevalence estimates ranging from 15-30%. Depression should be screened for and appropriately treated *(Kop, 2001)*.

Hyperlipidemia

A fasting lipid profile should be evaluated for appropriate patients with stable coronary artery disease. Secondary prevention is important in these patients who should be treated aggressively for hyperlipidemia. Many patients will require both pharmacologic and non-pharmacologic interventions to reach target goals. Target goals for hyperlipidemic patients with coronary artery disease include:

LDL - less than 100 mg/dL

HDL - 40 mg/dL or greater

Triglycerides - less than 150 mg/dL

There is now an *ideal* LDL-C goal of less than 70 mg/dL for patients considered to be very high risk. Several trials have shown clinical benefit using high dose statins to treat to lower LDL levels. The Treat to Numbers Trial (TNT) assigned 10,001 patients with SCAD to either 80 mg atorvastatin with achieved LDL level of 77 mg/dl, or a 10 mg dose with LDL level of 101 mg/dl, and followed them for a median of 4.9 years. In the high dose group there was a 22% relative reduction in the primary outcome of death from coronary heart disease, nonfatal myocardial infarction, cardiac arrest, and stroke. There was no reduction in overall mortality due to a 25% increase in non-cardiovascular deaths in the high dose atorvastatin group. Another concern was significantly higher rates of side effects in the high dose group, including myalgias and elevated liver enzymes; this higher rate of side effects occurred even with a run-in period that excluded patients intolerant to the study drug *(LaRosa, 2005)*. The Prove It TIMI-22 trial compared 4,162 patients with acute coronary syndrome treated with 80 mg of atorvastin to 40 mg of pravastatin, and followed then for a mean of 24 months. The atorvastatin group achieved an LDL level of 62 mg/dl and the pravastatin group had an average LDL level of 95 mg/dl. There was a 16% reduction in the hazard ratio for the combined primary end point death, myocardial infarction, unstable angina, need for revascularization, and stroke. Most of the benefit occurred within 30 days of randomization, and was unaccompanied by further incremental benefit through the end of the follow up period *(Ridker, 2005)*.

At present the clinician will need to individualize therapy with statins by the degree of risk in their patients, considering a target LDL of 70 or less, especially for patients at highest risks as described by Grundy (2004). Very high risk patients include patients with established cardiovascular disease plus any of the following: 1) multiple major risk factors, such as diabetes; 2) severe or poorly-controlled risk factors, especially smoking; 3) metabolic syndrome associated risk factor (triglycerides > 200 mg/dl, HDL< 40 mg/dl); and 4) patients with acute coronary syndromes. The benefits in reducing cardiac events with high dose statin therapy will need to be weighed against the higher potential for side effects, and the potential for increased non-cardiac mortality as seen in the TNT trial, which is either real, or due to chance. Further trials comparing different treatment intensities of statins should bring more clarity regarding which patients benefit most with the least side effects *(LaRosa, 2005)*.

Benefit has been demonstrated in all Stable CAD patients treated with statins, regardless of pretreatment cholesterol levels. This was well demonstrated in the MRC/BHF Heart Protection Study *(Heart Protection Study Collaborative Group, 2002)*. Simvastatin was shown to reduce major cardiovascular events, including death, nonfatal MI, and stroke, by 15-20%, in the subgroup of patients with pretreatment levels of < 100 mg/dl. A similar reduction in events was also observed in patients without documented CAD, but with peripheral vascular disease, diabetes, or hypertension.

This recommendation reflects the analysis of the NCEP report, the ACC/AHA Chronic Stable Angina guideline, and compelling evidence of mortality reduction from multiple clinical trials *(Gibbons, 2002; Grundy, 2004; Heart Protection Study Group, 2002; Hunninghake, 1998)*.

Please refer to the ICSI Lipid Management in Adults Guideline for recommendations on cholesterol lowering.

Every effort should be made to ensure all patients with coronary artery disease receive optimal lipid therapy. Statin medications are strongly supported as first-line medications due to compelling evidence of mortality reduction from multiple clinical trials *(Hunninghake, 1998; LIPID Study Group, 1998; Sacks, 1996; Scandinavian Simvastatin Survival Study Group, 1994)*.

If patients are intolerant to a statin, clinicians are strongly encouraged to have the patient try other statins in reduced doses before ruling out all statins.

The PROSPER trial showed a significant risk reduction in MI in the elderly, therefore age alone should not preclude treatment. The Heart Protection Study also showed benefit in patients up to age 80 years *(Shepherd, 2002; Heart Protection Study Group, 2002)*.

Patients with chronic stable coronary artery disease should be on statin therapy regardless of their lipid levels unless contraindicated. *[Conclusion Grade I: See Conclusion Grading Worksheet A – Annotation #5 (Statin Therapy)]*

Supporting evidence is of classes: A, R

Obesity

The American Heart Association (AHA) now considers obesity to be a major risk factor for CAD, particularly if the BMI is greater than 30. The loss of as little as 10-15% of an individual's weight can impact and decrease mortality *(Eckel, 1998)*.

Supporting evidence is of class: X

Hypertension

General health measures include the treatment of hypertension, which is not only a risk factor for development and progression of atherosclerosis but also causes cardiac hypertrophy, augments myocardial oxygen requirements, and thereby intensifies myocardial ischemia in patients with obstructive coronary disease.

Please refer to the Hypertension Diagnosis and Treatment guideline for recommendations regarding blood pressure management. The recommended target blood pressure is 130/80 or less.

Diabetes

Diabetes is associated with a marked increase in CAD. Patients with diabetes without known coronary artery disease have as high risk of an MI as patients without diabetes with coronary artery disease. Therefore, patients with diabetes should have aggressive lipid and blood pressure management (similar to patients with coronary artery disease), and should be treated per the recommendations of the ICSI Lipid Management in Adults and Hypertension Diagnosis and Treatment guidelines.

Please refer to the Management of Type 2 Diabetes Mellitus guideline for recommendations regarding management of diabetes.

Every attempt should be made to achieve meticulous glucose control in patients with diabetes, as there is a clear relationship between lower hemoglobin Alc's and lower risk of myocardial infarction *(Haffner, 1998)*. In the UKPDS *(United Kingdom Prospective Diabetes Study Group, 1998)*, obese patients with type 2 diabetes who were treated with metformin showed a statistically significant reduction in rates of myocardial infarction, suggesting metformin as a possible therapy of choice for these patients. A recent meta-analysis (*Selvin, 2004)* showed a 20% increase in cardiovascular events and mortality for every 1% increase in HbA_1c over 5%.

Supporting evidence is of classes: A, B

Hormone Therapy (HT)

The HERS II trial showed no cardioprotective benefit from HT, and in fact showed an increase in risk of other complications (breast cancer, venous thromboembolism, etc.) *(Hulley, 1998)*. Risk-benefit analyses unequivocally support NOT starting HT for primary prevention. Should a patient already on HT present with acute coronary syndrome or be at risk for venous thromboembolism (i.e., prolonged immobilization), HTshould be discontinued immediately. Clinical judgement is required in making the decision whether to continue HT in other circumstances. Please refer to the ICSI Menopause and Hormone Therapy guideline for more information.

Supporting evidence is of class: A

6. Assessment Yields High Risk of Adverse Event?

Some patients are considered to be at high risk for infarction or death on the basis of history, physical examination and initial laboratory findings. Patients presenting with accelerating symptoms of angina (NYHA Class III or IV, see Appendix C, "Grading of Angina Pectoris"), symptoms of peripheral vascular disease, or symptoms of left ventricular dysfunction should be referred to a cardiologist unless precluded by other medical conditions.

7. Need for Prognostic Testing?

Prognostic testing is appropriate for patients in whom risk determination remains unclear after the evaluations have been completed, or in whom cardiac catheterization is deemed inappropriate by the cardiologist. Prognostic testing may precede or follow an initial course of pharmacological therapy *(Frye 1989; Shub, 1990)*.

Supporting evidence is of class: R

8. Patient/EKG Allows Exercise Electrocardiography?

Sensitivity of exercise electrocardiography (Masters 2-Step Exercise Test, Graded Exercise Test, Bicycle Test, Ergometry) may be reduced for patients unable to reach the level of exercise required for near maximal effort, such as:

- Patients taking beta-blockers
- Patients in whom fatigue, dyspnea, or claudication symptoms develop
- Patients with vascular, orthopedic, or neurological conditions who cannot perform leg exercises

Reduced specificity may be seen in patients with abnormalities on baseline EKG, such as those taking digitalis medications, and in patients with left ventricular hypertrophy or left bundle branch block *(Rutherford, 1992)*. Please see the ICSI Cardiac Stress Test Supplement for more information.

Supporting evidence is of class: R

9. Perform Exercise Electrocardiography

Most patients with normal resting ECG's, who can exercise, and are not taking digoxin, can undergo standard treadmill exercise testing.

Please see the ICSI Cardiac Stress Test Supplement for more information.

10. Perform Non-Invasive Imaging Study

A noninvasive imaging study such as myocardial perfusion scintigraphy or stress echocardiography should best meet the patient's needs while providing the most clinical usefulness and cost-effectiveness within the provider's institution. An imaging study should be selected through discussion with the cardiologist or imaging expert *(Frye, 1989)*.

Supporting evidence is of class: R

11. Results Yield High Risk of Adverse Event?

Exercise electrocardiography and prognostic imaging studies may yield results that indicate high, intermediate or indeterminate or low risk of adverse clinical events. High-risk patients should have a cardiology consultation unless they are not considered to be potential candidates for revascularization. Patients who are at intermediate or indeterminate risk may benefit from cardiology consultation or further noninvasive imaging if an exercise electrocardiogram has been performed, or both. Low-risk patients can generally be managed medically, with a good prognosis. Low-risk patients may benefit from angiography if the diagnosis remains unclear; however, angiography is unlikely to alter outcome in these patients *(Rutherford, 1992)*.

Supporting evidence is of class: R

13. Is Medical Treatment Effective?

Effectiveness of pharmacologic treatment is measured by whether the anginal pain is controlled within the definition of stable coronary artery disease as stated in Annotation #1, "Patient with Stable Coronary Artery Disease."

14. Follow Regularly to Assess Risk Factors, Profile, Responses to Treatment

There is no consensus in the literature regarding frequency of follow-up; ongoing management needs and follow-up should be individualized *(Nease, 1995)*.

Patient perception of symptoms may impact the effect of the symptoms on quality of life and medical management.

Please refer to Appendix C, "Grading of Angina Pectoris" for information on grading angina pectoris.

Supporting evidence is of class: D

15. Worsening in Angina Pattern?

A new occurrence of angina or a worsening in the chronic stable angina pattern is considered to be present when any of the following occur:

- the symptom complex becomes less stable;
- there is change in frequency, duration, precipitating causes, or ease in relief of angina; or
- there is evidence of recent myocardial damage.

16. Change Suggests Need for Cardiology Referral?

When such change is no longer managed by alterations in the pharmacologic therapy prescribed, cardiology consultation or referral for possible invasive intervention may be appropriate *(Gibbons, 2002; Shub, 1990)*.

Please see Appendix C, "Grading of Angina Pectoris," for information on grading angina pectoris.

Supporting evidence is of class: R

20. Percutaneous Transluminal Coronary Angioplasty (PTCA), Coronary Artery Bypass Graft (CABG) or Other Revascularization Procedures

The relative benefits of revascularization compared with medical therapy are enhanced by an increase in absolute number of severely narrowed coronary arteries, the degree of left ventricular systolic dysfunction and the magnitude of myocardial ischemia. Among patients with lesser disease, PTCA and CABG have not been shown to reduce mortality or the risk of myocardial infarction, but do reduce the symptoms of angina and the intensity of antianginal therapy, as well as increase exercise capacity *(Bourassa, 1988; Frye, 1989; Kirklin, 1991; Ryan, 1993)*.

Although the actual intervention of an invasive modality such as angiography, PTCA or CABG is outside this guideline and may be found within another, those patients undergoing such procedures may, at best, be restored to a chronic stable anginal pattern, thus continuing to receive medical treatment under the purview of this guideline.

Supporting evidence is of class: R

Pharmacologic Algorithm Annotations

21a. Patient Education and Review Principles of Medication Therapy: ASA, ± Clopidogrel, Sublingual Nitroglycerin, Statins

The use of one aspirin tablet daily (81-162 mg) is strongly recommended unless there are medical contraindications *(Antiplatelet Trialists' Collaboration, 1994; CAPRI, 1996; Fuster, 1993; Juul-Möller, 1992; Kurth, 2003; Ridker, 1991)*.

The *Antithrombotic Trialists' Collaboration* is a meta-analysis that analyzed 287 studies involving 135,000 patients for different aspects of anti-platelet therapy. When comparing the 500-1500 mg versus 160-325 mg versus 75-150 mg daily regimens of ASA in multiple trials, there was a trend of reduction in vascular events with decreased dose (odds reduction: 19% versus 26% versus 32% respectively) *(Antithrombotic Trialists Collaboration; 2002)*. Although the meta-analysis concludes that risk of GI bleed was similar amongst doses 325 mg or less, other studies such as the CURE study showed increased bleeding risk with increasing the dose, without any increase in efficacy *(Peters, 2003)*.

The authors conclude that ASA dose in the range of 75-150 mg should be given for the long term prevention of serious vascular events in high risk patients, and that there may be a reduced benefit when increasing the dose over 150 mg daily. Doses available to most clinicians are in increments of 81 mg; therefore the recommended dose range is 81-162 mg daily.

A multi-center case-controlled study by Kelly et al. on 550 incident cases of first-time major upper GI bleed showed that the relative risks of bleeding in patients taking plain, enteric-coated, and buffered aspirin at average daily dose of 325 mg or less were 2.6, 2.7, and 3.1 respectively *(Kelly, 1996)*. The study cites few other endoscopic studies showing the opposite (gastro-protection of enteric-coated aspirin), but explains such differences by differences in trial design and population characteristics.

It remains difficult to conclude whether EC-ASA is gastro-protective or not, but clinicians should not assume that it is any safer than regular or buffered aspirin, and should treat it with the same level of caution.

Patients for whom aspirin is contraindicated (or insufficient) should be treated with clopidogrel (Plavix®) 75 mg daily indefinitely, in view of greater safety, equivalent efficacy, and cost savings when compared with ticlopidine as an antiplatelet treatment *(Harrington, 2004)*. The recently published CHARISMA trial involved 15,603 patients with vascular disease or multiple atherothrombotic risk factors, who were randomized to clopidogrel (75 mg daily) plus low dose aspirin (75-162 mg daily) or placebo plus low dose aspirin.

After a median follow-up of 28 months there was no difference between the two groups in the trial's primary composite endpoint of myocardial infarction, stroke, or death from cardiovascular causes, with an increased risk of moderate bleeding in the clopidogrel group. Rate of hospitalization was lower in the clopidogrel group when compared with placebo. Subgroup analysis showed (marginally significant) reduction in primary endpoint in those with documented atherothrombotic disease on the clopidogrel protocol. In contrast, those without documented atherothrombotic disease and only risk factors on the clopidogrel protocol had higher incidence of death from all causes and from cardiovascular causes. Accordingly, addition of clopidogrel to aspirin in Stable CAD patients comes with little benefit and some cost, and should not be recommended on routine basis. However, there may be proven benefits of clopidogrel such as in the setting of acute vascular injury (PTCA or acute coronary syndromes) or in selected patients with ongoing ischemic events on aspirin therapy *(Bhatt, 2006)*.

In appropriately selected patients, an aspirin dose of 81 mg is recommended for patients who are on chronic clopidogrel therapy. Different doses of aspirin may apply in the setting of acute coronary syndrome; refer to the ICSI Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome guideline for aspirin dosing.

Thrombotic Thrombocytopenic Purpura (TTP) may occur with clopidogrel, but it appears to be 1/100th as frequent as TTP from ticlopidine *(Bennett, 2000)*. In addition, severe neutropenia has not been reported with clopidogrel, but occurs in less than or equal to 1% of patients on ticlopidine.

Examples of precautions/contraindications to aspirin are:

- Patients allergic to aspirin
  - dose-related intolerance is not a contraindication for taking aspirin
- Patients with gastrointestinal disorders
  - recent GI bleeding and active treatment for peptic ulcer disease are contraindications
  - the use of H-2 antagonists or PPI is not a contraindication to aspirin use
  - consideration should be given for low-dose enteric-coated (81 mg) aspirin for patients with a questionable history of GI disorders

- Patients with recent intracranial bleeding
  - intracranial bleeding within the past six weeks is a contraindication
  - any history of intracranial bleeding necessitates evaluation on a case-by-case basis
- Patients with bleeding disorders or those receiving other anticoagulants
  - certain patients receiving anticoagulants may justifiably be on aspirin as well
- Patients with uncontrolled hypertension
  - systolic blood pressure is greater than 180 mm Hg
  - diastolic blood pressure is greater than 110 mm Hg
- Patients regularly taking NSAIDs
  - combined use of aspirin and NSAIDs may increase the risk of bleeding. Enteric coated aspirin with careful monitoring for clinical signs of gastropathy may be an acceptable strategy for patients regularly taking NSAIDs. Regular, not intermittent, use of NSAIDs inhibit the clinical benefits of aspirin. Caution should be used in prescribing COX-2 inhibitors to patients with CAD, as there is evidence of a class effect on cardiovascular risks *(Mukherjee, 2001; Nussmeier, 2005; Bresalier, 2005; Solomon, 2005)*.

