PreferredOne®
UPDATE A Newsletter for PreferredOne Providers & Practitioners
February 2008

PIN & NPI Paper Letters to be Discontinued

Beginning July 1, 2008 PreferredOne will discontinue mailing paper copies of the Provider Identification Numbers (PINs) and National Provider Identifier Numbers (NPIs) to PreferredOne providers. This information is available "live" on our secure website at www.PreferredOne.com. **To view PINs & NPIs**, registration at www.PreferredOne.com is required. Once registered, please **click on** "**For Providers**" on the home page. On the "PreferredOne User Account" page, **go to the gold box titled "Information**" and **click on "Provider ID Lookup and NPI Submission**." You can now view the available ID numbers by location or practitioner under your billing ID. You can also use the "Search" tool and search by key word. This information is posted in real time as it is added to our system. This is a very useful and convenient tool and you no longer need to wait for a PIN letter to arrive in the mail.

We strongly encourage you to register for secure access for this information and much more. **Just to list a few of the other available resources, you can check claim status, subscriber/dependant information, medication authorization, referral inquiry and submission and download forms!** To register, visit www.PreferredOne.com, click on "For Providers", in the menu bar. In the login registration page, click "Register" and fill in the requested information and submit. You will receive your login information within a few business days. We continue to enhance the PreferredOne website. Providers and clinics have indicated to us that our site is very user friendly and provides invaluable information.

In This Issue:

Clinic Closings and Changes

PreferredOne would like to remind you of the importance of notifying your Provider Relations Representative as soon as you are aware of changes in your clinics. PreferredOne is required to notify members 30 days in advance of clinic changes. Considering these requirements, we are asking that you please inform your Provider Relations Representative of any changes with as much advance notice as possible.

If a clinic is closing, PreferredOne needs to know what date the clinic will stop seeing patients, to what clinic the practitioners are moving and where medical records will be available to members.

If a clinic is being sold to another entity, PreferredOne needs the effective date of the change in ownership, the name of the purchasing entity and the Tax Identification Number the clinic will be operating under after the change in ownership.

Page 2...

PreferredOne
6105 Golden Hills Dr.
Golden Valley, MN 55416

Phone: 763-847-4000
800-451-9597
Fax: 763-847-4010

CLAIM ADDRESSES:

PreferredOne PPO
PO Box 1527
Minneapolis, MN 55440-1527

Phone: 763-847-4400
800-451-9597
Fax: 763-847-4010

PreferredOne Community Health Plan (PCHP)
PO Box 59052
Minneapolis, MN 55459-0052

Phone: 763-847-4488
800-379-7727
Fax: 763-847-4010

PreferredOne Administrative Services (PAS)
PO Box 59212
Minneapolis, MN 55459-0212

Phone: 763-847-4477
800-997-1750
Fax: 763-847-4010

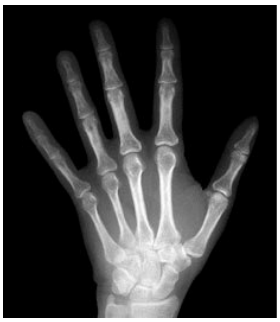
...Cont'd from front page

In addition to the information above, please forward to your Provider Relations Representative, a copy of any correspondence that is sent to PreferredOne members regarding the changes.

Timely Filing

PreferredOne would like to remind our provider community of our timely filing guidelines. We do uphold our billing requirements of receiving all claims within 120 days of date of service. If there is an extenuating circumstance that prevented filing within 120 days, we will review appeals on your behalf. The extenuating circumstance can be a primary payer decision or lack of information from the patient. Documentation of the extenuating circumstance is required with all appeals as is a copy of your claim filing history. All appeals must be made within 60 days of a primary payer decision or receipt of patient insurance information. Any appeals received after 60 days will be denied and considered the provider's responsibility. For your convenience, we have developed a cover sheet for your timely filing appeals. This form is available at www.PreferredOne.com in Information – Forms. Once you have completed the form and have all the necessary documents, please fax this information to your Provider Relations Representative.

Request for Information – Providers Using Electronic Health Records



We are requesting that providers who have implemented or are implementing Electronic Health Records in their offices send us notification of this. We would like to make this information available on the PreferredOne secure website (www.PreferredOne.com) so that PreferredOne members searching for a provider will know this extra information as we receive many calls asking about EHRs.

If you are a provider who has implemented the use of Electronic Health Records in your office, please notify us by simply sending an email to EHR@PreferredOne.com. Thank you in advance for your response!

Becoming an In-Network Provider with PreferredOne

Non-contracted providers can now find all of the necessary forms required to apply for participation in the PreferredOne network on the PreferredOne secure website at www.PreferredOne.com.

Registration is not required to access these forms. To view the forms and read more about the process of becoming contracted with PreferredOne, go to www.PreferredOne.com. Once on the Homepage, in the side menu bar, click on **"For Providers".** Once you're in the "Login/Registration" page, click on the link that reads "**If you are interested in becoming an In-Network Provider with PreferredOne, please CLICK HERE."** You're now in the "Pre-application" page. If interested, fill out the appropriate forms (by specialty) and mail or fax back to the contact listed on that page. The PreferredOne Internal Review Committee reviews all provider pre-applications against established Guidelines for Provider Expansion. At this level, provider recommendations are based primarily on PreferredOne's geographic and specialty needs. After you've submitted your pre-application, you should receive a reply within 4-6 weeks. Please note, provider submission of these pre-applications does not guarantee participation.

Coding Update

PreferredOne Participates with Administrative Uniformity Committee (AUC)

PreferredOne is participating with the (AUC) on standardized administrative processes. The AUC is a broad-based group representing Minnesota health care public and private payers, hospital health care providers and state agencies. The mission is to develop agreement among Minnesota payers and providers on standardized administrative processes assuming implementation of the processes will reduce administrative costs to both the providers who submit and payers who receive services electronically.

Minnesota Payers will accept all HIPAA code sets. While all HIPAA code sets will be accepted into payers' systems, claims will be adjudicated based on each payer's own coding policies, system edits, and each member's benefit package. Presence of a code on a claim does not imply any health insurance coverage or reimbursement.

Code selection for Claims Submitted in Minnesota Will Follow a Hierarchy of Preferred Instructions

Minnesota statute 62J.536 requires all claims to be submitted according to the guidelines of Medicare that are issued by the Center for Medicare and Medicaid Services (CMS) whenever possible.

In some instances, Medicare is either more restrictive than Minnesota payer's, or Medicare does not have coding submission guidelines for services that may be covered by Minnesota payers. In those instances there will be a Minnesota rule for submission of the codes.

Some of the areas under review are:

- Mental Health services
- Units of service
- Home Health
- Oxygen
- Skilled Nursing Inpatient billing
- Genetic testing/modifiers
- Modifiers in general and DHS modifiers

More detailed information will be distributed later this year. The official implementation date is July 15, 2009.

SL Modifier - State Supplied Vaccine

This modifier should be appended only to the CPT code for the vaccine and not for the E/M or the administration code. There should be no charge for the vaccine, or a minimal charge of .01 if your system does not allow 0 charges.

Bilateral Modifier Change - March 1, 2008

Effective 3/1/2008, Bilateral surgical procedures, can be submitted on the CMS 1500 using the one line method. **One** line for the CPT code appended by the **50** modifier and **one** unit of service.

Example: CPT 19318 -50 1 unit

- When the CPT code already contains the description unilateral or bilateral, do not report modifier 50, as the code is inherently considered bilateral *Page 4...*

...Cont'd from page 3

- When the CPT description already contains the word each, do not report modifier 50

Our system changes will be effective on 3/1/08. Providers who submit using the 2-line method **may not be paid appropriately**. We urge clinics to change their submission of bilateral surgery to the 1-line method beginning March 1, 2008. This will insure that you are paid appropriately and timely.

Home Health Visits Changes

PreferredOne will notify contracted Home Health Agencies of specific code changes for our April fee schedule.

As you are aware there are a variety of codes in HCPCS and CPT that have similar meaning and each payer may have had different requirements for submission. The AUC is addressing this.

Example: **RN hourly**

- S9123 is RN per hour
- T1002 RN services per 15 minutes
- G0154 Skilled nurse in the home per 15 minutes

The Minnesota Rule for this RN service will be to use T1002.

While the official date for change is July 15, 2009, PreferredOne will be making changes to the visit codes so that providers have an easier time submitting claims. The changes include adding several "T" codes that are per 15 minutes. A max of 8 units would be reported for the visit for PreferredOne. Only under unusual prior authorized circumstances would the units extend beyond 8 or (2 hours).

For infusion and subcutaneous drugs we will be requiring the J code and the number of **J code units administered**. This is the method that other payers have required for some time.

The NDC does not have to be submitted unless there is no specific J code. If there is no specific J code, use the J3490, the description of the drug, NDC code and # of doses given.

Under some circumstances DHS may require the NDC number for rebate purposes. PreferredOne will not reject the claim if the NDC number is on the claim. Adjudication will be based from the J code and J code units administered.

Updated Coding Policy

Please see updated Coding policy, (H-9) Reimbursement for Free Standing Ambulatory Surgery Centers and Hospital Outpatient Ambulatory Surgery Centers (Exhibit A).

Billing for DIAMOND (Depression Improvement Across Minnesota Offering a New Direction) Initiative

The DIAMOND Initiative is a new ICSI-driven initiative where the goal is to implement a new evidence-based best care management program for depression care that is based on a collaborative care model. Initially the scope is primary care, outpatient and adults.

We have received inquiries on billing for the DIAMOND Initiative that goes into effect March 1, 2008. PreferredOne has been notified of the selected medical groups participating and will continue to be notified as additional groups go through the training and are added. Once a patient is identified within the medical group as clinically eligible for the DIAMOND care management program they become activated when the care manager contacts the patient and the patient agrees to the program. The program is for 12 consecutive months, which is the defined length of time eligible for coverage by the care management fee. Medical groups may choose to keep a patient in the care *Page 5...*

...Cont'd from page 4

management program at their discretion after payment ceases.

To bill for this program use HCPCS code T2022, Case Management, per month. This code should be billed on the last day of every month for each patient activated and remaining active into the program during that month. Claims should be billed under the patient's primary care provider. Providers should verify eligibility with PreferredOne prior to billing. Please note that patient deductibles, co-pays, co-insurance and coverage still apply so PreferredOne strongly recommends discussing potential member liability with the patient.

PreferredOne has the right to conduct random retrospective spot checks of the medical groups using the ongoing DIAMOND clinical data. The audits will include confirming patient eligibility for the program and documentation regarding care manager communication.

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 have EDI connections with the following clearinghouses for the 835 transaction:

- McKesson
- Claimlynx
- ClearConnect (Testing)

We are currently in discussions with other clearinghouses and software vendors in order to submit 835 transactions to providers.

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

If you would like to receive the 835/EFT transaction, contact your clearinghouse, or you may contact your PreferredOne Network Management representative.

Pharmacy Update

PreferredOne currently works with two specialty pharmacies to provide specialty and injectable medications to our members who have their pharmacy benefit administered by Express-Scripts. These pharmacies include Fairview Specialty Pharmacy and CuraScript Specialty Pharmacy.

Fairview Specialty Pharmacy

An in-network provider for PreferredOne for many years now, Fairview Specialty Pharmacy provides the utmost in disease-specific medication management through its high service standards, flexibility, personalized care, and close collaboration with physicians.

Contact information:

Main phone (calls answered "live"): 612-672-5260 or 800-595-7140

Fertility phone: 612-672-1432 or 800-681-0459

Website: www.FairviewSpecialtyPharmacy.org

Fax: 612-672-5262 *Page 6...*

...Cont'd from page 5

Same-day fertility pickup locations: Go to http://www.fairview.org/Pharmacy/Specialty_Pharmacy/Infertility/index.asp

Prescription forms – customizable for each practice; contact Bill Seifert at 612-672-5141.