ASA and/or clopidogrel should be prescribed to all patients with stable coronary disease. *[Conclusion Grade I: See Conclusion Grading Worksheet B – Annotation #21a (ASA/Clopidogrel)]*

In patients with mild, stable CAD, drug therapy may be limited to short-acting sublingual nitrates on an as needed basis. Use of lower dose (i.e., 0.3 mg or one-half of a 0.4 mg tablet) may reduce the incidence of side effects such as headache or hypotension in susceptible patients.

For more information regarding drug selection, please see Appendix B, "Medication Tables."

Evidence supporting the aspirin recommendation is of classes: A, C, D, M, R

21b. Nutritional Supplement Therapy

The American Heart Association *(Gibbons, 2002)* recommends inclusion of omega-3 fatty acids in patients with Stable CAD because of evidence from randomized controlled trials. The GISSI study *(GISSI-Heyenzione Investigators, 1999)*, using 850 mg of eicosopentaenoic acid (EPA) and docosahexaenoic acid (DHA) daily, showed a 20% overall mortality reduction, and a 45% reduction in sudden death. Other studies showing benefit include the DART trial, Lyon trial, and data have been recently summarized by meta-analysis indicating significant reduction in risk of sudden death and overall mortality *(Bucher, 2002; Burr, 1989; deLorgeril, 1999; Kris-Etherton, 2002)*.

The recommended daily amount of omega-3 fatty acids in patients with stable coronary artery disease is 1 gram of EPA/DPA by capsule supplement, the equivalent amount in alpha-linolenic acid (ALA) from vegetable source, or by eating daily fatty fish. The amounts of omega-3 fatty acids in various foods are found in the table in the appendix. Plant-based sources of omega-3 fatty acids would be ground flax seed, flax seed oil, walnut oil, canola oil, and soybean oil. Daily fish meals can be difficult for patients to maintain, and there are issues of potential environmental contaminants including mercury, PCBs, dioxin, and others. Because of this, capsule supplements may be preferred although there is no uniformity of EPA/DHA content or purity. Patients should consult their health providers or nutritionists regarding this issue.

Dietary and non-dietary intake of n-3 polyunsaturated fatty acids may reduce overall mortality, mortality due to myocardial infarction, and sudden death in patients with Stable CAD. *[Conclusion Grade II: See Conclusion Grading Worksheet C – Annotation #21b (Omega III)]*

High doses of vitamin E supplement (greater than 400 IU/day) may increase or cause mortality and should be avoided *(Lee, 2005; Miller, 2005)*.

Supporting evidence is of classes: A, M, R

21c. Use of ACE Inhibitors for Risk Reduction

Among patients with stable angina, ACE inhibitors are most beneficial to patients with LV dysfunction post myocardial infarction, persistent hypertension and diabetes *(HOPE Study Investigators, 2000)*. Results of the PEACE trial showed no added benefit for patients with stable CAD with preserved LV function who are receiving "current standard" therapy including statins *(PEACE Trial Investigators, 2004)*.

Supporting evidence is of class: A

21d. Does Patient Need Daily Antianginal Therapy?

The decision to initiate daily drug therapy for coronary artery disease is based upon the symptom complex of the patient in combination with findings from the history, physical examination, laboratory studies and prognostic testing *(Frye, 1989; Gorlin, 1992; ISIS-4, 1995; Rutherford, 1992; Shub, 1990; SOLVD Investigators, 1991)*.

Supporting evidence is of classes: A, R

21e. Prescribe Monotherapy

Beta Blocking Agents

Beta-blockers should be used in all status post-myocardial infarction patients, based on studies showing mortality reduction. They are also the preferred first-line therapy for reducing symptoms of angina in patients with stable coronary artery disease. Drugs with intrinsic sympathomimetic activity should be avoided. Abrupt withdrawal of all beta-blockers should be avoided *(Cucherat, 1997; Frye, 1989; Shub, 1990)*.

Long-Acting Nitrates

If beta-blockers cannot be prescribed as first-line therapy, nitrates are the preferred alternative first-line therapy because of efficacy, low cost, and relatively few side effects. Tolerance to long-acting nitrates is an important clinical issue in some patients and can be avoided by appropriate daily nitrate-free intervals *(Cheitlin, 1999; Frye, 1989; Parker, 1998)*.

Adverse Interactions Between Nitrates and Phosphodiesterase-5 Inhibitors

Patients with stable CAD should be advised that due to potentially life-threatening hypotension, phosphodiesterase-5 inhibitors (like sildenafil [Viagra®], vardenafil [Levitra®], and tadalafil [Cialis®]) are absolutely contraindicated if they have used nitrates within the last 24 hours.

In any patient evaluated for acute coronary insufficiency, nitrates must also be avoided if there is a history of sildenafil or phosphodiesterase-5 inhibitor use in the previous 24-48 hours (avoid nitrates for 24 hours after Viagra® and Levitra®; avoid nitrates for 48 hours after Cialis®). All other interventions, including all non-nitrate antianginal medications may be used for these patients.

Calcium Channel Blocker

For patients who are unable to take beta-blockers or long-acting nitrates, the use of calcium channel blockers has been shown to be clinically effective in decreasing symptoms of angina. Calcium channel blockers have not been proven to reduce mortality. Because beta-blockers have reduced mortality in the post MI period, they are the preferred agent for patients with stable coronary artery disease *(Shub, 1990)*. Dihydropyridines as monotherapy may exacerbate angina.

Supporting evidence is of classes: A, R

21g. Prescribe Combination Therapy

Combination therapy may be necessary in selected patients, but it increases side effects and cost. A combination of beta-blockers and long acting nitrates is preferred because of cost, efficacy, and reduced potential for adverse side effects *(Akhras, 1991; Rutherford, 1992; Tolins, 1984)*. The following factors should be considered when beta-blockers and calcium channel blockers are combined *(Strauss, 1988)*:

- This combination may not be better than either agent used alone in maximum tolerated doses.
- If angina persists at the maximum optimal dose of beta-blocker, then addition of a calcium channel blocker is likely to reduce angina and improve exercise performance.
- Addition of verapamil or diltiazem to a beta-blocker does not usually enhance therapy, and may precipitate symptomatic bradycardia, but addition of a beta-blocker to nifedipine can have enhanced effects.
- With left ventricular dysfunction, sinus bradycardia, or conduction disturbances, treatment with calcium channel blockers and beta-blockers should be avoided or initiated with caution. In patients with conduction system disease, the preferred combination is nifedipine and a beta-blocker.
- The combination of dihydropyridines and long-acting oral nitrates is usually not optimal because both are potent vasodilators.
- If side-effects prohibit increased doses but symptoms persist, selected patients may need low doses of multiple drug therapy.

Supporting evidence is of classes: A, R

21h. Combination Therapy Effective?

If after several attempts at adjusting the medications a therapeutic combination is not achieved for the patient, a cardiology consultation or referral may be appropriate.

Appendix A – Comorbid Conditions

Medical Conditions

Condition	Recommended Treatment (and alternative)	Avoid
Systemic hypertension	Beta-blockers (calcium antagonists)	
Migraine or vascular headaches	Beta-blockers (verapamil or diltiazem)	
Asthma or COPD w/ bronchospasm	Verapamil **or** diltiazem	Gradual titration with low initial doses may allow some patients to tolerate beta-blockers; careful monitoring is required.
Hyperthyroidism	Beta-blockers	
Raynaud's Syndrome	Long-acting, slow-release calcium antagonists	Beta-blockers
Insulin-dependent diabetes mellitus	ACE Inhibitors, Beta-blockers (particularly if prior myocardial infarction), **or** long-acting, slow-release calcium antagonists	
Non-insulin-dependent diabetes mellitus	Optimize medical therapy per the ICSI Management of Type 2 Diabetes guideline	
Mild Peripheral Vascular Disease	Beta-blockers **or** calcium antagonists	
Severe Peripheral Vascular Disease with rest ischemia	Calcium antagonists	Beta-blockers

Cardiac Arrhythmias and Conduction Abnormalities

Sinus bradycardia	Long-acting, slow-release calcium antagonists that do not decrease heart rate	Beta-blockers, diltiazem, verapamil
Sinus tachycardia (not due to heart failure)	Beta-blockers	
Supraventricular tachycardia	Verapamil, diltiazem, **or** beta-blockers	
Atrioventricular block	Long-acting, slow-release calcium antagonists that do not slow A-V conduction	Beta-blockers, verapamil, diltiazem
Rapid atrial fibrillation (with digitalis)	Verapamil, diltiazem, **or** beta-blockers	
Ventricular arrythmias	Beta-blockers	

Left Ventricular Dysfunction

CHF	Optimize medical therapy per the ICSI Congestive Heart Failure guideline	
Mild aortic stenosis	Beta-blockers	
Aortic insufficiency	Long-acting, slow-release dihydropyridines	
Mitral regurgitation	Long-acting, slow-release dihydropyridines	
Mitral stenosis	Beta-blockers	
Hypertrophic cardiomyopathy	Beta-blockers, non-dihydropyridine calcium antagonists	Nitrates, dihydropyridine calcium antagonists

Appendix B – Medication Tables

Principle Medication Therapies

Generic name	Brand names	Usual dosage	Comments
Aspirin		81-162 mg daily	Every day administration is preferable, but 325 mg every other day is acceptable. Enteric-coated tablets or dosing with meals can minimize stomach upset. Patients on warfarin may take low dose aspirin (81 mg). Patients using aspirin should avoid regular use of NSAIDs.
Clopidogrel	Plavix®	75 mg daily	Plavix® is recommended for all patients with coronary artery disease that are truly intolerant of aspirin.
Sublingual nitroglycerin	Nitrostat®, Nitroquick®	0.3-0.6 mg SL, may repeat x3. Call for emergency assistance if pain is not relieved after three doses.	Nitroglycerin is also available as an aerosol spray. Because of its greater cost, it is generally recommended only for those patients who have difficulty administering the small nitroglycerin tablets.

Maintenance Therapies

	Generic name	Brand names	Usual dosage	Comments
Beta-blockers	Atenolol	Tenormin®	50-200 mg daily	A target heart rate is 55-60 beats per minute. Abrupt withdrawal of beta-blockers should be avoided
	Metoprolol	Lopressor®	50-200 mg twice daily	
	Propanolol	Inderal®	20-80 mg twice daily	
	Other beta-blockers are available.			
Long-acting nitrates	Isosorbide dinitrate	Isordil®	5-80 mg two to three times daily	Tolerance can be avoided by appropriate daily nitrate-free intervals. Isordil can be given at 7A, 12N, and 5P. Nitrate-free periods are also needed for the patches. The patches can be worn during the day and removed during the evening and night.
	Nitroglycerin patches	Minitran® Transderm Nitro® Nitrodur® Nitrek®	0.2-0.8 mg/hr	
	Isosorbide mononitrate	Imdur® Ismo® Monoket®	60-240 mg daily 20 mg twice daily (7 hours apart) 20 mg twice daily (7 hours apart)	
	Other forms of nitroglycerin are available.			
Calcium Channel blockers	Verapamil long-acting	Calan SR® Isoptin SR® Verelan®	120-480 mg daily	Monotherapy with nifedipine should be avoided because of a reflex increase in heart rate.
	Diltiazem long-acting	Cardizem CD® Dilacor XR®	120-320 mg daily	
	Nifedipine long-acting	Procardia XL® Adalat CC®	30-180 mg daily	
	Amlodipine	Norvasc®	5-10 mg daily	
	Other calcium channel blockers are available			

Source: ACC/AHA Chronic Stable Angina Guidelines, 2002.

Appendix C – Grading of Angina Pectoris

Grading of Angina Pectoris by the New York Heart Association Classification System

Class I

Cardiac disease without resulting limitation of physical activity.

Class II

Slight limitation of physical activity – comfortable at rest, but ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.

Class III

Marked limitations in physical activity – comfortable at rest, but less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.

Class IV

Inability to carry on any physical activity without discomfort – or symptoms at rest.

Source: ACC/AHA/ACP-ASIM Chronic Stable Angina Guidelines

Appendix D – EPA + DHA in Fish and Fish Oils

Amounts of EPA + DHA in Fish and Fish Oils and the Amount of Fish Consumption Required to Provide ~ 1 g of EPA + DHA per Day

	EPA + DHA Content, g/3-oz Serving Fish (Edible Portion) or g/g Oil	Amount Required to Provide ~ 1 g of EPA + DHA per Day, oz (Fish) or g (Oil)
Fish		
Tuna		
Light, canned in water, drained	0.26	12
White, canned in water, drained	0.73	4
Fresh	0.24-1.28	2.5-12
Sardines	0.98-1.70	2-3
Salmon		
Chum	0.68	4.5
Sockeye	0.68	4.5
Pink	1.09	2.5
Chinook	1.48	2
Atlantic, farmed	1.09-1.83	1.5-2.5
Atlantic, wild	0.9-1.56	2-3.5
Mackerel	0.34-1.57	2-8.5
Herring		
Pacific	1.81	1.5
Atlantic	1.71	2
Trout, rainbow		
Farmed	0.98	3
Wild	0.84	3.5
Halibut	0.4-1.0	3-7.5
Cod		
Pacific	0.13	23
Atlantic	0.24	12.5
Haddock	0.2	15
Catfish		
Farmed	0.15	20
Wild	0.2	15
Flounder/Sole	0.42	7
Oyster		
Pacific	1.17	2.5
Eastern	0.47	6.5
Farmed	0.37	8
Lobster	0.07-0.41	7.5-42.5
Crab, Alaskan King	0.35	8.5
Shrimp, mixed species	0.27	11
Clam	0.24	12.5
Scallop	0.17	17.5
Capsules		
Cod liver oil*	0.19	5
Standard fish body oil	0.30	3
Omega-3 fatty acid concentrate	0.50	2
Omacor (Pronova Biocare)	0.85	1

Data from the USDA Nutrient Data Laboratory.[104]
The intakes of fish given above are very rough estimates because oil content can vary markedly (greater than 300%) with species, season, diet, and packaging and cooking methods.
*This intake of cod liver oil would provide approximately the Recommended Dietary Allowance of vitamins A and D.

Source: Kris-Etherton, 2002

Document Drafted
July – Oct 1993

First Edition
Jul 1994

Second Edition
Nov 1995

Third Edition
Jan 1997

Fourth Edition
Feb 1998

Fifth Edition
Feb 1999

Sixth Edition
Mar 2000

Seventh Edition
Feb 2001

Eighth Edition
Feb 2002

Ninth Edition
Dec 2003

Tenth Edition
May 2005

Eleventh Edition
Begins May 2006

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Released in April 2006 for Eleventh Edition.
The next scheduled revision will occur within 12 months.

Availability of references

References cited are available to ICSI participating member groups on request from the ICSI office. Please fill out the reference request sheet included with your guideline and send it to ICSI.

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Evidence Grading System

I. CLASSES OF RESEARCH REPORTS

A. Primary Reports of New Data Collection:

Class A: Randomized, controlled trial

Class B: Cohort study

Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study

Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis

Class R: Consensus statement
Consensus report
Narrative review

Class X: Medical opinion

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in Section I, above, and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols **+**, **–**, **ø**, and **N/A** found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

– indicates that these issues have not been adequately addressed;

ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

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Conclusion Grading Worksheet A – Annotation #5 (Statin Therapy)

Work Group's Conclusion: Patients with chronic stable coronary artery disease should be on statin therapy regardless of their lipid levels unless contraindicated.

Conclusion Grade: I

Author/Year	Design Type	Class	Quality +, –, 0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Heart Protection Study (HPS) Collaborative Group, 2002	RCT	A	+	-20,536 patients not on statins with coronary disease, other occlusive arterial disease, or diabetes -patients randomized to simvastatin 40 mg daily (n=10,269 patients) or placebo (n=10,267) -patients recruited from 69 UK hospitals -mean 5 year follow-up -patients age 40-80 years -15% of simvastatin group stopped medication and 17% of placebo group started on statins	-all-cause mortality significantly reduced in simvastatin group (12·9% vs 14·7%, p=0·0003) as compared to placebo -18% (SE 5) proportional reduction in the coronary death rate (5·7% vs 6·9%, p=0·0005); non-significant reduction in other vascular deaths (1·9% vs 2·2%, p=0·07); and non-significant reduction in non-vascular deaths (5·3% vs 5·6%) -highly significant reductions in first event rate for non-fatal MI or coronary death (8.7% vs 11.8%, p<0·0001), non-fatal or fatal stroke (4.3% vs 5.7%, p<0·0001), and coronary or non-coronary revascularization (9.1% vs 11.7%, p<0·0001) -24% (95%CI 19%–28%) reduction in the event rate (19·8% vs 25·2%, p<0·0001) for first occurrence of any major vascular event	-Adding simvastatin to existing treatments safely produces substantial additional benefits for a wide range of high-risk patients, irrespective of their initial cholesterol concentrations. Allocation to 40 mg simvastatin daily reduced the rates of myocardial infarction, stroke, and revascularization by about one-quarter.
Hunninghake et al., 1998 Post-CABG Trial	RCT	A	–	-1,351 patients with elevated levels of LDL cholesterol (130-175 mg/dL) and a history of bypass surgery (1-11 years prior) -patients randomized to aggressive lowering (target <85 mg/dL; mean 76 mg/day lovastatin) of LDL cholesterol levels with statins (n=676 patients) vs moderate lowering (target <140 mg/dL; mean 4 mg/day lovastatin; n=675) -patient age ranged 21-74 years -mean follow-up 4.3 years -primary angiographic outcome was mean % per patient of grafts with decrease of > or = 0.6 mm in lumen diameter	-patients with aggressive therapy significantly more likely to achieve and maintain LDL cholesterol levels within recommended target of < or = 100 mg/dL (66% vs 5%, p<0.05) as compared to moderate therapy group -aggressive treatment group had 37-40% decrease in LDL cholesterol while maintaining mean LDL cholesterol of 93 mg/dL -moderate treatment group had 13-15% decrease in LDL cholesterol while maintaining mean LDL cholesterol of 136 mg/dL -mean percentage of grafts with progression of atherosclerosis was 27% for aggressively treated vs 39% for moderate-treatment group (p<0.001)	-Aggressive lipid lowering is practical and worthwhile in at-risk patients. Aggressive treatment is far more effective than moderate treatment in lowering LDL cholesterol levels to the NCEP target level (< or = 100 mg/dL), and this intervention decreases the progression of atherosclerosis.

Author/Year	Design Type	Class	Quality +,−,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
LIPID Study Group, 1998	RCT	A	ø	-9,014 patients 31 to 75 years of age with history of MI or hospitalization for unstable angina and initial plasma total cholesterol levels of 155 to 271 mg/dL -patients randomized to receive pravastatin 40 mg daily (n=4,512 patients) or placebo (n=4,502) -both groups received advice on following a cholesterol-lowering diet -mean follow-up period 6.1 years	-death from coronary heart disease occurred in 8.3% placebo and 6.4% pravastatin patients (relative risk reduction 24%, 95%CI 12-35%, p<0.001) -overall mortality was 14.1% in placebo group and 11% in pravastatin group (relative risk reduction 22%, 95%CI 13-31%, p<0.001) -incidence of MI (risk reduction 29%, p<0.001), death from CHD or nonfatal MI (24%, p<0.001), stroke (19%, p=0.048), and coronary revascularization (20%, p<0.001) lower in pravastatin group	-Pravastatin therapy reduced mortality from coronary heart disease and overall mortality as well as the incidence of all prespecified cardiovascular events in patients with a history of MI or unstable angina who had a broad range of initial cholesterol levels.
Sacks et al., 1996 CARE Trial	RCT	A	ø	-4159 patients (86% men) with myocardial infarction who had plasma total cholesterol levels below 240 mg/dL and LDL cholesterol levels of 115 to 174 mg/dL -patients randomly assigned to 40 mg of pravastatin per day (n=2,081 patients) or placebo (n=2,078) -primary end point was a fatal coronary event or a nonfatal MI -mean 5-year follow-up	-primary end point 10.2% in pravastatin group and 13.2% in placebo group (24% risk reduction, 95% CI 9-36%, p=0.003) -CABG (10% vs 7.5%, 26% reduction, p=0.005) and angioplasty (8.3% vs 10.5%, 23% reduction, p=0.01) needed significantly less often in pravastatin group as compared to placebo group -frequency of stroke reduced by 31% (p=0.03) -no significant differences in overall mortality or mortality from noncardiovascular causes	-These results demonstrate that the benefit of cholesterol-lowering therapy extends to the majority of patients with coronary disease who have average cholesterol levels.
Scandinavian Simvastatin Survival Study (4S), 1994	RCT	A	ø	-4444 patients with angina pectoris or previous MI and serum cholesterol 5.5-8.0 mmol/L on a lipid-lowering diet -randomized to treatment with simvastatin 20 mg (n=2,221 patients) or placebo (n=2,223) -5.4 years median follow-up period	-12% in placebo group died vs 8% in simvastatin group (RR of death in simvastatin group 0.70, 95%CI 0.58-0.85, p=0.0003); 6-year probabilities of survival 87.6% placebo and 91.3% simvastatin (p=0.0003); 189 coronary deaths in placebo group vs 111 in simvastatin group (relative risk 0.58, 95% CI 0.46-0.73) -28% in placebo group and 19% in simvastatin group had one or more major coronary events (RR 0.66, 95%CI 0.59-0.75, p<0.00001) -37% reduction (p<0.00001) in the risk of undergoing myocardial revascularization procedures	-Long-term treatment with simvastatin is safe and improves survival in CHD patients.

Conclusion Grading Worksheet B – Annotation #21a (ASA/Clopidogrel)

Work Group's Conclusion: ASA and/or Clopidogrel should be prescribed to all patients with stable coronary disease.

Conclusion Grade: I

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Ridker et al., 1991	RCT	A	0	-333 physicians with baseline chronic stable angina (178 patients received 325mg aspirin every other day, 155 received a placebo) -subgroup of 221 with baseline chronic stable angina and no previous coronary bypass or angioplasty -60.2 months average follow-up -baseline characteristics showed no significant differences (p>.05)	-7 of 178 aspirin and 20 of 155 placebo patients had MI during follow-up (RR 0.3; 95% CI, 0.14-0.63; p=.003) 87% reduction in risk of first MI was attributed to aspirin therapy (RR 0.13; 95% CI, 0.04-0.42; p<.001) -11 strokes in the aspirin group and 2 strokes in the placebo group (RR 5.37; 95% CI, 1.3-22.1; p=.02) -7 deaths in the aspirin group and 11 deaths in the placebo group (RR 0.51; 95% CI, 0.18-1.51; p>.02) -subgroup: 5 cases and 15 controls had an MI (RR 0.27; 95% CI, 0.11-0.66; p=.007) 86% reduction risk for 1st MI attributed to aspirin (RR 0.14; 95% CI, 0.04-0.56; p=.005)	-Alternate day aspirin therapy greatly reduced the risk for first myocardial infarction (MI) among patients with chronic stable angina.
Juul-Möller et al., 1992	RCT	A	0	-2035 patients from 94 centers in Sweden with symptoms of chronic stable angina (1009 cases received 75 mg daily aspirin, 1026 controls received placebo) All patients received sotalol for treatment of symptoms -median follow-up 50 months -779 patients stopped treatment prematurely (362 cases, 417 controls). The reasons were due to unwillingness to continue (154), protocol violations (6), study endpoints reached (267), unstable angina/bypass surgery (67), anticoagulation trx (13), NSAID trx (23), malignancy (29)	-34 % reduction in first MI or sudden death (81cases v 124 controls, p=.003); 7 aspirin v 78 placebo (p=.006) had non-fatal MI; 15v15 (p=NS) had fatal MI; 19v31 controls (p=.097) had sudden death -incidence of all secondary endpoints was lower among aspirin group; vascular deaths 51aspirin v 70 placebo (p=.114); all cause mortality 82v106 (p=.103); stroke 28v38 (p=.25); there was a 32% reduction in vascular events 108v161 (p<.001)	-The addition of a low-dose aspirin to sotalol treatment showed significant benefit in terms of cardiovascular events, including a significant reduction in the incidence of first myocardial infarction in patients with symptoms of stable angina pectoris.

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
CAPRIE Steering Committee, 1996	RCT	A	+	-19,185 patients with atherosclerotic vascular disease from 384 centers in 16 countries (9599 received clopidogrel, 9586 received aspirin) -mean follow-up 1.91 years -46 patients did not receive clopidogrel as allocated, 40 did not receive aspirin as allocated -42 patients lost to follow-up (22 clopidogrel, 20 aspirin) -4059 patients discontinued study drug for reasons other than outcome event (21.3% in clopidogrel group and 21.1% in aspirin group) including adverse events (11.4%), withdrawn consent (4.7%), contraindicated medications (2.4%), and non-compliance (1.8%)	-relative risk reduction of 8.7% (CI 0.3-16.5, p=.043) in favor of clopidogrel (5.32% event rate/year) over aspirin (5.83%) for first outcome events (ischemic stroke, MI, or vascular death) -specific relative risk reductions of 7.3% (CI -5.7-18.7, p=.26), -3.7% (CI -22.1-12.0, p=.66), 23.8% (CI 8.9-36.2, p=.003) for stroke, MI, and peripheral arterial disease. Test for heterogeneity of three trx groups was significant (p=.042) -no evidence of unusual findings of adverse effects in either treatment group	-Long-term administration of clopidogrel to patients with atherosclerotic vascular disease is more effective than aspirin in reducing the combined risk of ischemic stroke, myocardial infarction, or vascular death. -The overall safety profile of clopidogrel is at least as good as that of medium-dose aspirin. *-This is a large study giving strength and generalizability to the results. Also, they adhered to the well-defined inclusion/exclusion criteria.* *-Clopidogrel was superior to aspirin among patients with vascular disease tolerant of aspirin. Clopidogrel has not been compared with placebo among vascular disease patients intolerant of aspirin; it would probably be unethical to do so.*

Conclusion Grading Worksheet C – Annotation #21b (Omega III)

Work Group's Conclusion: Dietary and non-dietary intake of n-3 polyunsaturated fatty acids may reduce overall mortality, mortality due to myocardial infarction, and sudden death in patients with Stable CAD.

Conclusion Grade: II

Author/Year	Design Type	Class	Quality +,–,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Bucher et al., 2002	Systematic Review	M	ø	-identified 11 randomized controlled trials that compared dietary (n=2) or non-dietary (n=9) intake of n-3 polyunsaturated fatty acids with a control diet or placebo in patients with coronary heart disease -trials published between 1966 and 1999 -meta-analysis included 7951 intervention patients and 7855 control patients -studies had at least 6 months follow-up and clinical endpoint data	-risk ratio of overall mortality in patients on n-3 polyunsaturated fatty acid-enriched diets was 0.8 (95%CI 0.7-0.9, P<0.001) as compared to control diets or placebo -risk ratio of fatal myocardial infarction was 0.7 (95%CI 0.6-0.8, P<0.001) -sudden death was associated with a risk ratio of 0.7 (95%CI 0.6-0.9, P<0.01) in 5 trials -nonfatal myocardial infarction was not significant (risk ratio 0.8, 95% confidence interval [CI] 0.5-1.2)	-This meta-analysis suggests that dietary and non-dietary intake of n-3 polyunsaturated fatty acids reduces overall mortality, mortality due to myocardial infarction, and sudden death in patients with coronary heart disease. *-Over 70% of the patients in this meta-analysis were from the GISSI trial below. The only two trials from this meta-analysis using dietary intake are included below as well (de Lorgeril et al. and Burr et al.)*
GISSI-Prevenzione Trial Investigators, 1999	RCT	A	+	-11,324 patients surviving recent MI randomly assigned supplements of n-3 PUFA (1 g daily, n=2836), vitamin E (300 mg daily, n=2830), both (n=2830), or none (control, n=2828) for 3.5 years -primary endpoint: death, non-fatal myocardial infarction, and stroke -intention-to-treat analyses done by factorial design (2-way) and treatment group (4-way)	-n-3 PUFA decreased risk of death (relative-risk decrease 14% [95%CI 3%-24%] two-way, 20% [6-33] four-way) and cardiovascular death (17% [3-29] two-way, 30% [13-44] four-way) -n-3 PUFA significantly lowered risk of primary endpoint (relative-risk decrease 10% [1-18] by two-way analysis and 15% [2-26] by four-way analysis) -combined treatment significantly lowered risk of primary endpoint (14% [1-26]) and fatal events (20% [5-33]) but vitamin E alone did not	-Dietary supplementation with n-3 PUFA led to a clinically important and statistically significant benefit. Treatment with n-3 PUFA significantly reduced rate of death, non-fatal myocardial infarction, and stroke.

Author/Year	Design Type	Class	Quality +,–,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
de Lorgeril et al., 1999 Lyon Diet Heart Study	RCT	A	ø	-607 patients less than 70 years of age surviving 1st MI randomized to Mediterranean (n=302) or prudent Western diet (n=303) -mean follow-up 46 months -three composite outcomes: cardiac death or nonfatal myocardial infarction (CO1); the preceding plus major secondary end points (unstable angina, stroke, heart failure, pulmonary or peripheral embolism) (CO2); the preceding plus minor events requiring hospital admission (CO3)	-CO1 (14 vs 44 events, P=0.0001), CO2 (27 vs 90 events, P=0.0002) all significantly reduced in Mediterranean diet group as compared to Western diet group -total cholesterol (1 mmol/L associated with increased risk 18%-28%), systolic blood pressure (1 mm Hg associated with increased risk 1%-2%), leukocyte count (adjusted risk ratios ranged from 1.64-2.86 with count >9x10(9)/L), female sex (adjusted risk ratios, 0.27 to 0. 46), and aspirin use (adjusted risk ratios, 0.59 to 0.82) each significantly associated with recurrence	-The protective effect of the Mediterranean dietary pattern was maintained up to 4 years after the first infarction. Major traditional risk factors, such as high blood cholesterol and blood pressure, were shown to be independent and joint predictors of recurrence. Thus, a comprehensive strategy to decrease cardiovascular morbidity and mortality should include primarily a cardioprotective diet and other means aimed at reducing modifiable risk factors. *-The trial was stopped at 1 year and patients were informed of the statistically significant results but follow-up continued (mean follow-up 46 months).*
Burr et al., 1989	RCT	A	ø	-2033 patients with previous MI randomized to receive or not to receive advice on each of three dietary factors: a reduction in fat intake and an increase in the ratio of polyunsaturated to saturated fat; an increase in fatty fish intake; and an increase in cereal fibre intake -14% of fish advice group were taking Maxepa (3 capsules/day) at 6 months and 22% at 2-year follow-up as partial or total substitute for fatty fish	-subjects advised to eat fatty fish had 29% reduction ($p<0.05$) in 2 year all-cause mortality compared with those not advised -advice on fat not associated with any difference in mortality (perhaps because produced small reduction (3-4%) in serum cholesterol) -subjects given fibre advice had a slightly higher mortality than other subjects (but not significant) -2-year incidence of reinfarction plus death from ischemic heart disease not significantly affected by diet regimes	-A modest intake of fatty fish (two or three portions per week) may reduce mortality in men who have recovered from MI.

This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
  - Measurement Specifications
- Knowledge Products and Resources
- Other Resources Available

Priority Aims and Suggested Measures

1. Improve selection and education of patients with stable CAD on the use of aspirin and antianginal drugs.

   Possible measure of accomplishing this aim:

   a. Percentage of patients with stable CAD who have aspirin use documented in the medical record.

2. Improve patient understanding of management of stable CAD.

   Possible measure of accomplishing this aim:

   a. Percentage of patients with stable CAD who demonstrate an understanding of how to respond in an acute cardiac event: proper use of nitroglycerin, use of aspirin, and when to call 911.

3. Increase the percentage of patients with stable CAD who receive an intervention for modifiable risk factors.

   Possible measures of accomplishing this aim:

   a. Percentage of cigarette-smoking patients with stable CAD with documentation in the medical record of advice to quit or offered help in quitting at most recent visit.

   b. Percentage of patients with stable CAD who have had a lipid profile determination at target (less than 100) and measured within the last year.

   c. Percentage of patients with stable CAD and no comorbidities, within blood pressure control (less than 130/80).

   d. Improve the assessment of patient levels of sedentary activity level during the past 12 months.

COMPREHENSIVE MEASURE

   a. Percentage of patients who have an LDL at target (less than 100) who are on a statin and measured at least annually, aspirin use, BP control (less than 130/80), sedentary activity level, and who report an understanding of appropriate response in an acute cardiac event.

4. Improve assessment of patient's anginal symptoms.

   Possible measure of accomplishing this aim:

   a. Increase the percentage of patients who were evaluated for angina symptoms during the past 12 months.

5. Increase the use of ACE inhibitors in all patients with CAD who also have diabetes and/or LVSD, or other cardiovascular diseases.

   Possible measure of accomplishing this aim:

   a. Percentage of CAD patients with diabetes, LVSD, or other cardiovascular disease, who are prescribed ACE inhibitor therapy.

Measurement Specifications

Possible Success Measure #1a

Percentage of patients with stable CAD who have aspirin use documented in the medical record.

Population Definition

All patients age 18 and over with stable coronary artery disease.

Data of Interest

$$\frac{\text{\# patient records containing documentation of aspirin use}}{\text{Total \# records reviewed for stable coronary artery disease patients}}$$

Numerator/ Denominator Definitions

Numerator: Aspirin documentation should be treated as any medication and assessed at every visit. Any mention or documentation of regular aspirin intake found on the Medications List or in the progress notes should be counted as a "yes" for this measure.

For the purpose of this measure, the medical record should be reviewed for care provided during the previous 2 years. Documentation of regular aspirin use and/or contraindication to use should be found within this time span of current care.

Contraindications to aspirin use are not defined in the guideline (Algorithm box #12), but left to the provider's discretion. Some commonly found contraindications are allergy to the drug and history of bleeding ulcer or gastric hemorrhage. When contraindications are present, they need to be noted in the patient's record.

Denominator: A patient will be age 18 and over.

Patients for this measure are a subset of those used for the Lipid Management In Adults Guideline Measure #1.

If you are not collecting data for the Lipid Management in Adults guideline, then you may identify stable coronary artery disease patients by use of these suggested ICD-9 codes:

412.xx-414.xx; but should be excluded if there has been any visit with one or more of the following codes for acute MI events within the past year:
410.xx-411.xx
Patients with documented contraindications to aspirin are included in this measure as it is written. Patients with documented contraindications to aspirin may be excluded from the denominator of this measure at the discretion of the individual medical group.