Current drug therapies provided:

- Allergic Asthma
- Anemia/Neutropenia
- Arthritis
- Crohn's Disease
- Cystic Fibrosis
- Fabry Disease
- Gaucher's Disease
- Growth Hormone
- Hemophilia/von Willebrand's Disorder
- Hepatitis C
- HIV/AIDS
- Hunter Syndrome
- Immune Disorders/IVIG
- Infertility
- Multiple Sclerosis
- MPS 1
- Organ Transplant
- PKU
- Pompe's Disease
- Psoriatic Arthritis
- Pulmonary Hypertension
- Rheumatoid Oncology
- RSV

Patients appreciate Fairview Specialty Pharmacy's local base, nationwide service, and personal attention with features such as monthly reminder phone calls, insurance billing assistance, and free shipping. They also benefit from a proactive, case-managed program customized for specialty disease states that accommodates their entire health care picture.

A flexible referral process makes it easy to fax and call in orders for new prescriptions, prior authorizations, and facilitation of the entire patient drug regimen. With Fairview Specialty Pharmacy's medication management added to the clinical management and support that PreferredOne network physicians provide, patients are optimally equipped to manage their health. Phone calls are answered by a real person, not automated lines, and Patient Financial Advocates[SM] are available to help patients with insurance and billing issues.

2008 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 Express-Scripts National Preferred Formulary as of January 1, 2008 (Exhibit B).

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.

Minnesota Advantage Health Plan through the State Employees Group Insurance Program (SEGIP) and the Public Employees Insurance Program (PEIP) Transitions to Navitus Health Solutions

As of January 1, 2008, the Minnesota Advantage Health Plan through the State Employees Group Insurance Program (SEGIP) and the Public Employees Insurance Program (PEIP) transitioned to a new Pharmacy Benefit Manager (PBM) for their prescription services. Any pharmacy-related requests for Minnesota Advantage Plan members should be forwarded directly to the new PBM, Navitus Health Solutions at fax number 920-735-5342. Or, you may contact Navitus Customer Care at 866-333-2757. Pharmacy requests should not be sent to PreferredOne any longer.

RxWatch: Generic Drugs in 2008

In 2008, several large selling brand products are facing potential first-time generic competition. The drugs in the table attached table (Exhibit C) have a key patent or FDA granted exclusivity that will expire in 2008. Combined, these products represent annual brand sales totaling nearly $10 billion. Attached is a summary of the potential new generics in 2008 for your reference.

Medical Policy Update

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

Two new criteria sets are available in the medical surgical department—

- MC/N006 Acupuncture (Exhibit D) was developed to provide medical necessity guidelines. Many groups do not have benefits for acupuncture, but if they do this criteria set will help determine conditions where research has supported the efficacy of acupuncture.
- MC/F020 X STOP Interspinous Process Decompression System (Exhibit E) was developed to outline conditions where the literature supports the use of the device. This criteria set was developed following Medicare guidelines.

As always, cases that do not meet the guidelines of criteria will be referred for physician review. Four criteria sets were retired—

- MC/E010 Oncotype DX Test was incorporated into Medical policy MP/G001 Genetic Testing and will now be reviewed using this policy.
- MC/F018 Extracoporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis. ESWT for any orthopedic condition other than plantar fasciitis remains on the investigational list and will not be covered. Prior authorization is no longer required for ESWT for plantar fasciitis.
- MC/L001 Positron Emission Tomography (PET) Scan. Prior authorization will no longer be required for PET scans.

Page 8...

...Cont'd from page 7

- MC/L006 Wireless Capsule Endoscopy. Wireless capsule endoscopy will remain investigational and will not be covered when used as a screening test in the general population in the absence of signs or symptoms of disease. Prior authorization will no longer be required for wireless capsule endoscopy used to evaluate symptoms.

These criteria sets were retired either because there was low utilization of the service/technology, or there was no detection of inappropriate use of the service/technology. Retired criteria and policies will remain available on the Intranet for reference but will not be updated annually. Utilization of these services/technologies will continue to be monitored to determine if there is a need for reinstating the prior authorization requirement in the future.

There was one new medical policy—

- MP/P009 Preventative Screening Tests. This policy was developed to help determine tests that are eligible for coverage at the preventative screening level (Exhibit F).

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

Effective November 27, 2007:

Additions to List—

- Breast Gamma Scans/Scintimammography for First Line Screening Exams

Deletions from the List—

- Balloon Sinuplasty (this will be considered a tool for endoscopic sinus surgery, no additional payment will be allowed for the use of this tool over the payment for the endoscopic sinus surgery)
- X-STOP (criteria is now available for this and prior authorization is required)

The Pharmacy and Therapeutics Quality Subcommittee approved one new criteria set—

- PC/I002 Immune Globulin Intravenous Therapy (IGIV) or Intravenous Immune Globulin Therapy (IVIG) (Exhibit G). Prior authorization will now be required for the administration of IGIV/IVIG in the clinic and home settings.

One pharmacy policy was retired—

- PP/D001 Drugs with Potential Adverse Effects of Interactions. These issues are already addressed automatically with warnings in the Express Scripts claims system.

One pharmacy policy was renamed—

- PP/S002 Fairview Step Therapy was renamed to PP/P002 Pharmacy Programs for ClearScripts, since this policy addresses all groups using ClearScripts as their pharmacy benefit manager, not just the Fairview group.

The latest Medical, Pharmacy and Chiropractic Policy and Criteria indexes indicating new and revised documents approved at recent meetings of the PreferredOne Quality Management subcommittees are attached. Please add the attached documents (Exhibits H, I, J, & K) to the Utilization Management section of your Office Procedures Manual and always refer to the on-line criteria/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 on line 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.

Tobacco Cessation

The Minnesota Clinic Fax Referral Program allows health care professionals in participating clinics across the state to easily refer a patient to **stop-smoking phone coaching support**, regardless of the patient's health care coverage.

The new program allows physicians to fax a single, HIPAA-compliant quitline referral form to a central triage system. The result: an outbound call to the patient from that patient's appropriate quitline service. (PreferredOne members are referred to the Free & Clear Tobacco Cessation Program; individuals without health care coverage or who are underinsured are referred to QUITPLAN® Services.) The outbound call explains the program and invites the patient to enroll. Prior to this system, health care providers were required to look up a patient's insurance in order to direct patients to the correct quitline service offered by their health plan, then identify the corresponding quitline phone number, and then give it to the patient. The process was time consuming *and* the patient still had to call to initiate the coaching.

The Minnesota Clinic Fax Referral Program is the result of a partnership between PreferredOne and ClearWay Minnesota, Medica, HealthPartners, BlueCross Blue Shield of Minnesota, UCare Minnesota and Metropolitan Health Plan. These organizations are committed to helping Minnesotans quit their tobacco habit.

To learn more about *Call it Quits* or sign up to participate in the Minnesota Clinic Fax Referral Program, call 651-662-4054 or visit www.PreventionMinnesota.com and click on the *Call It Quits* icon on the home page.

Disease Management Program Update

Effective January 1, 2008 the State of Minnesota employees covered under PreferredOne are eligible participate in the LifeMasters Disease Management Program. (LifeMasters is under contract with PreferredOne to offer disease management services for eligible PreferredOne members.) The LifeMasters program being offered to State employees will include the management of CAD, CHF, COPD, diabetes, asthma, low back pain and depression. An oncology program will be added within the next few months of 2008.

If you have State of Minnesota patients covered under PreferredOne who are eligible for the LifeMasters program, you will receive their names and conditions from LifeMasters.

PreferredOne and LifeMasters are asking all of our participating providers to help encourage participation in the LifeMasters program. Let your patients know that this program can be an additional support and help in managing their chronic condition.

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 L). Additionally, to address behavioral health conditions, we have adopted two treatment guidelines developed by Behavioral Healthcare Providers (BHP). The guidelines that PreferredOne has adopted include ICSI's clinical guidelines for Coronary Artery Disease and Asthma and BHP's clinical guidelines for Depression and ADHD. The performance of these guidelines by our network practitioners will be monitored using HEDIS measurement data, PreferredOne's disease management vendor's data, and BHP's annual evaluation.

All of the ICSI guidelines that we have adopted can be found on ICSI's website at www.ICSI.org. ICSI's Coronary Artery Disease guidelines have been revised as of April 2007.

PreferredOne®

Is Proud to Sponsor

Join us for this early spring fitness event along the Mississippi River waterfront in Minneapolis and St. Paul.

To register or volunteer go to www.getingear10k.com

Exhibit A

PreferredOne

DEPARTMENT:	Coding Reimbursement	**APPROVED DATE:** 10/01/2007	
POLICY DESCRIPTION:	Reimbursement for Free Standing Ambulatory Surgery Centers and Hospital Outpatient Ambulatory Surgery Centers		
EFFECTIVE DATE:	1/1/08		
PAGE:	1 of 3	**REPLACES POLICY DATED: 4/1/06, 11/01/04**	
REFERENCE NUMBER:	H – 9 (P-10)	**RETIRED DATE**	

SCOPE: Claims, Coding, Customer Service, Medical Management, Finance, Network Management

PURPOSE: To provide guidelines for reimbursement and information on pricing methodology for Ambulatory Surgery Centers (ASC) (hospital-based and/or free-standing).

COVERAGE: Coverage is subject to the terms of an enrollee's benefit plan. To the extent there is any inconsistency between this policy and the terms of an enrollee's benefit plan, the terms of the enrollee's benefit plan documents will always control. Enrollees in PreferredOne Community Health Plan (PCHP) and some non-ERISA group health plans that PreferredOne Administrative Services, Inc, (PAS) administers are eligible to receive all benefits mandate by the state of Minnesota. Please call customer service telephone number on the back of the enrollee's insurance card with coverage inquiries.

PROCEDURE:

1. For free-standing Ambulatory Surgery Centers, accreditation by Centers for Medicare and Medicaid (CMS) is mandatory for ambulatory surgery centers capable of providing a number of surgical procedures. They must also submit claims with their PreferredOne facility number.

2. Claims should be submitted on the UB-04 Claim form

3. The CPT codes in the surgical range 10000 – 69999 and select surgical HCPCS codes will be considered for reimbursement.

4. The appropriate Revenue Codes need to be billed with the CPT surgical range listed in # 3 above are billed together in order to price according to the ASC fee schedule. The appropriate revenue codes are 36x, 49x, 75x and 790.

5. PreferredOne's standard reimbursement methodology for ASC, which is based on the groupers as designated by Center of Medicare and Medicaid Services (CMS), will be utilized to determine payment rate. Effective January 1, 2007 there will be the following exception. The new code changes that are published in November CPT and HCPCS that are to be effective for the following year will also be added to the fee schedule using the current year CMS groupers.

6. When there is no CMS grouper assigned, the CPT/HCPCS code pricing methodology defaults according to the following categories below. A Medical and Pricing Policy committee consisting of Executive Medical Director, Coding Manager and Director Pricing will review these categories on an annual basis.

   a. Procedures that are minor and should be performed in a clinic setting as defined by CMS are not separately payable when submitted on the same date of service as a valid ASC procedure. If submitted as the only service, reimbursement will not be ASC pricing groupers 01 - 00, but will be based according to the terms of the contract for ancillary pricing (CPT fee schedule or default %).

   b. Procedures that CMS deem as required to be performed as inpatient only will be assigned to an appropriate grouper as recommended by Medical and Pricing Policy Committee.

   c. Procedures that are not assigned by CMS, but have the APC status indicator of B, E, N or M are not separately payable when submitted on the same date of service as a valid ASC procedure. If submitted as the only service, reimbursement will not be ASC pricing, but will be based according to the terms of the contract for ancillary pricing (CPT fee schedule or default %).

   d. Other procedures not meeting the criteria listed 6a-6c will be assigned to a ASC grouper by the Medical and Pricing Policy committee.

7. The Ambulatory Surgery Center list of CPT/HCPCS codes will be reviewed annually and will be updated on January 1st of each calendar year. The update includes review of changes, deletions and additions in CPT, HCPCS, grouper assignment by CMS and PreferredOne Medical and Pricing Policy Committee.

8. Any changes to the ASC list will be communicated via the PreferredOne Provider Bulletin.

9. When multiple procedures are performed on the same date of service, PreferredOne will select the procedure classified in the highest payment group for the primary procedure. This procedure will be reimbursed at 100% of PreferredOne's ASC fee schedule. Subsequent allowable procedures will be reimbursed at the following rate: 50% for the second procedure, 25% for the third procedure and $0 for any additional surgical procedures.