Method/Source of Data Collection

The population for this measure is a subset of the population used for the Lipid Management in Adults measure. When a patient with a diagnosis of stable coronary artery disease is identified while doing the Lipid Management in Adults data collection, that patient's record will also be assessed for evidence that the patient is using low-dose aspirin on a regular basis. Data needs to be collected for at least 10 patients. If the sample for Lipid Management in Adults does not produce enough patients, other patients may be identified using the procedure that follows.

If not collecting data for the Lipid Management in Adults guideline or when it is necessary to identify more patients with coronary artery disease, then use a computer run to select patients with the suggested ICD-9 codes or the ICD-9 codes you determine your providers use to describe the type of patients included in the guideline. The medical records of these patients are reviewed for evidence that the patient is using low-dose aspirin on a regular basis. Data needs to be collected for at least 10 patients.

Count as patients in the denominator all patients whose records verify the stable coronary artery disease diagnosis. Count in the numerator all patients whose records contain documentation of regular use of low-dose aspirin.

Medical groups have the option to exclude patients with a documented contraindication to aspirin from this measure. It will be each medical group's determination whether the cost of doing this more specific measure is worth the benefit of the more precise result.

Time Frame Pertaining to Data Collection

Data may be collected monthly.

Notes

This measure may be done in conjunction with the data collection for the Lipid Management in Adults guideline. The evidence for low-dose aspirin regular use is Grade A. It is estimated that over 95% of the population would not have any contraindication to aspirin use. Therefore, the work group is comfortable with defining the ICSI-wide measure without excluding those patients with an aspirin contraindication. The work group anticipates improvement towards 100%.

Possible Success Measure #3b

Percentage of patients with stable CAD who have had a lipid profile determination at target (less than 100) and measured within the last year.

Population Definition

Adult patients 18 years of age and over with stable coronary artery disease.

Data of Interest

$$\frac{\text{\# of patient records with a lipid profile at target and measured within the last year}}{\text{total number of CAD patients whose medical records are reviewed}}$$

Numerator/Denominator Definitions:

Numerator: Those patients sampled in the denominator who have had a lipid profile that includes total cholesterol, HDL-cholesterol, calculated LDL-cholesterol and triglycerides at target (< 100) and measured within the last year.

Denominator: Patients age 18 and over.

Patients for this measure are a subset of those used for the Lipid Management in Adults measure.

If you are not collecting data for the Lipid Management in Adults guideline, you may identify stable coronary artery disease patients by one of these ICD-9 codes:

412.xx-414.xx;
but should exclude patients if there has been any visit with one or more of the following codes for acute MI events within the past year:
410.xx-411.xx.

Method/Source of Data Collection

The population for this measure is a subset of the population used for the Lipid Management in Adults measure. When a patient with a diagnosis of stable coronary artery disease is identified while doing the Lipid Management data collection, that patient's record will also be assessed for evidence that a lipid profile is at target and measured within the last year.

A monthly random sample of at least 10 patients is suggested. The data may be collected by chart audit or with administrative systems augmented by chart audit.

To be included in the numerator, the patient needs to have the test results and a date of the test within the last year (total cholesterol, HDL-cholesterol, calculated LDL-cholesterol and triglycerides).

Count as patients in the denominator all patients whose records verify the stable coronary artery disease diagnosis.

Time Frame Pertaining to Data Collection

Data may be collected monthly.

Notes

This measure is basically the percent of stable coronary artery disease patients who are up-to-date with their lipid profile. This measure does not include those who do not have clinic encounters. This measure should approach 100%.

Knowledge Products and Resources

Criteria for Selecting Resources

The following resources were selected by the *Stable Coronary Artery Disease* guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these sites.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author, and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

The following materials are available to ICSI members only. Also available is a wide variety of other knowledge products including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Products, go to http://www.icsi.org/knowledge.

To access these materials on the website you must be logged in as an ICSI member.

Patient Education PDFs

- Steps to Stay Healthy with Coronary Artery Disease 2/2005, *Park Nicollet Health Services*

Other Resources Available

Title/Description	Audience	Author/Organization	Websites/Order Information
Understanding Angina; 12-page pamphlet	Patients and Families	AHA	(800) 242-8721
Exercise & Your Health; 37-page book	Patients and Families	AHA	(800) 242-8721 #51-1048
Cholesterol Connections; 56-page manual	Patients and Families	Health Ed PNI	Health Source 952-993-3507
Weight Control Ways; 56-page manual	Patients and Families	Health Ed PNI	Health Source 952-993-3507
Aspirin & Cardiovascular Diseases; 8-page pamphlet	Patients and Families	AHA	(800) 242-8721 #64-9609
Home page for American College of Cardiology	Patients and Families/ Health Care Professionals	American College of Cardiology	http://www.acc.org
Home page for American Diabetes Association	Patients and Families/ Health Care Professionals	American Diabetes Association	http://www.diabetes.org
Home page for American Heart Association	Patients and Families/ Health Care Professionals	American Heart Association	http://www.americanheart.org
Home page for Mayo Clinic	Patients and Families/ Health Care Professionals	Mayo Clinic	http://www.mayoclinic.com
Home page for National Heart, Lung and Blood Institute	Patients and Families/ Health Care Professionals	National Heart, Lung and Blood Institute	http://www.nhlbi.nih.gov
What You Need to Know About Mercury In Fish and Shellfish; Trifold brochure	Patients and Families	U.S. FDA and U.S. EPA	888-SAFEFOOD
U.S. Food and Drug Administration; Information on the risks of mercury in fish and shellfish	Public	U.S. FDA	http://www.cfsan.fda.gov/seafood1.html
Coronary Artery Disease, Steps to Stay Healthy; pamphlet	Patients and Families	Park Nicollet Health Services	http://www.icsi.org/knowledge (select patient resources)
Understanding Hypertension; pamphlet	Patients and Families	Park Nicollet Health Services	http://www.icsi.org/knowledge (select patient resources)
Understanding Lipids; pamphlet	Patients and Families	Park Nicollet Health Services	http://www.icsi.org/knowledge (select patient resources)
Diabetes; pamphlet	Patients and Families	Park Nicollet Health Services	http://www.icsi.org/knowledge (select patient resources)

Other Resources Available

Title/Description	Audience	Author/Organization	Websites/Order Information
This website is an excellent resource for patient education and general heart health resources.	Patients and Families/ Health Care Professionals	National Institute of Health	http://www.nih.gov (Select Health Information. Then select Heart & Circulation)

Exhibit AA

Health Care Guideline:
Diagnosis and Outpatient Management of Asthma

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Seventh Edition
March 2005

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These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.

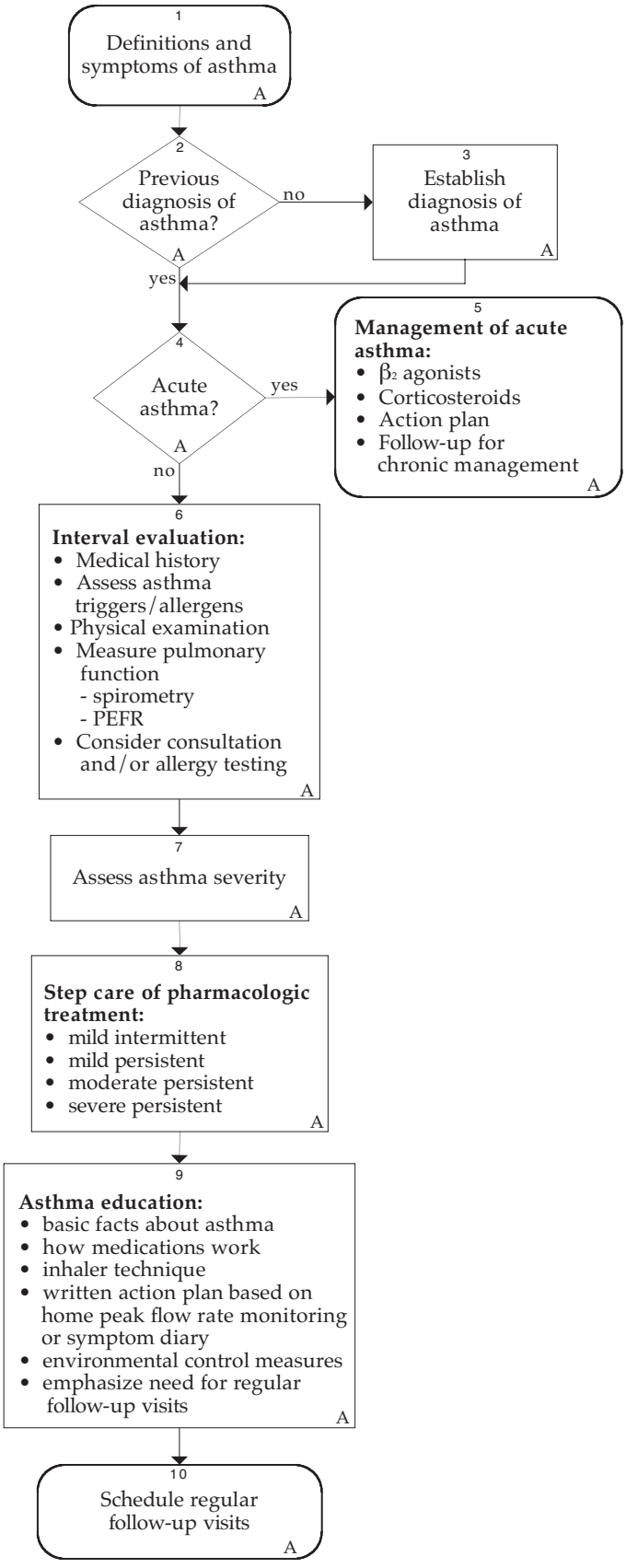

Table of Contents

Foreword

Scope and Target Population

This guideline addresses the diagnosis and outpatient management of acute and chronic asthma in all patients over five years of age who present with asthma-like symptoms or have been diagnosed with asthma.

Clinical Highlights and Recommendations

1. Conduct interval evaluations of asthma including medical history and physical examination, assessment of asthma triggers and allergens, measurement of pulmonary function, and consideration of consultation and/or allergy testing. *(Annotation #6)*
2. Regularly assess asthma control. *(Annotation #7)*
3. Match medical intervention with asthma severity and adjust to correspond with change over time. *(Annotation #8 and Table 8A)*
4. Achieve effective control of chronic persistent asthma through use of inhaled corticosteroid therapy. *(Table #8A)*
5. Provide asthma education to patients and parents of pediatric patients. Education should include basic facts about asthma, how medications work, inhaler technique, a written action plan including home peak flow rate monitoring or a symptom diary, environmental control measures, and emphasis on the need for regular follow-up visits. *(Annotation #9)*

Priority Aims

1. Promote the accurate assessment of asthma severity through the use of objective measures of lung function.
2. Promote long-term control of persistent asthma through the use of inhaled corticosteroid drug therapy.
3. Promote the partnership of patients with asthma and/or their parents with health care professionals through education and the use of written action plans.

Related ICSI Scientific Documents

Other ICSI guidelines whose scope and/or recommendations are closely related to the content of this guideline are:

1. Emergency and Inpatient Management of Asthma
2. Chronic Obstructive Pulmonary Disease
3. Rhinitis

Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

Key conclusions are assigned a conclusion grade: I, II, III, or Grade Not Assignable.

A full explanation of these designators is found in the Supporting Evidence section of the guideline.

Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at http://www.icsi.org.

Algorithm Annotations

1. Definition and Symptoms of Asthma

Definition of asthma

Asthma is a chronic inflammatory disorder of the airways. It is characterized by:

1. Airway inflammatory cells, including eosinophils, macrophages, mast cells, epithelial cells and activated lymphocytes that release various cytokines, adhesion molecules and other mediators.
2. Inflammation resulting in an acute, subacute or chronic process that alters airway tone, modulates vascular permeability, activates neurons, increases secretion of mucus, and alters airway structure reversibly or permanently.
3. Airway hyperresponsiveness in response to allergens, environmental irritants, viral infections and exercise.
4. Airflow obstruction caused by acute bronchial constriction, edema, mucus plugs, and frequently permanent remodeling.

A. Symptoms

1. Wheezing
2. Breathlessness
3. Cough, productive or dry
4. Chest discomfort

B. Pattern of symptoms

1. Perennial/seasonal
2. Episodic/continual
3. Diurnal

C. Severity of symptom classification

1. Number of symptom episodes per week
2. Number of nocturnal symptoms per month
3. Objective measures of lung function (FEV_1, PEF, PEF variability)

Symptoms of asthma

Symptoms suggestive of asthma include episodic wheezing and cough with nocturnal, seasonal or exertional characteristics. Infants and children with frequent episodes of "bronchitis" are likely to have asthma. Atopic and positive family histories for asthma, particularly when associated with previously mentioned symptoms, should encourage one to consider a diagnosis of asthma.

Eliciting symptoms should emphasize characterizing the current classification scheme that describes frequency per week, changes in physical activity, diurnal variation, and seasonal variation. It is important to recognize that patients with asthma are heterogeneous, falling into every age group, from infancy to older age, and presenting a spectrum of signs and symptoms that vary in degree and severity from patient to patient as well

as within an individual patient over time *(National Asthma Education and Prevention Program [NAEPP], 1997; National Asthma Education and Prevention Program [NAEPP], 2002).*

Supporting evidence is of classes: M, R

2. Previous Diagnosis of Asthma?

Key Points:

- At each evaluation, it is important to consider whether or not a previous diagnosis was correct.
- History and physical consistent with diagnosis.
- Diagnosis confirmed by spirometry.
- Response to therapy consistent with symptoms.

Diagnostic spirometry and a methacholine challenge test, if necessary, are important to clinching the diagnosis. The patient's history and response to therapy should guide other diagnostic tests when considering alternative diagnoses. Follow-up pulmonary function tests every one to two years in mild asthmatics will reconfirm the diagnosis and objectify serial change and level of control. More frequent monitoring should be considered for the moderate and severe persistent categories.

Spirometry is the cornerstone of the laboratory evaluation that enables the clinician to demonstrate airflow obstruction and establish a diagnosis of asthma with certainty. Spirometry is essential for assessing the severity of asthma in order to make appropriate therapeutic recommendations. The use of objective measures of lung function is recommended because patient-reported symptoms often do not correlate with the variability and severity of airflow obstruction. Testing should be performed in compliance with the American Thoracic Society standards. Obstructive and restrictive ventilatory defects can generally be determined using FEV_1/FVC ratio *(American Thoracic Society, 1991).*

Supporting evidence is of class: R

3. Establish Diagnosis of Asthma

Key Points:

- The diagnosis of asthma is based on the patient's medical history, physical examination, pulmonary function tests and laboratory test results.
- Spirometry is recommended for the diagnosis of asthma.

A. Asthma triggers

1. Viral respiratory infections
2. Environmental allergens
3. Exercise, temperature, humidity
4. Occupational and recreational allergens or irritants
5. Environmental irritants (perfume, tobacco smoke, wood-burning stoves)
6. Drugs (aspirin, NSAID, beta blocker) and food (sulfites)

B. Other historical components

1. Emergency room visits and hospitalization
2. Medication use (especially oral steroids)
3. Lung function, PEFR variability
4. Associated symptoms, e.g., rhinitis, sinusitis, gastroesophageal reflux (GERD)

C. Clinical testing

1. Accurate spirometry is recommended in every patient 5 years of age or older at the time of diagnosis.
2. Additional studies done, tailored to the specific patient.
   - allergy testing (skin testing, in vitro specific IgE antibody testing)
   - chest radiography, to exclude alternative diagnosis
   - bronchial provocation testing if spirometry is normal or near normal
   - sinus x-rays or CT scan
   - GERD evaluation
   - CBC with eosinophils, total IgE, sputum exam

Spirometry is generally valuable in children 5 years of age or older, however some children cannot conduct the maneuver depending on developmental ability. Spirometry measurements (FEV_1, FVC, FEV_1/FVC) before and after the patient inhales a short-acting bronchodilator should be undertaken for patients in whom the diagnosis of asthma is being considered. Airflow obstruction is indicated by reduced FEV_1 and FEV_1/FVC values relative to reference or predicted values. Significant reversibility is indicated by an increase of 12 percent or greater *and* 200 mL in FEV_1, after inhaling a short-acting bronchodilator.

Methacholine challenge testing may provide a useful confirmatory diagnostic test in patients with normal or near-normal spirometry. Investigation into the role of allergy, at least with a complete history, should be done in every patient, given high prevalence of positive skin tests among individuals with asthma and the benefits of limiting exposure to known allergens. Eosinophil count and IgE may be elevated in asthma, however, neither test has sufficient specificity or sensitivity to be used alone in a diagnosis. The chest x-ray and electrocardiogram are usually normal in asthma but may be useful to exclude other pulmonary or cardiac conditions. Sputum examination may be helpful if sputum eosinophilia or infection are suspected.

There are several clinical scenarios in children that have a frequent association with asthma and should strongly suggest asthma as a possible diagnosis. These include recurrent pulmonary infiltrates (especially right middle lobe infiltrates) that clear radiologically within two to three days, and the diagnosis of pneumonia without fever. Asthma may cause some radiologic uncertainty since mucus plugging and atelectasis may be interpreted as infiltrates.

Differential Diagnostic Possibilities for Asthma

1. Upper airway disease
   - allergic rhinitis and sinusitis
2. Obstruction involving large airways
   - foreign body in trachea or bronchus

- vocal cord dysfunction
- vascular rings or laryngeal webs
- laryngotracheomalacia, tracheal stenosis or bronchostenosis
- enlarged lymph nodes or tumor (benign or malignant)
- bronchiectasis of various causes, including cystic fibrosis

3. Obstruction of small airways
   - viral bronchiolitis or obliterative bronchiolitis
   - cystic fibrosis
   - bronchopulmonary dysplasia
   - pulmonary infiltrates with eosinophilia
   - chronic obstructive pulmonary disease (chronic bronchitis or emphysema)
4. Other causes
   - pulmonary embolism
   - congestive heart failure
   - cough secondary to drugs (angio-tension-converting enzyme [ACE] inhibitors)
   - aspiration from swallowing mechanism dysfunction or gastroesophageal reflux
   - recurrent cough not due to asthma

It is important to identify infant or early childhood diseases that might superficially resemble asthma but in reality are not asthmatic in pathophysiology. These symptoms should stimulate investigation of clinical etiologies other than asthma (failure to thrive, vomiting/choking, chronic bacterial infections, cardiovascular and pulmonary abnormalities).

An important under-recognized alternative diagnosis is vocal cord dysfunction. Patients have recurrent breathlessness and wheezing, usually inspiratory, but they can also have expiratory wheezing. It is often monophasic and loud over the glottis. Respiratory failure can occur with alveolar hypoventilation, requiring emergent intubation. It also coexists in patients who have asthma. The flow-volume loop and video image can help make the diagnosis.

4. Acute Asthma?

Symptoms of an acute asthma episode include progressive breathlessness, cough, wheezing or chest tightness. An acute asthma episode is characterized by a decrease in expiratory airflow that can be documented and quantified by measurement of lung function (spirometry or PEFR). The algorithm is intended for treatment of outpatients. Critically ill patients are beyond the scope of this guideline. See ICSI's Emergency and Inpatient Management of Asthma.

Indications for emergency care include:

- Peak flow less than 50% predicted normal
- Failure to respond to a beta agonist
- Severe wheezing or coughing

- Extreme anxiety due to breathlessness
- Gasping for air, sweaty, or cyanotic
- Rapid deterioration over a few hours
- Severe retractions and nasal flaring
- Hunched forward

5. Management of Acute Asthma

Key Points:

- Patients experiencing an acute asthma exacerbation need a focused history and physical examination and measurement of airflow.
- Treatment is begun with inhaled short-acting $ß_2$-agonists administered by meter dose inhaler (MDI)/spacer or nebulizer.
- Further intensification of therapy is based on severity, response, and prior history, but typically includes a short course of oral corticosteroids.
- Decision to hospitalize must be individualized.
- All patients should receive follow-up and short-term education.

The following is an outline of management:

Review history and physical exam which may include:

- History
  - Severity of symptoms, limitations, and sleep disturbance
  - Duration of symptoms
  - Current medical treatment plan
  - Adherence to medical treatment plan
  - Rescue medication use:

    recent use of short-acting $ß_2$-agonists

    number of bursts of oral steroids in past year
  - Review asthma action plan and daily charting of peak flows
  - Previous ER visits or hospitalization
  - Record triggers:

    URI

    Bronchitis, pneumonia

    Exposure to allergens or irritants

    Exercise

- Physical exam
  - Vital signs
  - Auscultation of chest
  - FEV_1 or peak flow rate
  - O_2 saturation (pulse oximetry)
  - Use of accessory muscles
  - Alertness
  - Color
- Laboratory studies

  Treatment with bronchodilators should not be delayed for laboratory studies. Tests which may be useful include:
  - Arterial Blood Gases (ABG's)
  - Chest X-Ray (CXR)
  - Complete Blood Count (CBC)
  - Electrocardiogram (EKG)
  - Electrolytes
  - Theophylline concentration
- Assess severity

  Assessment is based on history and physical exam.

Treatment

Usual initial treatment is with short-acting $ß_2$-agonist (albuterol) administered by nebulizer or MDI/spacer.

Alternatives:

Epinephrine: (1:1000)

Adult: 0.3-0.5 mg subq or IM q 20 min up to 3 doses

Pediatrics: 0.01 mg/kg up to 0.3-0.5 mg subq or IM every 20 min up to 3 doses

Ipratropium added to nebulized $ß_2$-agonist (albuterol)

- Nebulized dose for adults and those over 12 years of age is 0.5 mg every 4 hr. Not FDA approved for any indication in those under 12 years of age.
- Ipratropium is not currently FDA-approved for use in asthma.

Levalbuterol

- Dose for adolescents 12 years of age and over and adults is 0.63 mg (via nebulizer) TID (every 6-8 hr); may increase to 1.25 mg via neb TID (every 6-8 hr) if patient does not exhibit adequate response.

- Dose for children 6-11 years of age is 0.31 mg (via nebulizer) TID. Routine dosing should not exceed 0.63 mg TID.

Assess Response

Good response:

peak flow or FEV_1 greater than 70% predicted normal

no wheezing on auscultation

Incomplete response:

peak flow or FEV_1 50-70% predicted normal

mild wheezing

Consider hospitalization, particularly for high-risk patients:

- past history of sudden severe exacerbation
- prior intubation for asthma
- two or more hospitalizations for asthma in the past year
- three or more emergency care visits for asthma within the past year
- hospitalization or an emergency care visit for asthma within the past month
- use of more than 2 canisters per month of inhaled short-acting $ß_2$-agonists
- current use of systemic corticosteroids or recent withdrawal from systemic corticosteroids
- difficulty perceiving airflow obstruction or its severity
- comorbidity, as from cardiovascular disease or chronic obstructive pulmonary disease
- serious psychiatric disease or psychosocial problems
- low socioeconomic status and urban residence
- illicit drug use
- sensitivity to Alternaria

Poor response:

peak flow or FEV_1 less than 50% predicted

no improvement in respiratory distress

strongly consider hospitalization

continue inhaled $ß_2$-agonist every 60 minutes

start oral prednisone unless contraindicated

Adult: short course "burst" 40-60 mg/day as single or 2 divided doses for 3 to 10 days
Pediatric: short course "burst" 1-2 mg/kg day in 2 divided doses, maximum 60 mg/day for 3 to 10 days

Home treatment and revised asthma action plan

Medications

- Inhaled $ß_2$-agonist every 2-6 hours
- Initiate or increase anti-inflammatory medication:

  inhaled corticosteroids

  cromolyn/nedocromil

  consider leukotriene modifiers
- Strongly consider systemic corticosteroids in patients with acute asthma exacerbation. Corticosteroids aid symptom resolution and prevent asthma relapse *(Chapman, 1991; Fanta, 1983; Harris, 1987; Scarfone, 1993).*
- Antibiotics are not recommended for the treatment of acute asthma except for those patients with signs of acute bacterial infection, fever and purulent sputum.

Education

- Teach or check inhaler technique/teach nebulizer use
- Explain medications
- Review action plan
- Monitor peak flow
- Reinforce trigger control

Follow-up

- All patients need return appointment for management of asthma
- Review and discuss signs and symptoms requiring emergent care

(National Asthma Education and Prevention Program Expert Panel, 1997; National Asthma Education and Prevention Program Expert Panel Report: Guidelines for the Diagnosis and Outpatient Management of Asthma, 2002)

Supporting evidence is of classes: A, M, R

6. Interval Evaluation

- Interval evaluation of asthma should include the following:
  - Medical history
  - Assess asthma triggers/allergens
  - Physical examination
  - Measure pulmonary function
  - Consider specialty consultation

Medical History

- Disruption of usual activities (work, school, home)
- Sleep disturbance
- Level of usage of short-acting $ß_2$-agonist
- Adherence to medical treatment plan
- Interval exacerbation of symptoms (either treated by self or a health care provider)
- Symptoms suggesting comorbid conditions or alternative diagnosis
- Side effects of medications

Reassessment of medical history can elicit factors that effect overall asthma control and sense of well-being *(Juniper, 1993)*. The key symptoms that should alert the clinician include disruptive daytime symptoms and disturbances of sleep. It is also the consensus of the Expert Panel that symptoms early in the morning that do not improve fifteen minutes after short-acting $ß_2$-agonist are a predictor of poor control. The quantity of short-acting $ß_2$-agonist that is being used should be discussed since overuse can be a marker of the potentially fatality-prone asthmatic *(Spitzer, 1992)*. The use of a quality of life tool or questionnaire can assist to elicit history *(Juniper, 1992)*.

Supporting evidence is of classes: C, D

Assess asthma triggers/allergens

- Inquire about exposure to triggers and allergens (e.g., occupational, pets, smoke)
- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens

Studies of emergency room visits and near death show allergens as a factor in asthma exacerbation. Asthma triggers in the workplace also need to be considered. About 15 percent of asthma in adults is work related *(Blanc, 1987; Malo, 1992; O'Hollaren, 1991; Pollart, 1988)*.

The differential diagnosis, as previously discussed, can range from common to rare. The most common contributing disorders that exacerbate asthma are allergic rhinitis and sinusitis *(Corren, 1992; Rachelefsky, 1984)*. Another common condition to consider is gastroesophageal reflux disease (GERD). Reflux is three times more common in asthmatics, and treating GERD leads to improved asthma control *(Harper, 1987)*.

Supporting evidence is of classes: A, C, D

Physical Examination

- Assess signs associated with asthma, concurrent illness or medication side effects
- Height in children
- Head, eyes, ears, nose, throat, lungs, heart, skin

It is important to discuss any potential medication side effects as this often has a direct relationship to compliance. Common side effects from inhaled steroids include oral candidiasis and dysphonia. $ß_2$-agonists may cause tachycardia, tremor or nervousness. Individuals on long-term oral corticosteroids or frequent bursts of steroids need to be monitored for complications of corticosteroids use such as osteoporosis, hypertension, diabetes and Cushing's syndrome.

The height of individuals on corticosteroids should be monitored over time. The potential effect on linear growth in children is important because these drugs tend to be used over long periods of time. Cumulative data in children suggest that low-to-medium doses of inhaled corticosteroids may have the potential of decreasing growth velocity, but this effect is not sustained in subsequent years of treatment, is not progressive, and may be reversible *(Childhood Asthma Management Program Research Group, The, 2000; NAEPP Update, 2002)*.

Inhaled glucocorticoids used to treat asthma have been shown to have deleterious effects on bone mineral density and markers of bone mineral metabolism. The risk of fracture attributable to inhaled or nasal glucocorticoids is uncertain *(Lung Health Study Research Group, The, 2000)*.

The remainder of the physical exam either supports or refutes conditions and comorbidities discussed above (see history).

Supporting evidence is of classes: A, M

Measure Pulmonary Function

It is important to measure pulmonary function at each follow-up visit. The two main methods are spirometry and peak expiratory flow rate (PEFR). Spirometry is more precise and yields more information than PEFR. It is helpful to verify the accuracy of the peak flow meter. It is useful when certain physical limitations affect accuracy of PEFR (example: very young or elderly, neuromuscular or orthopedic problems) *(Miles, 1995; Enright, 1994)*.

Spirometry recommended:

- for initial diagnosis or to reassess or confirm diagnosis
- after treatment is initiated or changed, and once symptoms and PEFR have stabilized, to document attainment of "near normal pulmonary function"
- at least every 1 to 2 years to assess maintenance of airway function; more often as severity indicates

Regular monitoring of pulmonary function is particularly important for asthma patients who do not perceive their symptoms until obstruction is severe *(Kikuchi, 1994; Connolly, 1992)*.

PEFR

- Used for follow-up, not for diagnosis

PEFR provides a simple, quantitative and reproductive measure of severity of airflow obstruction. The results are more reliable if the same type, and preferably the patient's own meter are used.

During interval assessment the clinician should question the patient and review records to evaluate the frequency, severity and causes of exacerbation. Triggers that may contribute should be reviewed. All patients on chronic maintenance medication should be questioned about exposure to inhalant allergens.

Supporting evidence is of classes: C, R

Consider Specialty Consultation

- Adults with severe persistent asthma, consider for moderate persistent asthma
- Children with moderate to severe persistent asthma, consider for mild persistent asthma

- Poorly controlled or complex asthma including previous life-threatening asthma exacerbation, or asthma exacerbations requiring more than 2 bursts of oral corticosteroids in 1 year, or asthma complicated by other medical or psychosocial conditions
- Additional diagnostic evaluations and/or testing, e.g., allergy skin testing, bronchoprovocation
- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens
- Evaluation and treatment of allergy, e.g., address occupation-related asthma, environmental counseling, immunotherapy
- Patients who require additional or intensive asthma education not otherwise available
- For patients with moderate to severe persistent asthma, who are exposed to perennial indoor allergens, Omalizumab is available. They should be managed by an allergy specialist.

Referral to an asthma specialist should be considered when a patient's symptoms are severe or are not responding to standard care. Referral is also necessary when specialized testing, such as allergy testing or bronchoprovocation are needed. There is evidence that referral to an asthma specialist can reduce repeat visit to the emergency room *(Zieger, 1991)*.

Supporting evidence is of class: C

7. Assess Asthma Severity

The classification of asthma as mild intermittent, mild persistent, moderate persistent or severe persistent is based on the clinical characteristics as well as objective assessment of lung function through FEV_1 or peak flow monitoring. The presence of one of the features of severity is sufficient to place a patient in that category and an individual's classification may change over time. Patients at any level of severity can have mild, moderate or severe exacerbations. Some patients with intermittent asthma experience severe and life-threatening exacerbations separated by long periods of normal lung function and no symptoms *(National Asthma Education and Prevention Program, 1997; National Asthma Education and Prevention Program, 2002)*.

Step 1: Mild Intermittent

- symptoms twice a week or less
- asymptomatic and normal PEF between exacerbations
- exacerbations are brief (few hours to a few days)
- nighttime symptoms twice a month or less
- FEV_1 or PEF 80% predicted or greater and PEF variability 20% predicted or less

Step 2: Mild Persistent

- symptoms twice a week or more but once a day or less
- exacerbations may affect activity
- nighttime symptoms twice a month or more
- FEV_1 or PEF 80% predicted or greater and PEF variability 20-30% predicted

Step 3: Moderate Persistent

- daily symptoms
- daily use of inhaled short-acting $beta_2$-agonists
- exacerbations affect activity
- exacerbations twice a week or more; may last days
- nighttime symptoms once a week or more or 4 times per month
- FEV_1 or PEF between 60-80% predicted
- PEF variability 30% or greater

Step 4: Severe Persistent

- continual symptoms
- limited physical activity
- frequent exacerbations
- frequent nighttime symptoms
- FEV_1 or PEF 60% predicted or less and PEF variability 30% predicted or greater

Supporting evidence is of classes: M, R

8. Step Care of Pharmacologic Treatment

Key Points:

- Achieve effective control of chronic persistent asthma through use of inhaled corticosteroid therapy.

The aim of asthma therapy is to maintain control of asthma with the least amount of medication and hence minimize the risk for adverse effects. The stepwise approach to therapy in which the dose and number of medications and frequency of administration are increased as necessary and decreased when possible is used to achieve this control. Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long-term and prevent exacerbations. See tables 8A, 8B, 8C, and 8D.

Based on data comparing LTRAs to inhaled corticosteroids, inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults, and by extrapolation until published data become available, for children. LTRAs are an alternative, although not preferred, treatment.

(Bleecker, 2000; Ducharme, 2002; National Asthma Education and Prevention Program, 1997; Szefler, 2005)

[Conclusion Grade I: See Conclusion Grading Worksheet – Appendix A – Annotation #8 (Leukotriene Receptor Antagonists [LTRAs])]

Managing asthma during pregnancy is the same treatment used for non-pregnant asthma patients *(NAEPP Update, 2005)*.

NOTE: Annual influenza vaccinations are recommended for patients with persistent asthma *(National Asthma Education and Prevention Program, 1997)*.

Supporting evidence is of classes: A, M, R

Table 8A.