10. PreferredOne requires multiple procedures and bilateral procedures billed on the UB-04 claim form to be submitted on separate lines e.g. bilateral knee arthroscopy:

    a. 29870 LT on one line and 29870 RT on the second line, or 29870 on one line and 29870-50 on the second line.

11. Intraocular lenses (IOL) are included in the surgical grouper payments.

12. All other services, equipment, and supplies are considered part of the reimbursement for the surgical procedure

13. The C series of HCPCS codes with an APC status indicator of “N” are included in the surgical grouper payment and not separately payable. Centers for Medicare and Medicaid Services (CMS) defines the status indicator of “N” as items and services packaged into payment for other services.

14. Inpatient Health Services Following Scheduled Outpatient Surgical Procedure Payment for Hospital Outpatient Ambulatory Surgery Centers - Admission of an Enrollee to hospital as an inpatient within 24 hours of rendering of Scheduled Outpatient Surgical Procedure shall be reimbursed at the appropriate inpatient payment. Such payment shall be considered payment in full for all Health Services rendered to Enrollee for the entire of the Admission, including the scheduled outpatient surgical procedure. Charges for such scheduled outpatient surgical procedure shall not be separately billed by Hospital, but shall be included in the inpatient Admission charges.

15. Other coding and system edits may apply

DEFINITIONS:

REFERENCES: Contract Definition of Enrollee

EXPRESS SCRIPTS®

2008 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)
acebutolol
acetaminophen w/codeine
acetazolamide
ACTIVELLA
ACTONEL, with calcium
ACTOPLUS MET
ACTOS
ACULAR (excluding LS & PF)
acyclovir
ADVAIR DISKUS, HFA
ADVICOR
AGGRENOX
albuterol
ALLEGRA-D*
ALORA
ALPHAGAN P
ALTACE
amantadine
AMBIEN CR
aminophylline
amitriptyline
amlodipine besylate
ammonium lactate
amox tr/potassium clavulanate
amoxicillin
amphetamine salt combo
anagrelide
ANALPRAM-HC*
ANDRODERM
ANDROGEL
antipyrine w/benzocaine
apri
aranelle
ARANESP [INJ]
ARICEPT
ASACOL
ASCENSIA AUTODISC, BREEZE/2
ASCENSIA CONTOUR SYSTEM
ASCENSIA DEX2, ELITE/XL
ASCENSIA MICROFILL
ASTELIN
atenolol, -chlorthalidone
atropine sulfate
AUGMENTIN XR
AVANDAMET
AVANDARYL
AVANDIA
AVELOX
aviane
AVINZA
AXID solution only
azathioprine
azithromycin

B

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

C

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

D

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

E

econazole
EDEX [INJ]
EFFEXOR XR [SNRI]
ELIDEL
ENABLEX
enalapril, hctz
ENBREL [INJ]
enpresse
EPIPEN, JR [INJ]
errin
erythromycin
erythromycin/benzoyl perox.
estazolam
estradiol, tds
ESTRATEST, H.S.
estropipate
etidronate disodium
etodolac
EUFLEXXA [INJ]
EXELON
EXFORGE
EXUBERA

F

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

G

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

H

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

I

ibuprofen
imipramine
IMITREX*
indomethacin
INTAL inh
ipratropium bromide
ipratropium-albuterol
isosorbide mononitrate
isotretinoin
itraconazole

J

JANUMET
JANUVIA
jolessa
jolivette
junel, fe

K

kariva
kelnor
ketoconazole
KYTRIL* soln, tab

L

labetalol hcl
lactulose
LAMICTAL* (excluding disper tabs)
lamotrigine
LANTUS Vials Only [INJ]
leena
leflunomide
lessina
leucovorin
leuprolide acetate [INJ]
LEVAQUIN
LEVEMIR, FLEXPEN [INJ]
LEVITRA
levora
levothyroxine sodium
LEVOXYL
LEXAPRO
LIPITOR
lisinopril, /hctz
LOTEMAX
LOTREL*
lovastatin
LOVAZA
low-ogestrel
LUMIGAN
lutera
LYRICA

M

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
moexipril/hctz
mometasone
mononessa
morphine sulfate
MUSE

N

nabumetone
nadolol
naproxen
NASACORT AQ
NASONEX
necon
neomycin/polymyxin/dexamethasone
neomycin/polymyxin/hc
NEUPRO
NEXIUM
NIASPAN
nifedipine er
nitrofurantoin macrocrystal
nitroglycerin
nizatidine
nora-be
nortrel
NOVAREL [INJ]
NOVOFINE 30
NOVOLIN [INJ]
NOVOLOG [INJ]
NUTROPIN, AQ [INJ]
nystatin

O

ofloxacin
ogestrel
omeprazole
ondansetron
ONETOUCH II, BASIC, PROFILE
ONETOUCH FASTTAKE
ONETOUCH INDUO
ONETOUCH SURESTEP
ONETOUCH ULTRA,-2, -SMART
ONETOUCH ULTRAMINI
orphenadrine citrate
ORTHO TRI-CYCLEN LO*
oxybutynin, er
oxycodone w/acetaminophen
OXYCONTIN
OXYTROL

P

paroxetine
PATADAY
PATANOL
peg 3350/electrolyte
PEGASYS [INJ]
penicillin v potassium
PENLAC*
perphenazine
phentermine hcl
phenytoin sodium, extended
pilocarpine hcl
pindolol
PLAVIX
polymyxin b sul/trimethoprim
portia

(continued)

THIS DOCUMENT LIST IS EFFECTIVE JAN. 1, 2008 THROUGH DEC. 31, 2008. 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.

PRAMOSONE
PRANDIN
pravastatin
PRECISION SURE DOSE
PRECISION XTRA
prednisolone
prednisolone acetate
prednisone
PREMARIN
PREMPHASE
PREMPRO
PREVACID
PREVACID NAPRAPAC
previfem
PREVPAC
PROAIR HFA
prochlorperazine
PROCRIT [INJ]
promethazine
promethazine w/codeine
promethazine w/dm
PROMETRIUM
propranolol hcl, w/hctz
PROTOPIC*
PROVENTIL HFA
pseudoephedrine w/chlorpheniramine
PULMICORT

Q

quasense
quinapril
quinaretic
QVAR

R

RANEXA
ranitidine
REBIF [INJ]
reclipsen
RENAGEL
ribasphere
ribavirin
rimantadine
RISPERDAL* (excluding M-tabs)

S

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

T

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

U

ULTRASE, -MT
UNIPHYL [G]
urea
UROXATRAL
URSO, FORTE

V

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

W

warfarin
WELCHOL
WELLBUTRIN XL*

X

XALATAN
XENICAL
XOPENEX, HFA

Y

YASMIN
YAZ

Z

zenchent
ZETIA
ZOLADEX [INJ]
zolpidem tartrate
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	Nonformulary	Formulary Alternative
ACCOLATE	Singulair	INVEGA	Abilify (regular tabs), Risperdal* (non M-tabs), Seroquel/XR, Zyprexa (non-Zydis)
ACCU-CHEK	Ascensia/Glucometer, OneTouch		
ACEON	Generic Ace Inhibitor, Altace	IOPIDINE	brimonidine tartrate, Alphagan P, Cosopt*, Trusopt*
ACIPHEX	omeprazole, Nexium, Prevacid		
AEROBID, M	Flovent Diskus/HFA, Pulmicort, Qvar	ISTALOL	timolol maleate
ALAMAST	cromolyn sodium, Pataday, Patanol	LAMISIL tabs	terbinafine hcl
ALOCRIL	cromolyn sodium, Pataday, Patanol	LANTUS cartridges, solostar	Lantus vials, Levemir
ALREX	Generic steroids		
ALTOPREV	lovastatin, pravastatin, simvastatin, Crestor, Lipitor, Vytorin	LESCOL, XL	lovastatin, pravastatin, simvastatin, Crestor, Lipitor, Vytorin
AMBIEN	zolpidem tartrate	LOFIBRA	fenofibrate, Tricor
AMERGE	Imitrex*, Zomig/ZMT	LUNESTA	zolpidem tartrate, Ambien CR
ANGELIQ	Activella, Prempro/Premphase	MAXAIR AUTOHALER	albuterol, Proair HFA, Proventil HFA, Ventolin HFA, Xopenex HFA
ANTARA	fenofibrate, Tricor		
ANZEMET	ondansetron, Kytril* (soln, tabs)	MAXALT, MLT	Imitrex*, Zomig/ZMT
APIDRA	Humalog, Novolog	MENOSTAR	Generic patches, Alora, Vivelle/-Dot
ASMANEX	Flovent Diskus/HFA, Pulmicort, Qvar	METADATE CD	methylphenidate, Concerta*
ATACAND	Cozaar, Diovan	MICARDIS	Cozaar, Diovan
ATACAND HCT	Diovan HCT, Hyzaar	MICARDIS HCT	Diovan HCT, Hyzaar
AVALIDE	Diovan HCT, Hyzaar	NASAREL	fluticasone, Nasacort AQ, Nasonex
AVAPRO	Cozaar, Diovan	NEVANAC	Acular (non LS/PF), Voltarten Ophth.
AVITA	tretinoin, Differin	NORDITROPIN	Genotropin, Humatrope, Nutropin/AQ
AVODART	finasteride, Flomax, Uroxatral	NOROXIN	ciprofloxacin/er, ofloxacin, Avelox, Levaquin
AXERT	Imitrex*, Zomig/ZMT	NORVASC	amlodipine besylate
AZELEX	tretinoin, Differin, Finacea	NUVARING	Ortho Tri-Cyclen Lo*, Yasmin, Yaz
AZMACORT	Flovent Diskus/HFA, Pulmicort, Qvar	OMNICEF	cefdinir
AZOPT	brimonidine tartrate, Alphagan P, Cosopt*, Trusopt*	OMNITROPE	Genotropin, Humatrope, Nutropin/AQ
		OPTIVAR	cromolyn sodium, Pataday, Patanol
BECONASE AQ	fluticasone, Nasacort AQ, Nasonex	ORTHO EVRA	Ortho Tri-Cyclen Lo*, Yasmin, Yaz
BENICAR	Cozaar, Diovan	ORTHOVISC	supartz, Euflexxa
BENICAR HCT	Diovan HCT, Hyzaar	OVIDREL	chorionic gonadotropin, Novarel
BENZAMYCIN, PAK	erythromycin/benzoyl peroxide	PAXIL CR	paroxetine (immediate release), citalopram, fluoxetine (daily), sertraline, Lexapro
BETIMOL	betaxolol, timolol, other generics		
BIAXIN, XL	clarithromycin, er	PEG-INTRON, REDIPEN	Pegasys
BONIVA tabs	Actonel, Fosamax*	PRECISION QID, PCX	Ascensia/Glucometer, OneTouch
CARDENE SR	amlodipine, felodipine er, nifedipine er, Dynacirc CR*, Sular*	PREFEST	Activella, Prempro/Premphase
		PRILOSEC	omeprazole
CARDIZEM LA	diltiazem er	PROTONIX	omeprazole, Nexium, Prevacid
CEDAX	amox tr/potassium clavulanate, cefdinir, Augmentin XR	PROTROPIN	Genotropin, Humatrope, Nutropin/AQ
		PROZAC WEEKLY	fluoxetine (daily), citalopram, paroxetine, sertraline, Lexapro
CENESTIN	Menest, Premarin		
CIALIS	Levitra	PYLERA	Prevpac
CIPRO HC	Ciprodex*	QUIXIN	ciprofloxacin, ofloxacin, Vigamox, Zymar
COVERA-HS	verapamil er, Verelan PM*	RELENZA	Tamiflu
CYCLESSA	cesia, velivet	RELPAX	Imitrex*, Zomig/ZMT
DETROL, LA	oxybutynin/er, Enablex, Vesicare	RESTORIL	temazepam
DIPENTUM	Asacol, Colazal*, Pentasa	RETIN-A, MICRO	tretinoin, Differin
DITROPAN XL	oxybutynin cl er	RHINOCORT AQUA	fluticasone, Nasacort AQ, Nasonex
DIVIGEL	Generic patches, Alora, Vivelle/-Dot	RITALIN LA	methylphenidate, Concerta*
DYNACIRC	amlodipine, felodipine er, nifedipine er, Dynacirc CR*, Sular*	SAIZEN	Genotropin, Humatrope, Nutropin/AQ
		SANCTURA	oxybutynin/er, Enablex, Vesicare
ELESTAT	cromolyn sodium, Pataday, Patanol	SEASONIQUE	quasense, jolessa
ELESTRIN	Generic patches, Alora, Vivelle/-Dot	SKELID	Actonel, Fosamax*
ENJUVIA	Menest, Premarin	SOF-TACT	Ascensia/Glucometer, OneTouch
EPOGEN	Aranesp, Procrit	SONATA	zolpidem tartrate, Ambien CR
ESTRADERM	Generic patches, Alora, Vivelle/-Dot	SPECTRACEF	amox tr/potassium clavulanate, cefdinir, Augmentin XR
ESTRASORB	Generic patches, Alora, Vivelle/-Dot		
ESTROGEL	Generic patches, Alora, Vivelle/-Dot	SYNTHROID	levothyroxine sodium, Levoxyl
FACTIVE	ciprofloxacin/er, ofloxacin, Avelox, Levaquin	SYNVISC	supartz, Euflexxa
FAMVIR	acyclovir, Valtrex	TESTIM	Androderm, Androgel
FemHRT	Activella, Prempro/Premphase	TEVETEN	Cozaar, Diovan
FEMTRACE	Menest, Premarin	TEVETEN HCT	Diovan HCT, Hyzaar
FLOXIN OTIC	Ciprodex*	TEV-TROPIN	Genotropin, Humatrope, Nutropin/AQ
FML FORTE	Generic steroids, Lotemax	TOBRADEX	Zylet
FOCALIN, XR	dexmethylphenidate, methylphenidate, Concerta*	TRAVATAN, Z	Lumigan, Xalatan
		TRIGLIDE	fenofibrate, Tricor
FOSRENOL	Renagel	VERAMYST	fluticasone, Nasacort AQ, Nasonex
FREESTYLE	Ascensia/Glucometer, OneTouch	VEXOL	Generic steroids, Lotemax
FROVA	Imitrex*, Zomig/ZMT	VIAGRA	Levitra
GEODON	Abilify (regular tabs), Risperdal* (non M-tabs), Seroquel/XR, Zyprexa (non-Zydis)	VYVANSE	methylphenidate, Concerta*
		XIBROM	Acular (non LS/PF), Voltarten Ophth.
HELIDAC	Prevpac	ZEGERID	omeprazole, Nexium, Prevacid
HYALGAN	supartz, Euflexxa	ZIANA	tretinoin, Differin + clindamycin
INNOPRAN XL	propranolol er	ZOFRAN, ODT	ondansetron