Stepwise Approach for Managing Asthma in Adults and Children Older than 5 Years of Age	
Step	Long-Term Control
Step 1 - Mild Intermittent • symptoms ≤ 2 times a week • asymptomatic and normal PEF between exacerbations • exacerbations are brief (few hours to a few days) • nighttime symptoms ≤ 2 times a month • FEV_1 or PEF ≥ 80% predicted and PEF variability ≤ 20%	No daily medications needed
Step 2 - Mild Persistent • symptoms ≥ 2 times a week but ≤ 1 time a day • exacerbations may affect activity • nighttime symptoms ≥ 2 times a month • FEV_1 or PEF ≥ 80 percent predicted and PEF variability 20-30%	Daily medication: • Inhaled corticosteroids (low dose) (preferred) OR • Leukotriene modifiers, theophylline, nedocromil or cromolyn
Step 3 - Moderate Persistent • daily symptoms • daily use of inhaled short-acting ß$_2$-agonists • exacerbation affects activity • exacerbations >2 week, may last days • nighttime symptoms >1 time a week • FEV_1 or PEF ≥ 60% - ≤ 80% predicted • PEF variability ≥ 30%	Daily medications: • Inhaled corticosteroid (low or medium dose) plus inhaled long-acting β_2 agonist (preferred) OR • Inhaled corticosteroid (medium dose) plus leukotriene modifier, theophyline, or oral long-acting β_2
Step 4 - Severe Persistent • continual symptoms • limited physical activity • frequent exacerbations • frequent nighttime symptoms • FEV_1 or PEF ≤ 60 % and PEF variability ≥ 30 %	Daily medications: Inhaled corticosteroid (medium dose or high dose) PLUS: Long-acting β_2 agonist (preferred) and/OR Leukotriene modifier and/OR Theophylline Recommended for uncontrolled asthma: • Oral corticosteroids (See Table 8D)
Step down: Review treatment every 1-6 months; a gradual stepwise reduction in treatment may be possible.	Step up: If control not maintained, consider step up. First review patient medication technique, adherence and environmental control (avoidance of allergens or other factors that contribute to asthma severity)
Quick relief: • Short-acting bronchodilator: inhaled ß$_2$-agonists as needed for symptoms with MDI spacer/holding chamber • Intensity of treatment will depend on severity of exacerbation. • Use of short-acting inhaled ß$_2$-agonists on a daily basis, or increasing use, indicates the need for additional long-term control therapy.	
Education: Step 1: • Teach basic facts about asthma • Teach inhaler/spacer/holding chamber technique • Discuss role of medications • Develop self-management plan • Develop action plan for when and how to take rescue actions, especially for patients with a history of severe exacerbations • Discuss appropriate environmental control measures to avoid exposure to known allergens and irritants Step 2: • Teach self-monitoring • Refer to group education if available • Review and update self-management plan Step 3: • Refer to individual education/counseling	

Table 8B.

Usual Dosages for Long-Term Medications				
Medication	**Dosage Form**	**Adult Dose**	**Child Dose**	**Comments**
Inhaled Corticosteroids (refer to Table 8C)				
Systemic Corticosteroids				**(Applies to all three systemic corticosteroids)**
Methylprednisolone	2, 4, 8, 16, 32 mg tablets	• Divided 7.5-60 mg daily in a single dose or divided qid as needed for control • Short-course "burst" 40-60 mg per day as single or 2 divided doses for 3-10 days	• 0.25-2 mg/kg daily in single dose or qid as needed for control • Single course: "burst" 1-2 mg/kg/day, maximum 60 mg/day, for 3-10 days	• For long-term treatment of severe persistent asthma, administer single dose in a.m. either daily or on alternate days (alternate-day therapy may produce less adrenal suppression). If daily doses are required, one study suggests improved efficacy and no increase in adrenal suppression when administered at 3:00 p.m. (Beam et al. 1992) • Short courses or "bursts" are effective for establishing control when initiating therapy or during a period of gradual deterioration. • The burst should be continued until patient achieves 80% PEF personal best or symptoms resolve. This usually requires 3-10 days but may require longer. There is no evidence that tapering the dose following improvement prevents relapse if sufficient doses of inhaled corticosteroids are used simultaneously.
Prednisolone	5 mg tablets, 5 mg/5 cc, 15 mg/5 cc			
Prednisone	1, 2.5, 5, 10, 20, 50 mg tablets 5 mg/5 cc			
Cromolyn and Nedocromil				
Cromolyn	MDI 800 μg/puff Nebulizer solution - 20 mg/ampule	2-4 puffs tid-qid 1 ampule tid-qid	1-2 puffs tid-qid 1 ampule tid-qid	• One dose prior to exercise or allergen exposure provides effective prophylaxis for 1-2 hours.
Nedocromil	MDI 1.75 mg/puff	2-4 puffs bid-qid	1-2 puffs bid-qid	• See cromolyn above.

Table 8B. (cont)

Usual Dosages for Long-Term Medications (continued)				
Medication	**Dosage Form**	**Adult Dose**	**Child Dose**	**Comments**
Long-Acting ß$_2$-Agonists				
	Inhaled			
Salmeterol	DPI 50 µg/inhalation	1 inhalation q 12 hours	1 inhalation q 12 hours	• May use one dose nightly for symptoms. • Should not be used for symptom relief or for exacerbations. • FDA approved for children 5 years of age and older.
Formoterol Fumarate DPI	12 µg/dose (single use capsule by inhalation)	1 capsule by inhalation BID	1 capsule by inhalation BID	
Fluticasone propionate/ salmeterol DPI	Dosage strengths and adult dose (one inhalation) q 12 hr for all three strengths) with the strengths: 100 µg fluticasone/50µg salmeterol 250 µg fluticasone/50µg salmeterol 500 µg fluticasone/50µg salmeterol	1 inhalation BID	1 inhalation BID	• FDA approved for children 4 years of age and older.
	Tablet			
Sustained-Release Albuterol	4 mg tablet	4 mg q 12 hours	0.3-0.6 mg/kg/day, not to exceed 8 mg/day	
Methylxanthines				
Theophylline	Liquids, sustained-release tablets, and capsules	Starting dose 10 mg/kg/day up to 300 mg/day max	Starting dose 10 mg/kg/day; usual max: • <1 year of age: 0.2 (age in weeks) + 5 = mg/kg/day • ≥1 year of age: 16 mg/kg/day	• Adjust dosage to achieve serum concentration of 5-15 µg/mL at a steady-state (at least 48 hours on same dosage). • Due to wide interpatient variability in theophylline metabolic clearance, routine serum theophyline level monitoring is important. • Average adult dose 600-900 mg/day
Leukotriene Modifiers				
Montelukast	4 mg granules 4 mg tablet** 5 mg tablet** 10 mg tablet	10 mg/qhs	4 mg/qd evening or qhs (2-5 years of age) 5 mg/qd evening or qhs (6-14 years of age) 10 mg/qd evening or qhs (15 years of age and older)	
Zafirlukast	10 mg tablet 20 mg tablet	40 mg daily (20 mg bid) (≥ 12 years of age)	10 mg bid (7-11 years of age)	• For zafirlukast, administration with meals decreases bioavailability; take at least 1 hour before or 2 hours after meals.
Zileuton	600 mg tablet	2,400 mg daily (one 600 mg tablet, qid)	600 mg tablet QID (12 years of age and older)	• For zileuton, monitor hepatic enzymes (ALT).

* This list is not all-inclusive; for discussion of other factors, see package inserts.
** Children's dose – chewable tablets.

Table 8C.

Estimated Comparative Daily Dosage for Inhaled Corticosteroids			
ADULTS			
Drug	**Low Dose**	**Medium Dose**	**High Dose**
Beclomethasone dipropionate HFA (Hydrofluoroalkane) formulation with strengths of 40 μg/puff and 80 μg/puff)	80 mg-240 mg (2-6 puffs - 40 μg) (1-3 puffs - 80 μg)	240 μg- 480 μg (6-12 puffs - 40 μg) (3-6 puffs - 80 μg)	> 480 μg (> 12 puffs - 40 μg) (> 6 puffs - 80 μg)
Budesonide DPI 200 μg/dose	200-600 μg (1-3 inhalations)	600-1200 μg (3-6 inhalations)	> 1200 μg (> 6 inhalations)
Flunisolide 250 μg/puff	500-1,000 μg (2-4 puffs)	1,000-2,000 μg (4-8 puffs)	>2,000 μg (>8 puffs)
Fluticasone MDI: 44, 110, 220 μg/puff	88-264 μg (2-6 puffs - 44 μg) OR (2 puffs - 110 μg)	264-660 μg (2-6 puffs - 110 μg)	>660 μg (>6 puffs - 110 μg) OR (>3 puffs - 220 μg)
Combination Product – fluticasone propionate/salmeterol DPI	100 μg fluticasone/50 μg salmeterol – one inhalation q 12 hr	250 μg fluticasone/50 μg salmeterol – one inhalation q 12 hr	500 μg fluticasone/50 μg salmeterol – one inhalation q 12 hr
Triamcinolone acetonide 100 μg/puff	400-1,000 μg (4-10 puffs)	1,000-2,000 μg (10-20 puffs)	>2,000 μg (>20 puffs)

NOTES:

- The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy. The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effect.
- Some dosages may be outside package labeling.
- MDI dosages are expressed as the actuater dose (the amount of drug leaving the actuater and delivered to the patient), which is the labeling required in the United States. This is different from the dosage expressed as the valve dose (the amount of drug leaving the valve, all of which is not available to the patient), which is used in many European countries and in some of the scientific literature. DPI doses are expressed as the amount of drug in the inhaler following activation.
- Budesonide is the preferred inhaled for pregnant women corticosteroid because more data are available on using budesonide in pregnancy than are available on other inhaled corticosteroids, and the data are reassuring. It is important to note that there are no data indicating that the other inhaled corticosteroid preparations are unsafe during pregnancy.

Table 8C. (cont)

Estimated Comparative Daily Dosage for Inhaled Corticosteroids			
CHILDREN			
Drug	**Low Dose**	**Medium Dose**	**High Dose**
Beclomethasone dipropionate HFA 40 μg/puff 80 μg/puff	84-336 μg 80-160 μg (2-4 puffs - 40 μg) (1-2 puffs- 80 μg)	336-672 μg 160-320 μg (4-8 puffs - 40 μg) (2-4 puffs - 80 μg)	> 672 μg > 320 μg (> 8 puffs - 40 μg) (> 4 puffs - 80 μg)
Budesonide DPI 200 μg/dose For nebulization: strengths 0.25 mg/2 mL and 0.5 mg/2 mL	200-400 μg (1-2 inhalations) 0.5 mg	400-800 μg (2-4 inhalations - 200 μg) 1.0 mg/day	> 800 μg (> 4 inhalations - 200 μg) 2.0 mg/day
Flunisolide 250 μg/puff	500-750 μg (2-3 puffs)	1,000-1,250 μg (4-5 puffs)	>1,250 μg (> 5 puffs)
Fluticasone MDI: 44, 110, 220 μg/puff	88-176 μg (2-4 puffs - 44 μg)	176-440 μg (4-10 puffs - 44 μg) OR (2-4 puffs - 110 μg)	> 440 μg (> 4 puffs - 110 μg) OR (> 2 puffs - 220 μg)
Triamcinolone acetonide 100 μg/puff	400-800 μg (4-8 puffs)	800-1,200 μg (8-12 puffs)	> 1,200 μg (> 12 puffs)

NOTES:

- The most important determinant of appropriate dosing is the clinician's judgement of the patient's response to therapy. The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effect.
- The reference point for the range in the dosages for children is data on the safety of inhaled corticosteroids in children, which, in general, suggest that the dose ranges are equivalent to beclomethasone dipropionate 200-400 μg/day (low dose), 400-800 μg/day (medium dose), and > 800 μg/day (high dose).
- Some dosages may be outside package labeling.
- MDI dosages are expressed as the actuater dose (the amount of drug leaving the actuater and delivered to the patient), which is the labeling required in the United States. This is different from the dosage expressed as the valve dose (the amount of drug leaving the valve, all of which is not available to the patient), which is used in many European countries and in some of the scientific literature. DPI doses are expressed as the amount of drug in the inhaler following activation.

Table 8D.

Usual Dosages for Quick-Relief Medications				
Medication	**Dosage Form**	**Adult Dose**	**Child Dose**	**Comments**
Short-Acting Inhaled Beta$_2$-Agonists				
	MDIs			
Albuterol Albuterol HFA Pirbuterol	90 µg/puff, 200 puffs 90 µg /puff, 200 puffs 200 µg /puff, 400 puffs	• 2 puffs 5 minutes prior to exercise • 2 puffs tid-qid prn	• 1-2 puffs 5 minutes prior to exercise • 2 puffs tid-qid prn	• An increasing use or lack of expected effect indicates diminished control of asthma. • Not generally recommended for long-term treatment. Regular use on a daily basis indicates the need for additional long-term controller therapy. • Differences in potency exist so that all products are essentially equal in efficacy on a per puff basis. • May double usual dose for mild exacerbations. • Nonselective agents (i.e., epinephrine, isoproterenol, metaproterenol) are not recommended due to their potential for excessive cardiac stimulation, especially in high doses. • Spacer/holding chambers are recommended with MDI
	DPI			
Albuterol	***Nebulizer solution*** 5 mg/mL (0.5%) ***Premixed Vials*** 2.5 mg/3 mL (0.088%) 1.25 mg/3mL (0.042%)	1.25-5 mg (.25-1 cc) in 2-3 cc of saline q 4-8 hours	0.05 mg/kg (min 1.25 mg, max 2.5 mg) in 2-3 cc of saline q 4-6 hours	• May mix with cromolyn or ipratropium nebulizer solutions. May double dose for mild exacerbations.
Levalbuterol nebulization	0.63 mg/3 mL and 1.25 mg/3 mL	12 yrs and older is 0.63 mg to 1.25 mg TID	6-11 years is 0.31 mg to 0.63 mg TID	• Routine dosing should not exceed 0.63 mg TID in children
Anticholinergics				
	MDIs			
Ipratropium	18 µg/puff, 200 puffs	2-6 puffs q 6 hours	1-2 puffs q 6 hours	• Evidence is lacking for anticholinergice producing added benefit to ß$_2$-agonists in long-term asthma therapy.
	Nebulizer/solution .25 mg/mL (0.025%)	0.25-0.5 mg q 6 hours	0.25 mg q 6 hours	
Systemic Corticosteroids		(Applies to all three systemic corticosteroids)		
Methylprednisolone Prednisolone Prednisone	2, 4, 8, 16, 32 mg tablets 5 mg tabs, 5 mg/5 cc, 15 mg/5 cc 1, 2.5, 5, 10, 20 ~~25~~ mg tabs; 5 mg/cc; 5 mg/5 cc	• short course "burst": 40-60 mg/day as single or 2 divided doses for 3-10 days	• Short course "burst": 1-2 mg/kg/day, maximum 60 mg/day, for 3-10 days	• Short courses or "bursts" are effective for establishing control when initiating therapy or during a period of gradual deterioration. • The burst should be continued until patient achieves 80% PEF personal best or symptoms resolve. This usually requires 3-10 days but may require longer. There is no evidence that tapering the dose following improvement prevents relapse if sufficient doses of inhaled corticosteroids are used simultaneously.

9. Asthma Education

Key Points:

- Patient education is essential for successful management of asthma. It should begin at the time of diagnosis and be ongoing.

The following patient education is recommended:

- Basic facts about asthma
  - The contrast between asthmatic and normal airways
  - What happens to the airways in an asthma attack
- How medications work and the need for adherence
  - Long-term control: medications that prevent symptoms, often by reducing inflammation
  - Quick relief: short-acting bronchodilator relaxes muscles around airways
  - Stress the importance of long-term control medications and not to expect quick relief from them
- Inhaler technique
  - Metered dose inhaler (MDI) or nebulizer use (patient should repeat demonstration)
  - Spacer/holding chamber use with MDI
  - Dry powder inhaler
- Written action plan including home peak flow monitoring

  When and how to take actions
  - Symptom monitoring and recognizing early signs of deterioration.
  - Responding to changes in asthma severity. A written Asthma Action Plan including daily medications and instructions should be offered to all patients with asthma.

    Review and refine the plan at follow-up visits.
    - Home peak flow monitoring is recommended for patients with moderate to severe persistent asthma, or anyone with a history of severe exacerbations.
    - Discuss plan for children at school including management of exercise-induced bronchospasm.
    - Assess adherence to pharmacotherapy and environmental control measures.

Data are insufficient to support or refute the benefits of using written asthma action plans compared to medical management alone. However, a Cochrane review of 25 studies compared self-management interventions by adults with acute asthma episodes. Some had written action plans, others did not. The self-management interventions with written action plans had the greatest benefits, including reduced emergency department visits and hospitalizations and improved lung function *(NAEPP update 2002)*.

The NAEPP EPR-2 continues to recommend the use of written action plans as part of an overall effort to educate patients in self-management is beneficial especially for patients with moderate or severe persistent asthma and patients with a history of severe exacerbations.

- Environmental control measures
  - Identifying and avoiding exposure to allergens or other environmental triggers
- Emphasize need for regular follow-up visits and asthma treatment adherence

  Supervised self-management (using patient education and adjustments of anti-inflammatory medication based on PEF or symptoms coupled with regular medical review, utilization and adherence to medication) reduces asthma morbidity. This reduction includes lost work days, unscheduled office visits, and ER and hospital admissions *(Gibson, 2000; Ignatio-Garcia, 1995; Lahdensuo, 1996)*.

[Conclusion Grade I: See Conclusion Grading Worksheet – Appendix B – Annotation #9 (Asthma Education)]

A sample Asthma Action Plan is attached in Annotation Appendix A, "Asthma Action Plan."

See Minnesota Department of Health Action Plan at http://www.mnasthma.org/AAP/

Supporting evidence is of classes: A, M, R

10. Schedule Regular Follow-Up Visits

Asthma is a chronic inflammatory lung disease and all chronic diseases need regular follow-up visits. Practitioners need to assess whether or not control of asthma has been maintained and if a step down in therapy is appropriate. Further, practitioners need to monitor and review the daily self-management and action plans, the medications, and the patient's inhaler and peak flow monitoring techniques.

The exact frequency of clinician visits is a matter of clinical judgement

Severity	Regular follow-up visit
Mild Intermittent	6-12 months
Mild Persistent	6 months
Moderate Persistent	3 months
Severe Persistent	1 to 2 months and as often as needed to establish control

Annotation Appendix A – Asthma Action Plan

Asthma Action Plan

Patient Name _____

Date of Birth _____

Chart Number _____

Provider(s) _____

_____

Clinic Phone Number _____

To best manage your asthma, you will need to follow the instructions in this asthma action plan especially designed for you.

How to use the peak flow meter

1. Place indicator at base of the scale.
2. Stand up.
3. Take a deep breath.
4. Place the meter in mouth and close lips around the mouthpiece.
5. Blow out as hard and fast as possible.
6. Repeat the process two more times.
7. Record the highest of the three numbers.

How to use the inhaler

1. Shake the inhaler and attach spacer if needed.
2. Stand up.
3. Breathe in medication slowly through spacer.
4. Hold breath for 10 seconds.
5. Breathe out slowly.
6. Repeat puffs as directed and wait two to five minutes between puffs.
7. Rinse mouth with water after inhaling steroids to prevent thrush.

Community Asthma Education

Super Asthma Saturday
Asthma Camps
Open Airway for Schools
Asthma Support Groups
Asthma Update Newsletter

For information, call:
American Lung Association of Minnesota
at (612)227-8014 or 1-800-642-LUNG

American Lung Association of Hennepin County at (612)871-7332

Additional Information
Write or call:
Allergy and Asthma Network/
Mothers of Asthmatics, Inc.
3554 Chain Bridge Road, Suite 200
Fairfax, VA 22030-2709
(703)385-4403

Additional Reading
Children With Asthma by Thomas F. Plaut,MD
The Asthma Handbook and *The Best of Super Stuff* by the American Lung Association
What Everyone Needs to Know About Asthma by the Allergy and Asthma Network
Winning Over Asthma by Eileen Dolan Savage

Green Zone: All Clear

Personal best peak flow _____
Peak flow _____
(80-100% of personal best)

Symptoms:
- No symptoms of asthma
- Able to participate in usual activities
- No sleep disturbance by asthma such as coughing, wheezing, shortness of breath or chest tightness

Medications:

Name	Dose	Time

Medication side effects:

_____

_____

☐ Inhaler, spacer, nebulizer or rotocaps
☐ Participation in running, playing and sports; take _____ before exercise
☐ Diary can be used with peak flow meter and/or symptoms
☐ Environmental control of asthma triggers, e.g., cigarette smoke, exercise, illness, cold air, animals, etc.

Yellow Zone: Caution

Peak flow _____
(50-80% of personal best)

Early warning signs of acute asthma episode:
- Coughing
- Runny, stuffy or congested nose
- Sneezing
- Not sleeping or eating well
- Tired, weak or low energy
- Itchy or watery eyes
- Drop in peak flow meter reading

Symptoms of acute asthma episode:
- Rapid breathing
- Wheezing
- Frequent, tight cough
- Difficulty breathing out
- Sucking in the chest skin between the ribs

Begin or increase medications if warning signs or symptoms become worse or last more than 12 hours. If unsure, call your clinic.

Medications:

Name	Dose	Time

Medication side effects:

_____

If no symptom relief within 30 minutes of giving medication and peak flow is _____%, add oral steroid _____

_____

Red Zone: Medical Alert

Peak flow: _____
(less than 50% of personal best)

Severe symptoms requiring immediate medical care:
- Flared nostrils
- Hunched body
- Prolonged shortness of breath not relieved by medication or only brief relief

Medication instructions:

_____

_____

Give oral steroid: _____

Call clinic # _____

Call 911 if you observe these symptoms:
- Gasping for air with sweating
- Extreme anxiety due to difficulty breathing
- Condition rapidly getting worse

☐ Asthma in school or day care
☐ Next asthma appointment and how much time will be needed

Patient Name _____
Date of Birth _____
Provider Signature _____
Date _____

Document Drafted
Adults: Mar – Jun 1994
Peds: May – Aug 1993

First Edition
Jun 1998

Second Edition
Jul 1999

Third Edition
Jul 2000

Fourth Edition
Jul 2001

Fifth Edition
Jul 2002

Sixth Edition
Jun 2003

Seventh Edition
Begins April 2005

Availability of references

References cited are available to ICSI participating member groups on request from the ICSI office. Please fill out the reference request sheet included with your guideline and send it to ICSI.

Released in March 2005 for Seventh Edition.
The next scheduled revision will occur within 24 months.

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Evidence Grading System

I. CLASSES OF RESEARCH REPORTS

A. Primary Reports of New Data Collection:

Class A: Randomized, controlled trial

Class B: Cohort study

Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study

Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis

Class R: Consensus statement
Consensus report
Narrative review

Class X: Medical opinion

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in Section I, above, and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols **+**, **–**, **ø**, and **N/A** found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

– indicates that these issues have not been adequately addressed;

ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

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Zieger RS, Heller S, Mellon MH, et al. Facilitated referral to asthma specialist reduces relapses in asthma emergency room visits. *J Allergy Clin Immunol* 1991;87:1160-68. (Class C)

Conclusion Grading Worksheet – Appendix A – Annotation #8 (Leukotriene Receptor Antagonists [LTRAs])

Work Group's Conclusion: Based on data comparing LTRAs to inhaled corticosteroids, inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults, and by extrapolation until published data become available, for children. LTRAs are an alternative – although not preferred – treatment.

Conclusion Grade: I

Author/Year	Design Type	Class	Quality +,–,Ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Malmstrom et al., 1999	RCT	A	Ø	-Ages 15 yrs and older; males and females; healthy, nonsmoking; asthma for ≥1 yr; FEV_1 50-85% of predicted; increase of ≥15% in absolute FEV_1 after use of inhaled β-agonist (at least 2 of 3 visits); daytime asthma symptom score ≥64 (of 336 possible); average daily use of ≥1 puff of short-acting β-agonist -Excluded: use of inhaled and oral corticosteroids, cromolyn, or nedocromil within 4 wks before initial eval; use of long-acting β-agonists, antimuscarinics, or theophylline within 2 wks before initial eval; had used long-acting antihistamines -2 wk placebo run-in, 12 wk treatment period, 3 wk washout -Randomized to montelukast (10 mg 1X/day [evening]), inhaled beclomethasone (200µg 2X/day), or placebo (3:2:2 ratio) -Clinic: FEV_1 -Home: daily diary card for symptoms, PEFR, and need for salbutamol	-895 patients randomized (387 montelukast, 251 beclomethasone, 257 placebo); treatment completed by 91.5%, 92.8%, and 83.7%, respectively; total study completed by 89.4%, 90.4%, and 81.7% -Groups similar at baseline; mean compliance with inhaled medication (treatment phase) 88%-90% for all groups; mean compliance with oral medication >99% for all groups -Outcomes: Placebo Montelukast Beclomethasone FEV_1* 0.7% 7.4%[a] 13.1%[a] Symptom Score# -0.17 -0.41[a] -0.62[a] PEFR-am 0.8 l/min 23.8 l/min[a] 39.2 l/min[a] PEFR-pm 0.3 l/min 20.8 l/min[a] 32.1 l/min[a] Attacks^ 27.3% 15.6%[a] 10.1%[a] [a]p<0.001 compared with placebo; *morning value, % change from baseline; #daytime score, change from baseline; ^percentage of patients -During 3 wk washout, patients switched to placebo returned to baseline levels -Initial response greater for montelukast group; effect of beclomethasone surpassed montelukast 7-10 days after start of therapy -No interactions based on baseline FEV_1, symptom score, need for β-agonist, or PEFR -Improvements in quality of life greater with montelukast and beclomethasone (p<0.001) -Most common clinical adverse effects: worsening asthma (p<0.05 for active treatment vs. placebo), headache, upper respiratory infection (both NS)	-Oral montelukast therapy has been shown to be effective in chronic asthma, producing significant improvements in FEV_1 and significant alleviation of daytime asthma symptoms. Although inhaled beclomethasone had a larger average effect than montelukast, montelukast had a more rapid initial response. The two agents each protected against worsening episodes of asthma. NOTES: use of immunotherapy was permitted if it had been started ≥6 mos before initial evaluation; run-in was single-blind, treatment and washout was double-blind; during washout some patients continued active treatment and others switched to placebo; study done at 36 centers in 19 countries; patients could use short-acting inhaled β-agonist (salbutamol) as needed; if additional therapy was needed oral corticosteroids were given (if ≥2 such episode patient was dropped from study); compliance monitored by weighing inhalers and counting tablets; analysis included all patients with baseline and at least one measurement after randomization; did sample size estimation for 95% power to detect difference of 6% in change from baseline and 10% in daytime symptom scores (montelukast vs. placebo)

Bleeker et al., 2000	RCT	A	0	-Ages 12+; persistent asthma (≥6 mos); predose FEV_1 of 50-80% of predicted normal and increase FEV_1 ≥12% from baseline after 180µg inhaled albuterol; had used albuterol on schedule or as-needed bases during 4 wks before screening; no montelukast, zafirlukast, or zileuton within 2 wks of screening -Excluded: history of life-threatening asthma; >3 bursts of oral or parenteral corticosteroids within 1 yr; use of tobacco products in past yr or smoking history of >10 pack-yrs; respiratory infection within 2 wks of screening, current evidence of significant disorders -8-14 day run-in with rescue albuterol (baseline data, compliance assessment) -Eligible patients randomized to inhaled fluticasone propionate (FP) aerosol (88µg) or oral zafirlukast (20 mg); both 2X/day for 12 wks with albuterol as needed -Home: symptoms, PEFR, albuterol use -Clinic: FEV_1	-220 randomized to zafirlukast, 231 to FP; groups similar at baseline; 77% of zafirlukast and 87% of placebo groups finished protocol -Outcomes (change after 12 wks of treatment): FP Zafirlukast FEV_1-am (L) +0.42 +0.20* PEFR-am (L/min) +49.94 +11.68* PEFR-pm (L/min) +38.91 +10.50* Symptom score -0.46 -0.19* Symptom-free days (%) +28.5 +15.6* Albuterol (puffs/day) -2.39 -1.45* Rescue-free days +40.4 +24.2* # Night awakenings -0.28 -0.15* * p<0.001 -56% of physicians rated treatment with FP as "effective" or "very effective" compared with 41% for zafirlukast (p<0.001) -4% of FP group and 6% of zafirlukast group had an exacerbation (NS) -10% in each group had ≥1 adverse event considered potentially related to treatment; headache, dry mouth, & hoarseness were most common	-The clinical effectiveness of a low dose of FP as first-line therapy in patients with persistent asthma who are symptomatic on β_2-agonists alone is superior to that of zafirlukast. NOTES: concurrent use of medications that might affect the course of asthma or interact with zafirlukast were prohibited; antihistamines, decongestants, and intranasal medications for allergic rhinitis were allowed; double-blind treatment phase; patients with asthma exacerbation (requiring corticosteroids) during study phase were withdrawn; study designed with ≥80% power to detect difference of 0.178 L/min in FEV_1 between groups

Busse et al. for the Fluticasone Propionate Clinical Research Study, 2001	RCT	A	0	-Ages 15+; asthma diagnosed for ≥6 mos; predose FEV_1 50-80% of predicted normal and increase in FEV_1 of ≥15% after 180 µg albuterol; used inhaled or oral short-acting β_2-agonist on a regular or as-needed basis for 3 mos before screening -Excluded: use of ICSs in past 2 mos; use of tobacco products in past year; smoking history of ≥10 pack-yrs; hospitalized for asthma in past 3 mos; respiratory tract infection in past 4 wks; hypersensitivity to asthma drugs -8-14 day run-in period (confirm eligibility, baseline data); use of albuterol as needed -Randomized (see NOTES) to 88µg 2X/day FP + placebo capsule in evening or 10 mg oral montelukast in evening + 2 puffs placebo 2X/day for 24 wks; inhaled albuterol as needed -Clinic visits: FEV_1, adverse events; physician rating of effectiveness, quality of life, patient satisfaction with medication -Home (am/pm): symptoms, PEFR, puffs of albuterol, nighttime awakenings, compliance	-271 in FP group, 262 in montelukast group; groups comparable at baseline; study completed by 72% of FP group and 71% of montelukast group; reported compliance (inhaler and capsules) ≥91% -Outcomes (change from baseline): *p<0.001 -Physicians global assessment favored FP over montelukast (71% rated FP effective or very effective vs. 53% for montelukast, p<0.001) -Patient satisfaction favored FP over montelukast (85% of patients satisfied with FP vs. 65% for montelukast, p<0.001); quality-of-life scores significantly greater in FP patients (p<0.001) especially asthma symptoms and emotional function domains -Adverse events: 71% of FP patients, 68% of montelukast patients; few were considered drug related; most common (possibly drug related) were headache, sore throat, hoarseness, oral pharyngeal candidiasis -Asthma exacerbations: 4% of FP group, 8% of montelukast group		FP	Montelukast
				FEV_1 (L)	0.51	0.33*
				PEFR-am (L/min)	68.5	34.1*
				PEFR-pm (L/min)	53.9	28.7*
				Symptom score	-0.85	-0.60*
				Albuterol (puffs/day)	-3.10	-2.31*
						-Low-dose FP is more effective than montelukast as first-line maintenance therapy for patients with persistent asthma who are underrated and remain symptomatic while taking short-acting β_2-agonists alone. NOTES: at randomization patients had to demonstrate that additional therapy was warranted (unmedicated FEV_1 of 50-80% of predicted normal and within 15% of screening FEV_1, use of albuterol on ≥6 of 7 days before randomization, and asthma symptom score ≥2 [0-5 scale] on ≥4 of 7 days before randomization); use of mediations for rhinitis was allowed; did sample size estimation for ≥80% power to detect difference of 6 percentage points in FEV_1 change between 2 treatment groups; study conducted at 52 sites

Ducharme & Hicks, 2002	Systematic Review	M	+	-Search of clinical trials databases; contact with pharmaceutical companies -Quality of studies assessed by 2 masked reviewers -14 trials met inclusion criteria (including Bleeker, 2000, Busse 2001, and Malmstrom, 1999, [above]); all RCTs except one; 12 focused on adults; intervention duration of 4 to 37 wks; included montelukast, pranlukast, zafirlukast, beclomethasone, and fluticasone -10 trials had high quality (≥4 of 5 points); 11 with appropriate randomization methods; 11 double-blind; withdrawal rates of 0%-29%	**-Primary outcome (results from 11 trials):** rate of exacerbations requiring systemic corticosteroids; patients treated with anti-leukotrienes had 61% increased risk of exacerbation compared to patients treated with ICSs (RR=1.61; 95%CI 1.15-2.25); no apparent difference due to montelukast vs. zafirlukast, beclomethasone vs. fluticasone, quality of studies, published vs. unpublished data, source of funding; greater effect in trials of 12-16 wks vs 4-6 wks, patients with moderate vs. mild asthma **-Other outcomes:** improvements in FEV_1, PEFR-am, change in symptom score, nighttime awakenings, symptom-free days, and quality of life all favored ICSs; anti-leukotriene therapy associated with greater risk of overall withdrawals (RR=1.3; 95%CI 1.1-1.6) apparently due to poor asthma control; no difference in patients experiencing "any adverse effects"	-For most asthma outcomes, ICSs at 400 mcg/day of beclomethasone-equivalent are more effective than anti-leukotriene agents given in the usual licensed doses. The exact dose-equivalence of anti-leukotriene agents in mcg of ICSs remains to be determined.

Conclusion Grading Worksheet – Appendix B – Annotation #9 (Asthma Education)

Work Group's Conclusion: Supervised self-management (using patient education and adjustments of anti-inflammatory medication based on PEF or symptoms coupled with regular medical review, utilization and adherence to medication) reduces asthma morbidity. This reduction includes lost work days, unscheduled office visits, and ER and hospital admissions.