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, 2008 THROUGH DEC. 31, 2008. 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 C

RxWatch: Generics In 2008

Updated: November 26, 2007

In 2008, several large selling brand products are facing potential first-time generic competition. The drugs in the table below have a key patent or FDA granted exclusivity that will expire in 2008 Combined, these products represent annual brand sales totaling nearly $10 Billion. This figure does not include the drugs from our "Generics Watch List" (see page 2). For more information about their potential generic availability, please see the individual summaries on the following pages.

	Drug	Manufacturer	Patent Expiration	Annual Sales (Million)
1.	Fosamax® (alendronate)	Merck	February 6	$1,427
2.	Camptosar® (irinotecan)	Pfizer	February 20	$527*
3.	Cardura® XL (doxazosin e.r.)	Pfizer	February 22	$24*
4.	Fosamax Plus D™	Merck	April 7	$136
5.	Prograf® (tacrolimus)	Astellas	April 8	$446
6.	Sarafem® (fluoxetine)	Lilly	May 20	$52*
7.	Sular® (nisoldipine)	Sciele Pharma	June 8	$89*
8.	Kytril® (granisetron)	Roche	Launched 01/03/08	$90*
9.	Risperdal® (risperidone)	Johnson & Johnson	June 29	$1,657
10.	Metrogel® (metronidazole) 1%	Galderma	June 30	$75*
11.	Lamictal® (lamotrigine)	GlaxoSmithKline	July 22	$1,327
12.	Depakote® (divalproex)	Abbott	July 29	$542
13.	Imitrex® (sumatriptan)	GlaxoSmithKline	August 6	$1,130*
14.	Xibrom™ (bromfenac)	ISTA	September 24	$20*
15.	Casodex® (bicalutamide)	AstraZeneca	October 1	$193
16.	Paxil CR (paroxetine e.r.)	GlaxoSmithKline	October 1	$327
17.	Trusopt®/Cosopt®	Merck	October 28	$697*
18.	Sonata® (zaleplon)	King	December 6	$121*
19.	Razadyne™ (galantamine)	Janssen	December 14	$130*
20.	Wellbutrin XL® (bupropion e.r.) 150mg	GlaxoSmithKline	"2008"	$828*
21.	Prilosec OTC® (omeprazole)	Proctor & Gamble	1Q2008	$750 (OTC sales)*

Sales figures from "Drug Topics Top 200 Brand Name Drugs by retail dollars in 2006" unless indicated with "*", implying sales figures from other sources, such as company press releases, BioPharm Forecast, etc.

The dates in this document reflect our current understanding of the earliest dates that one or more patents covering the indicated brand drug will expire, and therefore, the earliest date on which generic versions of the drug might become available. However, in some cases other patents covering some aspect of the formulation or use of the brand drug may exist, or other circumstances, such as litigation or citizen petitions, could arise that could extend the exclusivity period of the brand drug beyond the date indicated.

Generics Watch List

The products in this table have either near term patent expiration dates or dates that have already expired. However, for one or more reasons, generics are not yet available. The resolution of the outstanding issues is difficult to predict, so we have placed them on a "Watch List".

	Drug (alphabetical)	**Manufacturer**	**Delay**
22.	Altace® (ramipril)	King	Litigation; Generics launched
23.	Allegra-D® (fexofenadine)	sanofi-aventis	Litigation
24.	Catapres® TTS (clonidine patch)	Boehringer Ingelheim	Citizen's Petition
25.	Clarinex® (desloratadine)	Schering-Plough	Litigation
26.	Colazal (balsalazide)	Salix	Citizens Petition; generics launched.
27.	Concerta® (methylphenidate, e.r.)	Johnson & Johnson	Citizen's Petition/Litigation
28.	Depakote ER (divalproex e.r.)	Abbott	Litigation
29.	Dipentum® (olsalazine)	Celltech	Patent expired
30.	Lovenox® (enoxaparin)	sanofi-aventis	Citizen Petition/Litigation
31.	Metadate® CD (methylphenidate, CR)	Celltech	Citizen's Petition
32.	PhosLo® (calcium acetate)	Nabi	Litigation
33.	Precose® (acarbose)	Bayer	Citizen's Petition
34.	Protonix® (pantoprazole)	Wyeth	Litigation; Generics launched

Factors that may influence generic availability:

1. **Citizens Petitions** – Petitions generally submitted on behalf of a brand manufacturer requesting FDA to review, alter or create policy prior to approving the generic drug. In general, these petitions recommend additional testing prior to granting approval of a generic product (e.g. pharmacokinetic profile, bioequivalency, etc.)
2. **Litigation** – The process of determining if a patent is valid and/or infringed can be a lengthy process spanning several years following the submission of an ANDA.
3. **Patent settlements** – Manufacturers (generally brand and generic) agree to discontinue litigation in exchange for other concessions.
4. **Final FDA approval** – A generic cannot be made available until receiving final approval from FDA. The average review time for a generic drug was about 16 months in 2004.
5. **At risk launches** – Once a generic is approved by FDA, the generic company can make a business decision to launch prior to resolution of ongoing litigation.

RxWatch – Generics in 2008
(Alphabetical)

1.

Drug:	Allegra D (fexofenadine/ pseudoephedrine)	**Patent/Exclusivity Exp:**	Litigation
Manufacturer:	sanofi-aventis	**Annual Sales:**	$335 million
Comments:	Barr claims 180 days of generic exclusivity. Unlike the regular formulation of Allegra, Barr has not launch generics to Allegra D "at risk", or before the patent litigation has been resolved. The main compound patent on Allegra expired in 2001. However, sanofi-aventis is defending a compound patent that expires in 2014. A trial date has yet to be established.		

2.

Drug:	Altace (ramipril)	**Patent/Exclusivity Exp:**	July 27,2005
Manufacturer:	King	**Annual Sales:**	$717 million
Comments:	Lupin Pharmaceuticals recently invalidated a patent on Altace set to expire in October 2008. Previously, Cobalt Pharmaceuticals reached a patent settlement agreement with King that would have delayed generics until after this patent expired. UPDATE: Cobalt launched generics to the 2.5 and 5mg capsules late December 2007.		

3.

Drug:	Camptosar (irinotecan)	**Patent/Exclusivity Exp:**	February 20, 2008
Manufacturer:	Pfizer	**Annual Sales:**	$527 million
Comments:	The main compound patent on Camptosar expires in 2008, including a granted pediatric exclusivity. Currently, three manufacturers have received "tentative approval", meaning that they have met FDA's requirements for final approval.		

4.

Drug:	Cardura XL (doxazosin e.r.)	**Patent/Exclusivity Exp:**	February 22, 2008
Manufacturer:	Pfizer	**Annual Sales:**	$24 million
Comments:	The last patient in FDA's Orange Book expires on February 22, 2008. Since this drug treats benign prostatic hyperplasia (BPH), a pediatric extension is unlikely.		

5.

Drug:	Casodex (bicalutamide)	**Patent/Exclusivity Exp:**	October 01, 2008
Manufacturer:	Pfizer	**Annual Sales:**	$193 million
Comments:	The last patent in FDA's Orange Book expires on October 1, 2008. Since this product treats prostate cancer, a pediatric extension is unlikely.		

6.

Drug:	Catapres TTS (clonidine patches)	**Patent/Exclusivity Exp:**	Litigation/ Citizen's Petition
Manufacturer:	Boehringer Ingelheim	**Annual Sales:**	$174 million
Comments:	The patents on clonidine patches have expired.		

7.

Drug:	Clarinex (desloratadine)	**Patent/Exclusivity Exp:**	Litigation
Manufacturer:	Schering-Plough	**Annual Sales:**	$321 million
Comments:	One of Clarinex' patents expired in October 2007. However, additional patent on the drug could protect through 2020. Several manufacturers have submitted applications to market generic Clarinex. Litigation is ongoing.		

8.

Drug:	Concerta (methylphenidate e.r.)	**Patent/Exclusivity Exp:**	Litigation/ Citizen's Petition
Manufacturer:	Johnson & Johnson	**Annual Sales:**	$963 million
Comments:	The patent on methylphenidate has already expired. Patents on the extended release of the drug may protect through 2018. The company has also submitted a Citizen's Petition asking FDA not to approve generics until more thorough testing is conducted to ensure bioequivalence.		

9.

Drug:	Cosopt (dorzolamide/timolol)	**Patent/Exclusivity Exp:**	October 28, 2008
Manufacturer:	Merck	**Annual Sales:**	$697 million (Trusopt and Cosopt sales)
Comments:	The main drug patent on dorzolamide expires on October 28, 2008. However, additional patents on the combination of dorzolamide and timolol expire in 2011.		

10.

Drug:	Depakote (divalproex)	**Patent/Exclusivity Exp:**	July 29, 2008
Manufacturer:	Abbott	**Annual Sales:**	$542 million
Comments:	The last patent in FDA's Orange Book expires in January 2008. However, this product will likely receive an additional 6 months for a pediatric exclusivity. This would result in a patent expiration of July 29, 2008. As an FYI, Depakote ER has additional patents that may delay generic availability (see below).		

11.