Conclusion Grade: I

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Mayo, Richman, & Harris, 1990	RCT	A	0	-Patients hospitalized with acute asthma exacerbation; 18+ yrs old; >4 ER visits in past 12 mos or >1 hospitalization in past 24 mos -Randomized to special clinic group or routine clinic group; after 8 months, 19 patients from routine group selected (based on multiple hospitalizations) to cross to special clinic group	-104 randomized (47 to special clinic, 57 to routine clinic); 10 of 47 never attended special clinic; after 8 months 19 from routine clinic group joined special clinic group (n=56 with 1 lost to follow-up) -Special clinic, routine clinic, and cross-over groups similar at baseline except fewer in cross-over group ever required intubation -After enrollment in special clinic (n=56): less use of oral beta agonists and daily prednisone, greater use of chronic inhaled corticosteroids, brief prednisone pulses, reservoir spacer devices, and home peak flow monitors -Special clinic group (n=47) had lower hospital use than routine clinic (n=57) (0.4 vs. 1.2 admissions per patient [p<0.004] and 3.1 vs. 6.7 re-hospitalization days per patient [p<0.02]) -For 34 of 37 who attend special clinic re-admission rate per patient per month decreased from 0.13 before enrollment to 0.04 after (p=0.003) and re-hospitalization days per patient per month decreased from 0.73 to 0.26 (p=0.003); similar findings for cross-over group -No deaths from asthma in special clinic group; one death in routine group; 4 special clinic patients required intubation in 32 months follow-up	-A vigorous medical regimen and intensive education program was able to decrease hospital use among a group of adult asthmatics who had previously required repeated readmissions for acute asthma exacerbations. NOTES: a special outpatient asthma clinic was developed to reduce re-admissions for asthma exacerbation; all patients treated by same physician; clinic program included patient education and individual medication regimens with emphasis on self-management; hospital usage before special clinic enrollment was limited to 1 hospital while usage after enrollment included other hospitals in the area; no attempt was made to determine what element of the program, if any, was essential *Work Group's Comments: different observation schedules; no statistics for drug use data; population was largely Hispanic; no data on compliance with programs*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Ignacio-Garcia & Gonzalez-Santos, 1995	RCT	A	0	-Patients from one outpatient asthma clinic; 14 to 65 years with asthma diagnosed ≥2 yrs prior -Randomized to experimental (self management with peak-flow readings as basis for treatment plan plus education program) or control (symptoms and spirometric data for following physician's treatment plan) -Medical regimens tailored to individual patient -Follow-up: 1, 3, 5, and 6 mos -Degree of illness: morbidity parameters, spirometric data, consumption of drugs, rates attained by peak flow metering -Compared 6 mos before intervention with 6 mos after	-94 enrolled; 24 completed initial assessment but later dropped out or were excluded for protocol violations (9 control, 15 experimental) -Analysis based on 70 patients (32M, 38F), mean age 42 (range 16-64); 35 experimental, 35 control; groups comparable at baseline in age, gender, social class, smoking, years of asthma, chronic bronchitis -After intervention groups differed ($p<0.05$) in days lost from work, exacerbations, days on antibiotics, physician consultations, ER admissions, nocturnal wakening -Control group: fewer exacerbations and physician consultations after study period (both $p<0.01$) -Experimental group: fewer days lost from work, exacerbations, days on antibiotics, physician consultations, ER admissions after study period (all $p<0.01$) -FEV_1, FVC, and FEV_1/FVC improved over study period in experimental group (all $p<0.003$ from baseline); control group improved FEV_1 and FEV_1/FVC at first follow-up but returned toward baseline thereafter -Mean peak expiratory flow rate (PEFR) higher in experimental group at all follow-up visits (all $p<0.05$); mean PEFR and morning PEFR increased significantly from baseline in experimental group ($p<0.001$); PEFR more variable in control group -Experimental group used less fenoterol and prednisone (both $p<0.05$) than control and decreased use of albuterol, terbutaline, fenoterol, theophylline, and budesonide during study period (all $p<0.05$);	-Peak flow monitoring associated with an education program reduced morbidity, improved lung function, and optimized the use of medication in adult asthma patients. NOTES: one physician (unblinded) assessed patients' condition and modified treatment at follow-up visits; before intervention groups comparable in days lost from work, acute exacerbations, days on antibiotics, physician consultations, ER admissions, hospital admissions *Work Group's Comments: Little information about inclusion/exclusion criteria or comorbidities; analysis was not intention-to-treat*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Lahdensuo et al., 1996	RCT	A	0	-Adults (18+) from 3 outpatient centers; mild to moderately severe asthma; inclusion/exclusion criteria based on peak flow rate and medications (see NOTES) -Randomized to self-management (personal education sessions, daily morning peak flow measurements with medication plan based on results) or traditional treatment (info. on inhaler use, no changes in medications on their own) -Baseline and 3 follow-up visits over 12 months	-122 initially enrolled, analysis based on 115 with at least 4 mos follow-up (56 self-management, 59 traditional); more women and lower mean weight in self-management group (p=0.02) otherwise comparable at baseline -Outcome Self-mgmt Traditional p Admissions for asthma 2 patients 3 patients Unscheduled outpatient visits* 0.5 1.0* 0.04 Days off work* 2.8 4.8 0.02 Courses of antibiotics* 0.4 0.9 0.009 Courses of prednisone* 0.4 1.0 0.006 Total (any incident caused by asthma)* 0.6 2.1 <0.001 *mean numbers per patient -Incidence free survival (p<0.0001) and quality of life (p=0.009) favored self-management group (p<0.0001) throughout study period -Exploratory analyses: 62% adhered to self-management instructions for budesonide dose; 77% to instructions to start oral prednisolone; adherence was related to severity of symptoms	-Guided self-management, using patient education and adjustment of anti-inflammatory treatment based on peak expiratory measurements, reduced by half or more the number of incidents caused by asthma when compared with traditional treatment and improved quality of life. It is not possible to determine whether early treatment of inflammation, peak flow measurement per se, patient education, or improved compliance is most important. NOTES: study was single-blind; eligible patients had a) morning-evening peak flow value that varied by >15% in 2 days within 1 wk during past 6 mos, b) optimal peak flow ≥250 l/min, c) anti-inflammatory treatment with budesonide (400-1600µg/day) or beclomethasone dipropionate (500-2000 µg/day) in past 6 mos, d) ≥4 wks since last course of oral corticosteroids; sample size estimation of 60 per group based on estimated number of incidents per year caused by asthma (1 with traditional tx, 0.47 with self-management); patients with severe asthma were excluded as most already have peak flow meters *Work Group's Comments: Little information about comorbidities; analysis was not intention-to-treat*

This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
  - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Products
- Recommended Resources

Priority Aims and Suggested Measures

1. Promote the accurate assessment of asthma severity through the use of objective measures of lung function.

   Possible measures of accomplishing this aim:

   a. Percentage of patients with asthma with spirometry or peak flow documented at the last visit.

   b. Percentage of patients with asthma, for whom a peak flow meter is appropriate, who report using a home peak flow meter.

   c. Percentage of patients with asthma with any assessment of asthma severity documented at the last visit.

2. Promote long-term control of persistent asthma through the use of inhaled corticosteroid drug therapy.

   Possible measure of accomplishing this aim:

   a. Percentage of patients with persistent asthma who are on inhaled corticosteroid medication.

3. Promote the partnership of patients with asthma and/or their parents with health care professionals through education and the use of written action plans.

   Possible measures of accomplishing this aim:

   a. Percentage of patients with asthma with an asthma action plan in the medical record.

   b. Percentage of patients with asthma with education about asthma documented in the medical record.

Measurement Specifications

Possible Success Measure #1a

Percentage of patients with asthma with spirometry or peak flow meter reading documented in the medical record at the last visit.

Population Definition

Patients age 5 through 55 years diagnosed with asthma, continuously enrolled for 6 months.

Data of Interest

$$\frac{\text{\# of patients with asthma with spirometry or peak flow meter reading documented at the last visit}}{\text{total \# of patients ages 5-55 with asthma}}$$

Numerator/Denominator Definitions

Numerator: Documented is defined as any evidence in the medical record that spirometry or peak flow reading was done at the last visit as recommended in the guideline.

Denominator: Patients with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for 6 months.

Method/Source of Data Collection

Data may be collected electronically using the claims/encounter database or the enrollment database. Medical groups should identify patients with asthma seen at the clinic. Each medical group can then generate a list of all eligible patients with asthma seen during the target month/quarter. A random sample of 20 charts can be chosen from this list. The eligible patients are those who are 5-55 years old and have been diagnosed with asthma. The patient medical records are reviewed for any evidence that spirometry or peak flow meter reading was done at the last visit as recommended in the guideline.

Time Frame Pertaining to Data Collection

A minimum of 20 charts per month can be reviewed.

Notes

It is important to periodically assess pulmonary function. The main methods are spirometry or PEFR. Spirometry is more precise and yields more information than PEFR. It is helpful to verify the accuracy of the peak flow meter. It is useful when certain physical limitations affect accuracy of PEFR (e.g., very young or elderly, neuromuscular or orthopedic problems). PEFR provides a simple, quantitative and reproductive measure of severity of airflow obstruction. The results are more reliable if the same type and preferably the patient's own meter are used.

Possible Success Measure #2a (children)

Percentage of children with persistent asthma who are on inhaled corticosteroids medication.

Population Definition

Children aged 17 and under with persistent asthma, continuously enrolled for 6 months.

Data of Interest

$$\frac{\text{\# children in denominator who have one or more prescriptions for inhaled corticosteroids medications}}{\text{\# of children with persistent asthma}}$$

Numerator/ Denominator Definitions

Numerator

Among the children in the denominator, the number who have one or more prescriptions for inhaled corticosteroids medications:

- beclomethasone HFA (Vanceril®, Beclovent®, QVAR®)
- triamcinolone (Azmacort®)
- fluticasone (Flovent®, Advair®)
- flunisolide (Aerobid®)
- budesonide (Pulmicort®)

Denominator

Children with persistent asthma with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for 6 months.

Method/Source of Data Collection

This measure may be collected electronically using the pharmacy data base, the claims/encounter data base, or the enrollment data base.

Time Frame of Data Collection

It is suggested that data are collected quarterly.

Notes

Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long-term and prevent exacerbations.

Possible Success Measure #2a (adults)

Percentage of adults with persistent asthma who are on inhaled corticosteroids medication.

Population Definition

Adults age 18 through 39 with persistent asthma, continuously enrolled for 6 months.

Data of Interest

$$\frac{\text{\# of adults in the denominator who have 1 or more prescriptions for inhaled corticosteroids medications}}{\text{\# of adults with persistent asthma}}$$

Numerator/Denominator Definitions

Numerator: Persons in the denominator who have 1 or more prescriptions filled for inhaled anti-inflammatory medications

Inhaled anti-inflammatory medications are:

- beclomethasone HFA
- flunisolide
- triamcinolone
- budesonide
- fluticasone
- fluticasone propionatel salmeterol DPI

Denominator: Adults age 18 through 39 with persistent asthma with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for 6 months, identified by having received one or more refills of the following medications during the 6 month period:

- beclomethasone HFA
- flunisolide
- triamcinolone
- budesonide
- fluticasone
- fluticasone propionatel salmeterol DPI

Method/Source of Data Collection

Data may be collected electronically using the pharmacy database, the claims/encounter database or the enrollment database.

Time Frame Pertaining to Data Collection

It is suggested that data are collected quarterly.

Possible Success Measure #3b

Percentage of patients with asthma with education about asthma documented in the medical record.

Population Definition

Patients age 5 through 55 years diagnosed with asthma continuously enrolled for 6 months.

Data of Interest

$$\frac{\text{\# of patients in the denominator with documentation in the record of education about asthma}}{\text{total \# of patients with asthma whose medical records are reviewed}}$$

Numerator/Denominator Definitions

Numerator: Documented is defined as any evidence in the medical record that a clinician provided patient (or parent) education related to:

- basic facts about asthma
- role of medications
- skills (in managing asthma)
- environmental control measures
- when and how to take actions
- need for follow-up visits

Denominator: Patients with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for 6 months.

Method/Source of Data Collection

Data may be collected electronically using the claims/encounter database or the enrollment database. Medical groups should identify patients with asthma seen at the clinic. Each medical group can then generate a list of all eligible patients with asthma seen during the target month/quarter. The eligible patients are those who are 5-55 years old and have been diagnosed with asthma. A random sample of 20 charts can be chosen from this list. The patients' medical records will be reviewed for any evidence that a clinician provided patient education.

Time Frame Pertaining to Data Collection

A minimum of 20 charts per month can be reviewed.

Notes

Patient education is essential for successful management of asthma. It should begin at the time of diagnosis and be ongoing.

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Facilitate timely and accurate diagnosis of asthma and asthma severity.
2. Educate providers in the use of spirometry as a diagnostic tool.
3. Educate providers and patients in the importance of developing and maintaining an asthma action plan and assessing adherence.

Knowledge Products

Resources and knowledge products are developed by the guideline work group, member and non-member organizations, or identified by ICSI staff as useful implementation tools.

1. Scientific Documents
    - Related guidelines
        - Emergency and Inpatient Management of Asthma
        - Chronic Obstructive Pulmonary Disease
        - Rhinitis

3. Educational Resources
    - Improvement Case Report on Asthma: Family HealthServices Minnesota PA, Process Improvement Report #19
    - HealthEast Case Improvement Report on Asthma, Process Improvement Report #4
    - Asthma Toolkit – Action Plans; Assessment Surveys; Education (ideas for elementary classrooms); Flow Sheets, Information/Patient Education Modules, Manual for Families of Children with Special Needs; NAEPP Export Panel Report, Shingle; other tools.

ICSI has a wide varity of other knowledge products including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Products, go to http://www.icsi.org/knowledge.

Many of the materials listed in the Knowledge Products resource are only available to ICSI members.

Recommended Resources

Title/Description	Audience	Author/Organization	Websites/Order Information
A national nonprofit network of families whose desire is to overcome allergies and asthma through knowledge. This web-site provides accurate, timely, practical, and livable alternatives to suffering.	Patients Professionals	Allergy and Asthma Network/Mothers of Asthmatics	http://www.aanma.org
Offers comprehensive information for patients of all ages. In-depth information on medications, exacerbations, peak flow meters and control over environmental allergens. Español material as well.	Patients Professionals	ALA (American Lung Association)	http://www.lungusa.org/ Resources from the American Lung Association (ALA) are available from: American Lung Association of Minnesota, 490 Concordia Avenue, St. Paul, MN 55103. (651)227-8014. For clinics in Hennepin County contact the American Lung Association of Hennepin County, 4220 West Old Shakopee Road, Suite 101, Bloomington, MN 55437. (952)885-0338. http://www.alamn.org
The website offers asthma education resources for patients and providers. The site includes special sections for children and seniors, seasonal educational materials. Health Headlines are posted daily.	Patients Professionals	American Academy of Allergy, Asthma and Immunology (AAAAI)	http://www.aaaai.org/ 611 East Wells Street Milwaukee, WI 53202 (800) 822-2762
Focus is on improving the quality of life for people with asthma and allergies and their caregivers, through education, advocacy and research. Provides practical information, community-based services, support and referrals through a national network of chapters and educational groups.	Patients Professionals	Asthma and Allergy Foundation of America	http://www.aafa.org

Title/Description	Audience	Author/Organization	Websites/Order Information
Offers asthma education that incorporates an awareness of indoor environmental asthma triggers (e.g., secondhand smoke, dust mites, mold, pet dander, and cockroaches) and actions that can be taken to reduce children's exposure to them in homes, schools and child care settings.	Patients Professionals	EPA (U.S. Environmental Protection Agency)	http://www.epa.gov/iaq
Offers information for healthcare professionals, schools and patients about asthma. An asthma action plan is also included in English and Spanish.	Patients and Professionals	Minnesota Department of Health	http://www.health.state.mn.us
Provides asthma health education resources for patients, school/day care providers and health professionals. Materials written in Spanish are available.	Patients Professionals	National Heart, Lung, and Blood Institute (NHLBI)	http://www.nhlbi.nih.gov
Brochure. Signs, symptoms, management, MDI use	Patients	Mayo Clinic, Asthma	Mayo members call Mary Ann Djonne at (507) 284-8780
Your Child's Asthma Book, 26 pages	Patients	Mayo Clinic	Mayo members call Mary Ann Djonne at (507) 284-8780

Criteria for Selecting Websites

The preceding websites were selected by the *Diagnosis and Outpatient Management of Asthma* guideline work group as additional resources for practitioners and the public. The following criteria were considered in selecting these sites.

- The site contains information specific to the particular disease or condition addressed in the guideline.
- The site contains information that does not conflict with the guideline's recommendations.
- The information is accurate and/or factual. The author of the material or the sponsor of the site can be contacted by means other than e-mail. For example, a nurse line or other support is provided.
- The material includes the source/author, date and whether the information has been edited in any way. The site clearly states revision dates or the date the information was placed on the internet.
- The site sponsor is an objective group without an obvious or possible bias. For example, the site does not promote a product, service or other provider.
- The coverage of the topic is appropriate for the guideline's target audience. It is clearly written, well-organized and easy to read. The site is easy to navigate.

Summary of Changes – March 2005

Diagnosis and Management of Asthma

Algorithm, Clinical Highlights, Annotations

Title: Revised the title of this guideline to: Diagnosis and Outpatient Management of Asthma. This clearly differentiates it from the ER and Inpatient Management of Asthma Guideline.

Added a bullet to Box #9 Asthma Education—*how medications work.* This was also added to the Clinical Highlight #5 (provide asthma education) and revised as an independent item in Annotation #9 Asthma Education.

*1: Added *Objective measures of lung function (FEV_1 PEF, PEF variability)* to C—Severity of symptom classification.

Throughout the guideline, added *administered by nebulizer or metered dose inhaler (MDI),* either is acceptable.

*8: Added a statement and reference regarding Pregnancy in Asthma. *Managing Asthma during pregnancy is the same treatment used for non-pregnant asthma patients. NAEPP Update, 2005.* And, in table 8C, added a comment that Budesonide is the preferred inhaled corticosteroid for use in pregnancy.

Also added reference *Characterization of within-subject responses to flucticasone and montelukast in childhood asthma. Szefler, 2005.* This recent article also supports the statement, *Inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults, and LTRA's are an alternative.*

Added a statement recommending annual influenza vaccinations for patients with persistent asthma

ICSI has developed a new format for all guidelines. Key additions and changes are:

- The annotation and discussion section have been combined. Any duplicated statements have been removed.
- Most of the annotations will have "Key Points" at the beginning. This informs the reader of key recommendations, highlights, or information pertinent to the steps of the algorithm.
- References in support of recommendations or conclusions are listed in the body of the annotation. A complete list of references is included in the Supporting Evidence section.
- Priority Aims only will be listed in the front of the guideline section. Both aims and measures are contained in the Support for Implementation section as usual.

Support for Implementation

Added new website from Minnesota Department of Health for asthma action plans

**An asterisk indicates any changes in clinical practice recommendation*.