Drug:	Depakote ER (divalproex e.r.)	**Patent/Exclusivity Exp:**	Litigation
Manufacturer:	Abbott	**Annual Sales:**	$502 million
Comments:	Although the main compound patent expires on July 29, 2008, additional patents on Depakote ER will likely delay generic into at least 2009. A trial date has been set for January 19, 2009. Mylan could launch "at risk" after the drug patent expires on July 29, 2008.		

12.

Drug:	Dipentum (olsalazine)	**Patent/Exclusivity Exp:**	Expired
Manufacturer:	UCB	**Annual Sales:**	<
Comments:	The main patent on Dipentum expired on January 31, 2005. No additional patents are listed in FDA's Orange Book.		

13.

Drug:	Fosamax (alendronate)	**Patent/Exclusivity Exp:**	February 6, 2008
Manufacturer:	Merck	**Annual Sales:**	$1,427 million
Comments:	The main patent on Fosamax will expire in February 2008. Barr and Teva successfully challenged the once weekly patents. As a result, both companies claim 180 days of generic exclusivity for the 35mg and 70mg tablets.		

14.

Drug:	Fosamax Plus D (alendronate/cholecalciferol)	**Patent/Exclusivity Exp:**	April 7, 2008
Manufacturer:	Merck	**Annual Sales:**	$136 million
Comments:	The main patent on Fosamax will expire in February 2008 (see above). According to a recent quarterly report form Merck, the company expects generic competition for Fosamax Plus D in April 2008, following the expiration of three years exclusivity for a new formulation. However, other sources at Merck indicated that generics are unlikely.		

15.

Drug:	Imitrex (sumatriptan)	**Patent/Exclusivity Exp:**	August 06, 2008
Manufacturer:	GlaxoSmithKline	**Annual Sales:**	$1,130 million
Comments:	Following patent litigation settlements, generics to Imitrex tablets and injection will reach the market during the fourth quarter of 2008. Spectrum announced plans to launch a generic to Imitrex injection beginning on August 6, 2008 and no later than November 6, 2008. A similar agreement was likely reached with Dr. Reddy's regarding the launch of generic Imitrex tablets.		

16.

Drug:	Kytril (granisetron)	**Patent/Exclusivity Exp:**	Launched
Manufacturer:	Roche	**Annual Sales:**	$90 million
Comments:	The main drug patent on Kytril will expire on June 29, 2008, including a pediatric exclusivity. Other patents (including use for post-op nausea and vomiting and on a multi-dose vial) will expire in 2016 and 2019, respectively. Several manufacturers have received "tentative approval" to market tablets and injectable version of the drug. UPDATE: The company did not receive pediatric exclusivity and generics launched 1/2/2008.		

17.

Drug:	Lamictal (lamotrigine)	**Patent/Exclusivity Exp:**	July 22, 2008
Manufacturer:	GlaxoSmithKline	**Annual Sales:**	$1,327 million
Comments:	Following a patent litigation settlement, Teva will launch an AB-rated generics to Lamictal tablets in 2008. The July 22, 2008 date reflects a launch 6 months prior to the expiration of the last patent in FDA's Orange Book.		

18.

Drug:	Lovenox (enoxaparin)	**Patent/Exclusivity Exp:**	Litigation/ Citizen's petition
Manufacturer:	sanofi-aventis	**Annual Sales:**	$597 million
Comments:	Two sets of manufacturers are attempting to bring generics to Lovenox to the market. In early November, one set (Momenta and Sandoz) received a "not approvable" designation for their generic to Lovenox. The other set (Teva and Amphostar) have recently announced a delay in the approval of their product. In general, FDA appears hesitant to approve generics to drugs with complex molecules. As a result, additional testing is required to secure final FDA approval.		

19.

Drug:	Metadate CD (methylphenidate e.r.)	**Patent/Exclusivity Exp:**	Citizen's Petition
Manufacturer:	UCB	**Annual Sales:**	<
Comments:	This case is similar to Concerta (see above). An extended-release formulation patent for this product expires in 2020.		

20.

Drug:	Metrogel (metronidazole 1%)	**Patent/Exclusivity Exp:**	June 30, 2008
Manufacturer:	Galderma	**Annual Sales:**	$75 million
Comments:	Three years exclusivity for the 1% formulation will expire in June 2008. However, the company recently received an additional patent (expiring February 21, 2022) which may delay generics.		

21.

Drug:	Paxil CR (paroxetine e.r.)	**Patent/Exclusivity Exp:**	October 1, 2008
Manufacturer:	GlaxoSmithKline	**Annual Sales:**	$327 million
Comments:	Following a patent litigation settlement, Mylan will launch an AB-rated generic to Paxil CR no later than October 1, 2008.		

22.

Drug:	Precose (acarbose)	**Patent/Exclusivity Exp:**	Citizen's Petition
Manufacturer:	Bayer	**Annual Sales:**	---
Comments:	Bayer recently delisted the only remaining patent in FDA's Orange Book. Generics are pending FDA's resolution of whether or not a manufacturer is entitled to 180 days of generic exclusivity.		

23.

Drug:	PhosLo (calcium acetate)	**Patent/Exclusivity Exp:**	Litigation
Manufacturer:	Fresenius Medical	**Annual Sales:**	$32 million
Comments:	The patent using calcium acetate as a phosphorus binder expired on April 07, 2007. A patent on a new capsule formulation expires April 03, 2021. Roxane Laboratories is currently challenging the later listed patent.		

24.

Drug:	Prilosec OTC (omeprazole magnesium tablets)	**Patent/Exclusivity Exp:**	1Q2008
Manufacturer:	Proctor & Gamble	**Annual Sales:**	$750 million (OTC)
Comments:	Following a patent litigation settlement, Perrigo announced plans to market generic Prilosec OTC once the company secures final FDA approval. Perrigo anticipates launching a generic during the first quarter of 2008. UPDATE: Perrigo received final FDA approval in December 2007. Launch still to occur during 1Q2008.		

25.

Drug:	Prograf (tacrolimus)	**Patent/Exclusivity Exp:**	April 8, 2008
Manufacturer:	Fujisawa	**Annual Sales:**	$446 million
Comments:	This product is not eligible for a pediatric extension. No active patents in FDA's Orange Book.		

26.

Drug:	Protonix (pantoprazole)	**Patent/Exclusivity Exp:**	Litigation
Manufacturer:	Wyeth	**Annual Sales:**	$2.3 billion
Comments:	Teva has received final approval. A trial date has not been established but is expected to talk place in late 2007. The main drug patent will expire on January 19, 2011 (including an anticipated pediatric extension). Teva will attempt to invalidate this patent. UPDATE: Teva launched limited supplies of generic "at risk" December 24, 2007. Settlement talks ongoing.		

27.

Drug:	Razadyne (galantamine)	**Patent/Exclusivity Exp:**	December 14, 2008
Manufacturer:	Janssen	**Annual Sales:**	$130 million
Comments:	This date reflects the expiration of the main drug patent. Several manufacturers are challenging the fast dissolving and controlled-release patents on Razadyne and Razadye ER, respectively.		

28.

Drug:	Risperdal (risperidone)	**Patent/Exclusivity Exp:**	June 29, 2008
Manufacturer:	Janssen	**Annual Sales:**	$1,657 million
Comments:	Several manufacturers claim 180 days of generic exclusivity. However, Teva has submitted petitions to become only company to gain generic exclusivity.		

29.

Drug:	Sarafem (fluoxetine)	**Patent/Exclusivity Exp:**	May 20, 2008
Manufacturer:	Lilly	**Annual Sales:**	$52 million
Comments:	In 2005, this "use" patent (reflected in the expiration date above) for the treatment of Premenstrual Dysphoric Disorder (PMDD) was ruled valid and infringed upon by Teva.		

30.	**Drug:**	Sonata (zaleplon)	**Patent/Exclusivity Exp:**	December 06, 2008
	Manufacturer:	King	**Annual Sales:**	$121 million
	Comments:	This date includes an anticipated pediatric extension. This is the last listed patent in FDA's Orange Book.		

30.	**Drug:**	Sular (nisoldipine)	**Patent/Exclusivity Exp:**	June 08, 2008
	Manufacturer:	Sciele Pharma	**Annual Sales:**	$89 million
	Comments:	This is the last listed patent in FDA's Orange Book. UPDATE: Company recently received approval for new formulations of Sular.		

31.	**Drug:**	Trusopt (dorzolamide)	**Patent/Exclusivity Exp:**	October 28, 2008
	Manufacturer:	Merck	**Annual Sales:**	$697 million (Trusopt and Cosopt sales)
	Comments:	The main drug patent on dorzolamide expires on October 28, 2008.		

32.	**Drug:**	Wellbutrin XL 150mg (bupropion e.r.)	**Patent/Exclusivity Exp:**	2008
	Manufacturer:	GlaxoSmithKline	**Annual Sales:**	$828 million
	Comments:	Following patent litigation settlements, generics to Wellbutrin XL 300mg are currently available on the market. However, generics to the 150mg strength have been delayed until "2008". An actual launch date is not known.		

33.	**Drug:**	Xibrom (bromfenac)	**Patent/Exclusivity Exp:**	September 24, 2008
	Manufacturer:	Ista	**Annual Sales:**	$20 million
	Comments:	A recently listed patent in FDA's Orange Book (expiring January 24, 2009) may delay generics until the expiration of this patent.		

Exhibit D

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 11/27/07
Department(s) Affected: Medical Management	**Effective Date:** 11/27/07	
Medical Policy Document: Acupuncture	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/N006	**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.

Benefits must be available for *healthcare services*. *Healthcare services* must be ordered by a physician, physician assistant, or nurse practitioner. *Healthcare services* must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

This policy applies only when the employer group has elected to provide benefits for acupuncture. Benefits for acupuncture are only available as addressed in the SPD/COC. If benefits are not specifically addressed in the SPD/COC verify with the appropriate account manager the availability of benefits.

Acupuncture that is part of a chiropractic treatment program must meet chiropractic benefits outlined in the SPD/COC.

This criteria set does not apply to acupuncture that is being provided as part of a chronic pain program.

PURPOSE:

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

DEFINITIONS:

Acupuncture:

Acupuncture describes a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques. There are a variety of approaches to diagnosis and treatment in American acupuncture that incorporate medical tradition from China, Japan, Korea, and other countries. The most studied mechanism of stimulation of acupuncture points employs penetration of the skin by thin, solid, metallic needles, which are manipulated manually or by electrical stimulation.

Healthcare service:

A medical or behavioral pharmaceutical, device, technology, treatment, supply, or procedure

Physician:

A licensed Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), Doctor of Podiatry (D.P.M.), Doctor of Optometry (O.D.), or Doctor of Chiropractic (D.C.)

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 11/27/07
Department(s) Affected: Medical Management	**Effective Date:** 11/27/07	
Medical Policy Document: Acupuncture	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/N006	**Page:** 2 of 3	

GUIDELINES:

I. An initial series of 10 (ten) treatments may be recommended if both of the following A and B are met:

A. Must have one of the following diagnosis – any of 1 - 3:

1. Chronic painful condition – any of a - c
   a. Headache
   b. Back pain (cervical, thoracic and lumbar)
   c. Neuritis/neuralgia (e.g. trigeminal, Herpes Zoster, post herpetic, nerve impingement syndromes)

2. Nausea and vomiting associated with chemotherapy, surgery or pregnancy

3. Post operative dental pain if the dental surgery was covered by medical benefits

B. Acupuncture is administered by a qualified practitioner practicing within the scope of his/her license under the direction of a *physician*

II. Continuation of acupuncture beyond 10 visits: physician review required

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date approved:** 11/27/07
Department(s) Affected: Medical Management	**Effective Date:** 11/27/07	
Medical Policy Document: Acupuncture	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/N006	**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:

1. Acupuncture. NIH Consensus Statement Online 1997 Nov 3-5; month, day]; 15(5):1-34. Available: http://odp.od.nih.gov/consensus/cons/107/107_statement.htm May 1, 2007.
2. Medicare Coverage Policy National Coverage Determinations (NCD); Coverage Issues Manual Section 35-8 Acupuncture: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=30.3&ncd_version=1&basket=ncd%3A30%2E3%3A1%3A Acupuncture Available May 1, 2007.
3. National Guideline Clearinghouse. Acupuncture and electroacupuncture: evidence-based treatment guidelines. NGC summary was completed by ECRI on August 24, 2006. http://www.guideline.gov/summary/summary.aspx?doc_id=9343&nbr=005010&string=acupuncture Available June 27, 2007.
4. Institute for Clinical Systems Improvement. Technology Assessment Abstract: Acupuncture for Chronic Osteoarthritis Pain, Headache, and Low Back Pain. TA #35 March 2000.

DOCUMENT HISTORY:

Created Date: 11/27/07
Reviewed Date:
Revised Date:

Exhibit E

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date Approved:** 11/27/07
Department(s) Affected: , Medical Management	**Effective Date:** 11/27/07	
Medical Criteria Document: X STOP Interspinous Process Decompression System (X STOP)	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F020	**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.

Benefits must be available for *healthcare services*. *Healthcare services* must be ordered by a physician, physician assistant, or nurse practitioner. *Healthcare services* must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

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:
Healthcare service:
A medical or behavioral pharmaceutical, device, technology, treatment, supply, or procedure

Foraminal Stenosis:
At every level of the spine the nerves will exit through a small canal. This canal is called the foramen or foraminal canal. Foraminal stenosis is a narrowing of this canal. Foraminal stenosis is similar to spinal stenosis but is singled out because it primarily affects one or more vertebral foramen.

Spinal Stenosis:
Spinal stenosis is a narrowing of spaces in the spine (backbone) that results in pressure on the spinal cord and/or nerve roots. This disorder usually involves the narrowing of one or more of three areas of the spine: (1) the canal in the center of the column of bones (vertebral or spinal column) through which the spinal cord and nerve roots run, (2) the canals at the base or roots of nerves branching out from the spinal cord, or (3) the openings between vertebrae (bones of the spine) through which nerves leave the spine and go to other parts of the body. The narrowing may involve a small or large area of the spine. Pressure on the lower part of the spinal cord or on nerve roots branching out from that area may give rise to pain or numbness in the legs. Pressure on the upper part of the spinal cord (that is, the neck area) may produce similar symptoms in the shoulders, or even the legs.

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date Approved:** 11/27/07
Department(s) Affected: , Medical Management	**Effective Date:** 11/27/07	
Medical Criteria Document: X STOP Interspinous Process Decompression System (X STOP)	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F020	**Page:** 2 of 3	

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

The X STOP device is used to relieve symptoms of lumbar spinal stenosis. It is not meant to be used for foraminal stenosis, or treatment of degenerative spondylolisthesis. It is made from titanium alloy and consists of two components: a spacer assembly and a wing assembly. The X STOP implant is placed between the spinous processes of the symptomatic lower (lumbar)spine. Spinous processes are the thin projections from the back of the spinal bones to which muscle and ligaments are attached. The X STOP implant is designed to limit extension of the spine in the affected area, which may relieve the symptoms of lumbar spinal stenosis.

GUIDELINES:
All of the following I - IV and none of V:

I. Patient is 50 years of age or older

II. Has neurogenic intermittent claudication (pain or cramping of legs) secondary to confirmed diagnosis of lumbar spinal stenosis

III. Has had at least six (6) months of non-operative treatment

IV. Implant is being planned at no more than two lumbar levels

V. Exclusions – none of the following:

- A. Allergy to titanium or titanium allow
- B. Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable such as:
  1. Significant instability of the lumbar spine
  2. An ankylosed segment at the affected level(s)
  3. Acute fracture of the spinous process or pars interarticularis
  4. Significant scoliosis
- C. Neural compression causing neurogenic bowel or bladder dysfunction
- D. Diagnosis of severe osteoporosis
- E. Active systemic infection or infection localized to the site of implantation

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Medical-Surgical Quality Management Subcommittee	**Date Approved:** 11/27/07
Department(s) Affected: , Medical Management	**Effective Date:** 11/27/07	
Medical Criteria Document: X STOP Interspinous Process Decompression System (X STOP)	**Replaces Effective Policy Dated:** N/A	
Reference #: MC/F020	**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:

1. Lauryssen C. Appropriate selection of patients with lumbar spinal stenosis for interspinous process decompression with the X STOP device. Neurosurg Focus. 2007 Dec 15;22(1):E5.
2. Lindsey DP, Swanson KE, Fuchs P et al. The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. Spine. 2003 Oct 1;28(19):2192-7.
3. Richards JC, Majumdar S, Lindsey DP, Beaupre GS, Yerby SA. The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. Spine. 2005 Apr 1;30(7):74409.
4. Siddiqui M, Smith FW, Wardlaw D. One-year results of X STOP interspinous implant for the treatment of lumbar spinal stenosis. Spine. 2007 May 20;32(12):1345-8.
5. Talwar V, Lindsey DP, Fredrick A, Hsu KY, Zucherman JF, Yerby SA. Insertion loads of the X STOP interspinous process distraction system designed to treat neurogenic intermittent claudication. Eur Spine J. 2006 Jun;15(6):908-12.
6. Verhoof OJ, Bron JL, Wapstra FH, van Royen BJ. High failure rate of the interspinous distraction device (X STOP) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. Eur Spine J. 2007 Sept 11.
7. Zucherman JF, Hsu KY, Hartjen CA et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication : two-year follow-up results. Spine 2005 Jun 15;30(12):1351-8.

DOCUMENT HISTORY:

Created Date: 11/27/07
Reviewed Date:
Revised Date:

Exhibit F

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Chief Medical Officer	**Date approved:** 12/10/07
Department(s) Affected: Coding, Claims, Customer Service, Medical Management	**Effective Date:** 12/10/07	
Medical Policy Document: Preventative Screening Tests	**Replaces Effective Policy Dated:** N/A	
Reference #: MP/P009	**Page:** 1 of 7	

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.

Benefits must be available for *healthcare services*. *Healthcare services* must be ordered by a physician, physician assistant, or nurse practitioner. *Healthcare services* must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

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:
The intent of this policy is to provide guidelines as to when health care services are covered at the preventative/screening level.

DEFINITIONS:
Healthcare service:
A medical or behavioral pharmaceutical, device, technology, treatment, supply, or procedure

Preventative Health Care:
Health supervision including evaluation and follow-up, immunization, detection of asymptomatic disease and *educational* services as ordered by a *provider*.

Provider:
A health care professional or facility licensed, certified or otherwise qualified under state law to provide health care services.

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:
Screening tests that are determined to be standard of care for the general population or group of the general population would be eligible for coverage at the screening/preventative benefit level if:
- The test requested is listed on this policy as being an accepted screening test; and
- The patient is asymptomatic for the condition being tested for; and

- The patient has not been actively treated in the last 12 months for the condition being screened for;
- Results of test will influence treatment of patient.

Health care services (tests may or may not be included in list of acceptable screening tests) would be paid at the diagnostic/treatment level if they are done to:

- Confirm a diagnosis due to symptoms, exposure, or injury; or
- Needed to direct treatment of a specific condition.

GUIDELINES:
Both of the following I and II, III when applicable and none of IV:

I. Covered screening tests - all the following are required A- C:

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

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

C. Test is not being ordered due to patients symptoms or personal history of a condition that has been actively evaluated or treated in the last 12 months

II. Appropriate screening tests as part of a routine physical and the patient is asymptomatic include but are not limited to (*Test with special requirements addressed below in III.):

Note: Duplication of tests will not be covered

A. Laboratory Tests:

1. General Tests
   - Blood Sugar
   - Cholesterol
   - Complete Blood Counts (CBC's)
   - Fecal Occult Blood Test
   - Hemoglobin/Hematocrit
   - Urinalysis

2. Screening Panels
   - Basic Metabolic Panel (Includes calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium and urea nitrogen)
   - Comprehensive metabolic panel (includes albumin, total bilirubin, calcium, carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, alanine amino transferase, aspirate aminotransferase)
   - General Health Panel (includes albumin, total bilirubin, calcium, carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, alanine amino transferase, aspartate amino transferase, urea nitrogen, complete blood count and differential, thyroid stimulating hormone)
   - Electrolyte Panel (includes carbon dioxide, chloride, potassium, and sodium)

- Hepatic function panel (includes albumin, total bilirubin, direct bilirubin, alkaline phosphatase, total protein, alanine amino transferase, aspartate amino transferase)
- Lipid Panel (Includes total serum cholesterol, high density cholesterol, triglycerides)
- Renal function panel (includes albumin, calcium, carbon dioxide, chloride, creatinine, glucose, phosphorus inorganic, potassium, sodium, urea nitrogen)

3. Infectious Disease Screening Tests
   - Chlamydia
   - Gonorrhea
   - HPV
   - HIV
   - Rubella
   - Syphilis
   - Tuberculosis Screening (PPD, Mantoux, TB skin test)

4. Prenatal Screening Tests
   - Chlamydia/Neisseria
   - Gestational Diabetes
   - Gonorrhea
   - Group B Streptococcus
   - Hemoglobin
   - Hepatitis B AG[25]
   - HIV
   - Maternal Serum Alpha-fetoprotein (MSAFP)
   - Nuchal Translucency Screening (ultrasound in conjunction with serum analyte tests)
   - Quad Screen
   - RH Blood Typing
   - RPR or VDRL
   - Rubella/Rubeola Titer
   - Triple Screen
   - Urine Culture

5. Pediatric Screening Tests (age 18 and under)
   - Hemoglobin/Hematocrit
   - Lead
   - HIV
   - HPV
   - Newborn Screening Panels including hearing test (see http://www.health.state.mn.us/divs/fh/mcshn/pdfdocs/nbspanel.pdf for complete list of tests)
   - Urinalysis
   - Vision Screening

6. Cancer Screening Tests
   - CA 125* (must meet ovarian cancer screening requirements outlined in section III.)
   - CEA
   - PAP Smear
   - PSA

B. Imaging Tests
- Abdominal Aortic Aneurysm Screening* (must meet AAA screening requirements outlined in section III.)
- Breast MRI* (must meet breast cancer screening requirements outlined in section III.)
- Double Contrast Barium Enema when used for screening in place of colonoscopy
- Mammography
- Nuchal Translucency Screening (ultrasound in conjunction with serum analyte testing)
- Osteoporosis Screening (DEXA scan, CT bone mineral density, X-ray absorptiometry, peripheral quantitative computed tomography)
- Vaginal Ultrasound* (must meet ovarian cancer screening requirements outlined in section III.)
- Virtual Colonoscopy* (must meet colon cancer screening requirements outlined in section III.)

C. Scopes
- Colonoscopy
- Sigmoidoscopy

D. Other Tests

- Resting EKG
- Routine Eye Screening Exams Including Refraction's and Limited Visual Field Studies
- Routine Hearing Exams

III. *Test covered when special requirements are met

A. One Time Abdominal Aortic Aneurysm (AAA) Screening (this is limited to once in a lifetime):

1. Female: both a and b
   a. Family history of AAA
   b. The test must be performed in a setting with adequate quality assurance (i.e., in an accredited facility with credentialed technologists)

2. Male: must have a - c
   a. Age 65 to 75
   b. Must be a smoker or have a history of smoking
   c. The test must be performed in a setting with adequate quality assurance (i.e., in an accredited facility with credentialed technologists)

B. Breast Cancer Screening- Breast MRI must have 1 or 2:

1. Women at high risk of developing breast cancer due to family history or personal history - any of the following:
   a. Confirmed presence of BRCA1 or BRCA2 mutation
   b. There are three or more affected first or second-degree relatives with breast cancer regardless of age at diagnosis
   c. There are fewer than three affected relatives with breast or ovarian cancer, but:
      (1) the patient was diagnosed with breast or ovarian cancer at 45 years of age or less
      (2) two first degree relatives with breast cancer, 1 of whom received the diagnosis at age 50 years or younger
      (3) a family member has been identified with a detectable BRCA mutation
      (4) there are one or more cases of ovarian cancer at any age, and one or more members on the same side of the family with breast cancer at any age
      (5) a combination of two or more first or second degree relatives with ovarian cancer regardless of age at diagnosis
      (6) there are multiple primary or bilateral breast cancers in the patient or one family member
      (7) there is breast cancer in a male patient, or in a male relative
      (8) the patient is at increased risk for specific mutation(s) due to ethnic background (for instance: Ashkenazi Jewish descent) and has one or more relatives with breast cancer or ovarian cancer at any age

2. Patients with breast characteristics limiting the sensitivity of mammography (i.e. dense breasts, implants or scarring after treatment for breast cancer)

C. Ovarian Cancer Screening (CA-125 or Transvaginal Ultrasound) for high risk patients due to family history of any of the following:

1. One or more first or second degree relatives with ovarian cancer

2. Cluster of women relatives with breast cancer

3. Nonpolyposis colorectal cancer

4. Positive BRCA1 or BRCA2 mutations

5. Personal history of breast cancer

D. Colon Cancer Screening with Virtual Colonoscopy with either of the following 1 or 2:

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

2. In anticoagulated patients who cannot safely discontinue anticoagulation therapy

E. Genetic Screening Tests Eligible for Payment at the Preventative Level – must have all of the following 1 – 4:

1. Genetic test must meet guidelines outlined in Medical Policy MP/G001 Genetic Testing
2. Benefits must be available for genetic testing
3. Patient has not been diagnosed with the disease/condition that the genetic test is designed to detect
4. Patient is asymptomatic for the disease/condition the genetic test is designed to detect

IV. The following tests are considered investigational/unproven as screening test for the screening of asymptomatic low risk patients because they have not been shown to be effective as a screening test (see investigational/unproven list):

A. Screening whole body CT scan

B. CT scans/EBCT for lung cancer screening

C. Virtual/CT Colonoscopy for routine screening for colon cancer

D. Cervicography

E. EBCT/Coronary Artery Calcium Scoring

F. Lipid Associated Sialic Acid Tumor Marker for cancer screening

G. Signal-Averaged Electrocardiography

H. Wireless Capsule Endoscopy for screening

V. Exclusions/Limitations:

A. Refer to applicable Certificate of Coverage or Summary Plan Description.

B. Services that PCHP/Plan Administrator determines are not medically necessary.

C. Those services that PCHP/Plan Administrator determines are investigative, including associated expenses.

D. Services not performed in the most cost-efficient setting appropriate for the condition based on medical standards and accepted practice parameters of the community, or provided at a frequency other than that accepted by the medical community as medically appropriate

E. Any mobile group screening service (e.g. vascular screening providers including but not limited to Life Line Screening, Stroke Prevention Plus, Stroke Detection Plus)

PreferredOne®

Department of Origin: Medical Management	**Approved by:** Chief Medical Officer	**Date approved:** 12/10/07
Department(s) Affected: Coding, Claims, Customer Service, Medical Management	**Effective Date:** 12/10/07	
Medical Policy Document: Preventative Screening Tests	**Replaces Effective Policy Dated:** N/A	
Reference #: MP/P009	**Page:** 7 of 7	

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
Medical Policy MP/I001 Investigational/Experimental Services or Unproven Comparative Effectiveness of Services
Medical Policy MP/I003 Preventative Immunization

REFERENCES:

1. U.S. Preventive Services Task Force. Screening for HIV: Recommendation Statement. March 2007. AHRQ Publication No. 07-0597-2-EF.
2. Minnesota State Statute 62A.30 and 62Q.50
3. American College of Gastroenterology. New Recommendations by the American College of Gastroenterology Call for changes in Colorectal Cancer Screening of African Americans. March 21, 2005.
4. U.S. Preventive Services Task Force. Screening for abdominal Aortic Aneurysm. 2005.
5. U.S. Preventive Services Task Force. The Guide to Clinical Preventative Services 2006. Agency for Healthcare Research and Quality.

DOCUMENT HISTORY:

Created Date: 12/10/07
Reviewed Date:
Revised Date:

Exhibit G

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/14/07
Department(s) Affected: Pharmacy	**Effective Date:** 12/03/07	
Pharmacy Criteria Document: Immune Globulin Intravenous Therapy (IGIV) or Intravenous Immune Globulin Therapy (IVIG)	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/I002	**Page:** 1 of 7	

PRODUCT APPLICATION:

☒ PreferredOne Community Health Plan (PCHP)
☒ PreferredOne Administrative Services, Inc. (PAS)
☐ PreferredOne (PPO)
☒ PreferredOne Insurance Company (PIC)[l1]

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:

The intent of the Intravenous Immune Globulin Therapy criteria set is to provide medical necessity criteria for the prior authorization process to ensure appropriate use.

BACKGROUND:

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

Immune Globulin Intravenous (IGIV) commonly known as Intravenous immunoglobulin (IVIG) is a blood product administered intravenously. It contains the pooled IgG immunoglobulins (antibodies extracted from the plasma of over a thousand blood donors). IGIV's effects last between 2 weeks and 3 months. It is FDA approved for four conditions:

- Primary (inherited) immunodeficiencies
- Acute and chronic idiopathic (immune) thrombocytopenic purpura (ITP)
- B-cell chronic lymphocytic leukemia (CLL)
- Kawasaki disease

Individual products are labeled for use in other conditions.

Table 1:
Drugs Affected*:

Generic Name	Generics available	Brand Name
immune globulin intravenous	N	Carimune NF
immune globulin intravenous	N	Flebogamma
immune globulin intravenous	N	Gammagard S/D
immune globulin intravenous	N	Iveegam EN
immune globulin intravenous	N	Polygam S/D
immune globulin intravenous	N	Octagam
immune globulin intravenous	N	Gamunex

* 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:** 11/14/07
Department(s) Affected: Pharmacy	**Effective Date:** 12/03/07	
Pharmacy Criteria Document: Immune Globulin Intravenous Therapy (IGIV) or Intravenous Immune Globulin Therapy (IVIG)	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/I002	**Page:** 2 of 7	

GUIDELINES:[12]
Medical Necessity Criteria:

I. Initiation of IGIV

A. IGIV is considered medically necessary for any of the following indications:

1. FDA Approved Indications:
   - Primary (inherited) Immunodeficiencies (e.g. common variable immunodeficiency, severe combined immunodeficiency, congenital agammaglobulinemia, X-linked agammaglobulinemia, Wiskott-Aldrich Syndrome, X-linked immunodeficiency with hyper IgM, congenital hypogammaglobulinemia)
   - Acute and chronic idiopathic (immune) thrombocytopenic purpura (ITP)
   - B-cell Chronic Lymphocytic Leukemia (CLL)
   - Kawasaki disease

2. Off Label Use for Indications where it is considered community standard or research supports efficacy:
   - Allogeneic bone marrow transplantation or hematopoietic stem cell transplantation
   - Human immunodeficiency virus (HIV) infected infants and children
   - Acquired factor VIII inhibitors (acquired hemophilia A)
   - Adult Still's disease
   - Autoimmune hemolytic anemia (AIHA)
   - Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita)
   - Autoimmune-mediated diabetic proximal neuropathy (severe diabetic polyradiculopathy and/or plexopathy)
   - Chronic inflammatory demyelinating polyneuropathy (CIDP or polyradiculoneuropathy)
   - Churg-Strauss syndrome (allergic granulomatosis and angiitis)
   - Cytomegalo Virus (CMV) interstitial pneumonia in allogeneic bone marrow transplant or stem cell transplantation patients
   - Dermatomyositis
   - End stage heart failure, renal, lung or liver disease awaiting transplant to lower allosensitization
   - Intractable pediatric epilepsy
   - Graft versus host disease
   - Graves ophthalmopathy
   - Guillain-Barre syndrome (includes Miller Fisher syndrome)
   - HIV associated thrombocytopenia, adults
   - HIV associated thrombocytopenia, infants and children
   - Hyperimmunoglobulinemia E (hyper IgE) syndrome (Jab's syndrome)
   - IgM paraproteinemic demyelinating neuropathy
   - Inclusion body myositis
   - Juvenile rheumatoid arthritis (JRA), juvenile idiopathic arthritis

- Lambert-Eaton myasthenic syndrome
- Multifocal acquired demyelinating sensory and motor neuropathy (MADSAM)
- Multifocal motor neuropathy
- Multiple myeloma
- After the first neurological event suggestive of demyelinative disease (multiple sclerosis)
- Myasthenia gravis, crisis
- Neutropenia, immune-mediated (autoimmune)
- Opsoclonus myoclonus (infantile polymyoclonia, acute cerebellar encephalopathy, oculocerebellomyoclonic syndrome, dancing eyes-dancing feet syndrome)
- Parvovirus B19 infection with chronic and severe anemia (pure red cell aplasia in patients with parvovirus B19 infection)
- Polymyositis
- Post transfusion purpura
- Pyoderma gangrenosum
- Scleromyxedema
- Selective IgG subclass deficiency
- Stiff-person syndrome (Moersch-Woltman syndrome)
- Systemic lupus erythematosus (SLE)
- Thrombocytopenia refractory to platelet transfusions
- Thrombocytopenia, fetal alloimmune
- Urticaria, chronic autoimmune
- Uveitis, noninfectious
- Vasculitic syndromes, systemic (Wegener's granulomatosis or microscopic polyangiitis)
- Von Willebrand's syndrome, acquired

B. IGIV is not covered for the following off label indications since literature is not available to support the efficacy, and use of IGIV for these indications is not considered community standard. Requests for use of IGIV would be considered investigational/unproven (see Investigational/Unproven List) for any of the following:

- Acquired red cell aplasia due to causes other than parvovirus B19
- Adrenoleukodystrophy
- Alzheimer's disease
- Anemia, aplastic
- Anemia, Diamond-Blackfan
- Asthma
- Atropic dermatitis
- Autism
- Autologous bone marrow transplantation or stem cell transplant
- Behcet's syndrome, ocular manifestations
- BK virus associated nephropathy (BKVAN) in kidney transplant patient
- Clostridium Difficile (c-dif), refractory
- Chronic fatigue syndrome
- Cystic Fibrosis
- CMV prophylaxis

- Diabetes mellitus
- Endotoxemia
- Heart block, congenital
- Hemolytic disease of the newborn
- Hemophagocytic syndrome
- Human immunodeficiency syndrome (HIV) for prophylaxis of infections in adults
- In vitro fertilization (IVF)
- Leukemia, acute lymphoblastic
- Motor neuron syndromes
- Multiple Sclerosis
- Myelopathy, HTLV I associated
- Neonates suspected or proven infection (includes preterm and low birth weight neonates)
- Neonates prophylaxis of infections in preterm and low birth weight
- Neonates, high-risk hypogammaglobulinemic
- Nephropathy, membranous
- Nephrotic syndrome
- Neuropathy, paraproteinemic
- Ophthalmopathy, euthyroid
- Otitis media, recurrent
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)
- Recurrent spontaneous pregnancy loss (RSPL)
- Renal failure, acute
- Rheumatoid arthritis
- Sickle cell anemia
- Surgery or trauma, when used as prophylaxis for infection
- Systemic sclerosis (systemic scleroderma)
- Thrombotic thrombocytopenic purpura (TTP)/hemolytic uremic syndrome (HUS)
- Thrombocytopenia, nonimmune
- Toxic necrotizing fasciitis due to group A streptococcus
- Toxic shock syndrome
- Transfusion reaction
- Treatment of CMV infections s/p solid organ transplant(e.g. heart, kidney)
- West syndrome (infantile spasms)

II. Continuation of IGIV

A. Expected duration of therapy should be documented on initiation of therapy by the requesting physician. Continued therapy reviews will be done accordingly, or at least every six months to determine continued effectiveness

B. Some type of measurable objective will be required for continued therapy. On initiation of therapy, the requesting physician must indicate what measurable objective or scale they will use to document improvement or effectiveness of treatment.

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/14/07
Department(s) Affected: Pharmacy	**Effective Date:** 12/03/07	
Pharmacy Criteria Document: Immune Globulin Intravenous Therapy (IGIV) or Intravenous Immune Globulin Therapy (IVIG)	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/I002	**Page:** 5 of 7	

C. There should be an attempt to decrease/wean the dosage of IGIV to the lowest effective dose when improvement and stabilization has occurred. If weaning is not possible documentation will be required and will be case reviewed.

D. There should be an attempt to stop the IGIV if improvement is sustained with dosage reduction. If weaning is not possible documentation will be required and will be case reviewed.

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/14/07
Department(s) Affected: Pharmacy	**Effective Date:** 12/03/07	
Pharmacy Criteria Document: Immune Globulin Intravenous Therapy (IGIV) or Intravenous Immune Globulin Therapy (IVIG)	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/I002	**Page:** 6 of 7	

RELATED CRITERIA/POLICIES:
Medical Management Process Manual MI007 Use of Medical Policy and Criteria
Medical Policy MP/I001 Investigational/Experimental Services or Unproven Comparative Effectiveness of Services
Pharmacy Policy PP/O001 Off-label Drug Use

REFERENCES:

1. Express Scripts. Prior authorization and continuation policy for exclusive clients: Immune globulin intravenous. Revised 08/09/06
2. Ahmed AR, Dahl MV. Consensus statement on the use of intravenous immunoglobulin therapy in the treatment of autoimmune mucocutaneous blistering diseases. Arch Dermatol. 2003 Aug;139(8):1051-9.
3. Anderson d, Ali K, Blanchette V et al. Guidelines on the use of intravenous immune globulin for hematologic conditions. Transfus Med Rev. 2007 Apr;21(2 Suppl 1):S9-56.
4. Baschieri L, Antonelli A, Nardi S, Alberti B, Lepri A, Canapicchi R, Fallahi P. Intravenous immunoglobulin versus corticosteroid in treatment of Graves' opthalmopathy. Thyroid. 1997 Aug;7(4):579-85.
5. Dalakas MC. The role of high-dose immune globulin intravenous in the treatment of dermatomyositis. Int Immunopharmacol. 2006 Apr;6(4):550-6.
6. Dalakas MC. The use of intravenous immunoglobulin in the treatment of autoimmune neuromuscular diseases: evidence-based indications and safety profile. Pharmacol Ther. 2004 Jun;102(3):177-93.
7. Danieli MG, Cappelli M, Malcangi G, Logullo F, Salvi A, Danieli G. Long term effectiveness of intravenous immunoglobulin in Churg-Strauss syndrome. Ann Rheum Dis. 2004 Dec;63(12):1649-54.
8. Dykes AC, Walker ID, Lowe GD, Tait RC. Combined prednisolone and intravenous immunoglobulin treatment for acquired factor VIII inhibitors: a 2-year review. Hemophilia. 2001 Mar;7(2):160-3.
9. Gold R, Stangel M, Dalakas MC. Drug Insight: the use of intravenous immunoglobulin in neurology – therapeutic considerations and practical issues. Nat Clin Pract Neurol. 2007 Jan;3(1):36-44.
10. Gray O, McDonnell GV, Forbes RB. Intravenous immunoglobulins for multiple sclerosis. Cochrane Database Syst Rev. 2003;(4):CD002936.
11. Gurcan HM, Ahmed AR. Efficacy of various intravenous immunoglobulin therapy protocols in autoimmune and chronic inflammatory disorders. Ann Pharmacother. 2007 May;41(5):812-23.
12. Harvey RD. The patient: Emerging clinical applications of intravenous immunoglobulin. Pharmacotherapy. 2005 Nov;25(11Pt 2):85S-93S.
13. Hughes RA, Wijdicks EF, Barohn R, et al. Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2003 Sep 23;61(6):736-40.
14. Jahnke L, Applebaum S, Sherman LA, Greenberger PA, Green D. An evaluation of intravenous immunoglobulin in the treatment of human immunodeficiency virus-associated thrombocytopenia. Transfusion. 1994 Sep;34(9):759-64.
15. Orange JS, Hossny EM, Weiler CR et al. Use of intravenous immunoglobulin in human disease: A review of Evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology
16. Ou CY, Hsieh KS, Chiou YH, Chang YH, Ger LP. A comparative study of initial use of intravenous immunoglobulin and prednisolone treatments in childhood idiopathic thrombocytopenic purpur. Acta Paediatr Taiwan. 2006 Sep-Oct;47(5):226-31.
17. Prins C, Gelfand EW, French LE. Intravenous immunoglobulin: properties, mode of action and practical use in dermatology. Acta Derm Venereol. 2007;87(3):206-18.
18. Quinti I, Soresina A, Spadaro G et al. Long-term follow-up and outcome of a large cohort of patients with common variable immunodeficiency. J Clin Immunol. 2007 May;27(3):308-16.

PreferredOne®

Department of Origin: Pharmacy	**Approved by:** Pharmacy and Therapeutics Quality Management Subcommittee	**Date approved:** 11/14/07
Department(s) Affected: Pharmacy	**Effective Date:** 12/03/07	
Pharmacy Criteria Document: Immune Globulin Intravenous Therapy (IGIV) or Intravenous Immune Globulin Therapy (IVIG)	**Replaces Effective Policy Dated:** N/A	
Reference #: PC/I002	**Page:** 7 of 7	

19. Ruetter A, Luger TA. Efficacy and safety of intravenous immunoglobulin for immune-mediated skin disease: current view. Am J Clin Dermatol. 2004;5(3):153-60.
20. Sokos DR, Berger M, Lazarus HM. Intravenous immunoglobulin: appropriate indications and uses in hematopoietic stem cell transplantation. Biol Blood Marrow Transplant. 2002;8(3):117-30.
21. Stella M, Clemente A, Bollero D, Risso D, Dalmasso P. Toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS): experience with high-dose intravenous immunoglobulins and topical conservative approach. A retrospective analysis. Burns. 2007 Jun;33(4):452-9.
22. Zinman L, Ng E, Bril V. IV immunoglobulin in patients with myasthenia gravis: a randomized controlled trial. Neurology. 2007 Mar 13;68(11):837-41.

DOCUMENT HISTORY:

Created Date: 11/14/07
Reviewed Date:
Revised Date: 12/03/07

Exhibit H

Medical Policy Table of Contents

Reference #	Description
C001	Court Ordered Mental Health & Substance Related Disorders Services
C002	Cosmetic Treatments *Revised*
C003	Criteria Management and Application
C008	Oncology Clinical Trials, Covered / Non-covered Services *Revised*
C009	Coverage Determination Guidelines *Revised*
D002	Diabetic Supplies
D004	Durable Medical Equipment, Supplies, Orthotics and Prosthetics *Revised*
D007	Handicap Dependent Eligibility *Revised*
D008	Dressing Supplies
E004	Nutrition Therapy
G001	Genetic Testing *Revised*
H003	Home Prothrombin Time Testing Devices
H004	Healthcares Services with Demonstrated Lack of Therapeutic Benefit
H005	Home Health Care (HHC)
I001	Investigational/Experimental Services
I002	Infertility Treatment *Revised*
I003	Preventative Immunizations *Revised*
N002	Nutritional Counseling
P008	Medical Policy Document Management and Application
P009	Preventative Screening Tests *New*
R002	Reconstructive Surgery
S008	Scar Revision
S010	Stereotactic Radiosurgery (Cyberknife, Gamma Knife, Linear Accelerator)
T002	Transition of Care for Continuity and Safety *Revised*
T004	Therapeutic Overnight Pass
T005	Transfers from an Acute Care Facility to a Lower Level of Care for Rehabilitation
W001	Physician Directed Weight Loss Programs

Revised 12/17/07

Exhibit I

Pharmacy Policy Table of Contents

Reference #	Description
C001	**Coordination of Benefits** *Revised*
C002	**Cost Benefit Program** *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**
P002	**Pharmacy Programs for ClearScript** *Revised*
Q001	**Quantity Limits per Prescription per Copayment** *Revised*
S001	**Step Therapy**

Revised 12/11/07

Exhibit J

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

M001	Disorders	**Mental Health Disorders: Inpatient Treatment**
M002	BH/Substance Related Disorders	**Electroconvulsive Treatment (ECT): Inpatient Treatment** ***Revised***
M004	BH/Substance Related Disorders	**Mental Health Disorders: Day Treatment Program** ***Revised***
M005	BH/Substance Related Disorders	**Eating Disorders-Level of Care Criteria** ***Revised***
M006	BH/Substance Related Disorders	**Mental Health Disorders: Partial Hospital Program (PHP)** ***Revised***
M007	BH/Substance Related Disorders	**Residential Treatment: Mental Health/Substance Related Disorders** ***Revised***
M008	BH/Substance Related Disorders	**Psychotherapy: Outpatient Treatment**
M009	BH/Substance Related Disorders	**Chronic Pain: Outpatient Program**
M010	BH/Substance Related Disorders	**Substance Related Disorders: Inpatient Primary Treatment** ***Revised***
M014	BH/Substance Related Disorders	**Detoxification: Inpatient Treatment** ***Revised***
M019	BH/Substance Related Disorders	**Pathological Gambling: Outpatient Treatment** ***Revised***
M020	BH/Substance Related Disorders	**Autism Spectrum Disorders Treatment** ***Revised***
M021	BH/Substance Related Disorders	**Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression and Treatment Resistant Bipolar Depression**
N001	Rehabilitation	**Acute Inpatient Rehabilitation**
N002	Rehabilitation	**Skilled Nursing Facilities** ***Revised***
N003	Rehabilitation	**Occupational and Physical Therapy: Outpatient Setting** ***Revised***
N004	Rehabilitation	**Speech Therapy: Outpatient** ***Revised***
N005	Rehabilitation	**Torticollis and Positional Plagiocephaly Treatment for Infants/Toddlers**
N006	Rehabilitation	**Acupuncture** ***New***
T001	Transplant	**Bone Marrow / Stem Cell Transplantation**
T002	Transplant	**Kidney/Pancreas Transplantation** ***Revised***
T003	Transplant	**Heart Transplantation** ***Revised***
T004	Transplant	**Liver Transplantation**
T005	Transplant	**Lung Transplantation**
T006	Transplant	**Intestinal Transplant**

Exhibit K

Pharmacy Criteria Table of Contents

Reference #	Category	Description
A001	Pharmacy	ACE Inhibitors Step Therapy
A002	Pharmacy	Oral Antifungal Treatment *Revised*
A003	Pharmacy	Combination Beta2-Agonist Inhailers
A004	Pharmacy	Antihistamines Step Therapy *Revised*
B003	Pharmacy	Botulinum Toxin
B004	Pharmacy	Drugs for Rheumatoid Arthritis
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
B008	Pharmacy	Beta-Blocker Step Therapy
C002	Pharmacy	Cyclooxygenase-2 (COX-2) Inhibitors (Celebrex)
C003	Pharmacy	Topical Corticosteroids Step Therapy *Revised*
D002	Pharmacy	Dihydropyridine Calcium Channel Blocker (DHP CCB) Step Therapy
E001	Pharmacy	Erectile Dysfunction Medications
G001	Pharmacy	Growth Hormone Therapy
H001	Pharmacy	HMG - CoA Reductase Inhibitor
I001	Pharmacy	Topical Immunomodulators
I002	Pharmacy	Immune Globulin Intravenous Therapy (IGIV) or Intravenous Immune Globulin Therapy (IVIG) *New*
L002	Pharmacy	Leukotriene Pathway Inhibitors Step Therapy
L003	Pharmacy	Lyrica Step Therapy
N002	Pharmacy	Nasal Steroids Step Therapy
O001	Pharmacy	Overactive Bladder Medication Step Therapy
P001	Pharmacy	Proton Pump Inhibitor (PPI) Step Therapy
R002	Pharmacy	RSV Prohylaxis - American Academy of Peds
S002	Pharmacy	Selective Serotonin Reuptake Inhibitors (SSRIs) Step Therapy
S003	Pharmacy	Sedative Hypnotics Step Therapy
S004	Pharmacy	Serotonin and Norepinephrine Reuptake Inhibitors (SNRI) Step Therapy for Adults (age 25 and over)
T001	Pharmacy	Tekturna Step Therapy
W001	Pharmacy	Weight Loss Medications *Revised*
X001	Pharmacy	Xolair (omalizumab) *Revised*

Revised 11/16/07

Exhibit L

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 - baseline assessment to be conducted in fall of 2007

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: 1/24/06
Reviewed Date:
Revised Date: 10/26/06