

# PreferredOne®

## UPDATE *A Newsletter for PreferredOne Providers*

JUNE 2006

### Network Management Update

#### **Secured Site Now Provides Information on Member High Deductible/Out-of-Pocket Balances**

As the number of patients who carry high-deductible health plans with Health Saving Accounts (HSAs) increase, patients are becoming more responsible for a significant portion of their bill. This leaves physicians and their administrative staffs spending more time on the collection process.

In order to assist you, PreferredOne has provided a link to PCHP and PAS member's Deductible and Out-of-Pocket Balances. By logging into the secured site, and clicking on Subscriber/Dependent Eligibility, then Deductible & Out-of-Pocket Balances, you will find information designed to provide an "estimation" of what dollar amount the patient might be responsible for before meeting the deductible.

Although this information does not reflect claims in process or claims yet to be submitted, it will help you in setting up potential financial arrangements with your patients.

If you do not yet have access to the secured site, you can register at [www.PreferredOne.com](http://www.PreferredOne.com) and click on "For Providers". You will be prompted to provide clinic information and after receipt, PreferredOne will provide you with a password for access.

Following are additional tips that can help improve your practice's collection rate from patients with high-deductible health plans.

1. Ask for insurance and payment information at the time the appointment is made.
2. Verify benefits before the visit. Some preventive services could be covered 100% by the health plan before the patient's deductible has been satisfied.
3. When the patient arrives for the appointment, verify insurance and payment information and make a copy of the insurance card. A signed informed consent statement by the patient will help in guaranteeing payment.
4. Collect past-due amounts in the office. If a patient has an outstanding balance, collect it from the patient as soon as he or she enters the office for another appointment.
5. Collect the deductible and/or coinsurance at the time of service.
6. Provide the patient with details of the service rendered and associated charges immediately after medical service. *Page 2...*

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800-451-9597  
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**CLAIM ADDRESSES:**

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PO Box 1527  
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**PreferredOne Community Health Plan (PCHP)**  
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Minneapolis, MN 55440-1512

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# Account Management

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7. File electronic claims within 24 hours.

## HPV Vaccine Now Approved

The FDA recently announced the approval of Merck's Human Papillomavirus Vaccine (HPV), Gardasil, for sale and marketing. Merck, in October 2005 announced that Gardasil in clinical trials was 100% effective in preventing infection with HPV strains 16 and 18, which together cause about 70% of cervical cancer cases.

PreferredOne is currently studying the FDA and Pediatric Society guidelines as well as working on approval of an internal policy to support those guidelines.

Once approved, PreferredOne will recommend coverage for the HPV vaccination. Pricing will be based at 90% of AWP listed on the RJ Health reimbursement schedule.

## AMS Misdirected Claims

In agreement with industry standards, AMS will soon change the way they handle misdirected claims. Misdirected claims are claims that are sent to AMS rather than PreferredOne, as directed on our member's ID cards.

Currently, when AMS receives misdirected claims from providers, they fax or mail them to PreferredOne for re-pricing.

Going forward, AMS will close out misdirected claims with instructions on the EOB that educate providers on proper claims submission.

We are hopeful that the new process will decrease turnaround issues and create more efficient claim re-pricing procedures.



## CIGNA Appeals Address

Effective April 1, 2006, Cigna created one mailing address for all appeals. Send appeals to:

CIGNA HealthCare Inc.  
National Appeals Unit  
PO Box 5225  
Scranton PA 18505-5225

## Medical Management Update

### Providing Feedback to Medical Management Department

Our Medical Management Department attempts to process all reviews in a most efficient manner. We look to you, our practitioners, to supply us with the information required to complete a review in a timely fashion. We then hold ourselves to the timeframes and processes dictated by the circumstances of the case and our regulatory bodies.

Practitioners may, at any time, request to speak with a case/peer reviewer at PreferredOne regarding the outcome of a review by calling 763-847-4488, option 2, and the Intake Department will facilitate this request. You or your staff may also make this request of the nurse reviewer with whom you have been communicating about the case and she/he will facilitate this call.

If, at any time, we do not meet your expectations and you would like to issue a formal complaint regarding the review process, criteria or any other component of the review, you may do so by calling or writing to our Customer Service Department. The phone number is 763-847-4488, option 3. The address is PreferredOne, Grievance Department, 6105 Golden Hills Dr., Golden Valley, MN 55416.

We will continue to strive for a hassle free, expeditious review process for all our practitioners and facilities.



## Medical Policy



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

New in the medical/surgical area is the criteria set MC/E009 Erectile Dysfunction Treatment (**Exhibit A**). This criteria set was developed in response to a benefit language change requiring prior authorization of erectile dysfunction drugs. The use of erectile dysfunction drugs will be covered only if they are determined to be medically necessary as outlined in the criteria set. A new medical policy MP/W001 Physician-Directed Weight-Loss Programs (**Exhibit B**) was also developed to outline weight-loss programs that are eligible for benefits.

The following medical policies were retired by the Medical/Surgical or the Behavioral Health Subcommittee:

- A001 Elective Abortion (benefits are clearly outlined in COC and SPD)
- A002 Mifepristone/RU486 (infrequent requests and benefits are outlined in COC and SPD for elective abortion)
- E005 Vacuum Therapy for Treatment of Female Sexual Dysfunction (this is listed on the investigational list)
- H001 Home Health Aide Services (this policy was combined with H005 Home Health Care)
- S007 Sensory Integration (this is listed on the investigational list)

The following items have been added to the investigational list by the Medical/Surgical or the Behavioral Health Subcommittee:

Effective March 28, 2006

- Computer-Assisted Navigation for Total Knee Arthroplasty

- Exhaled Nitric Oxide Testing for Management of Asthma
- Laser-Assisted Uvuloplasty for Sleep Apnea
- Monochromatic Infrared Therapy for Wound Healing and Diabetic Neuropathy
- Neuromuscular Stimulation for Pain Control and Muscle Disuse Atrophy
- Ortho DX Stimulation System for Pain Control
- Photodynamic Therapy with Topical 5-Aminolevulinic Acid for Dermatological Conditions (does not include actinic keratosis)
- Pressure-Specified Sensory Testing for Assessment of Nerve Function
- Quantitative Sensory Testing for Assessment of Nerve Function
- RS-4I Sequential Stimulator for Pain Control

Effective May 9, 2006

- Vagus Nerve Stimulation (VNS) for Treatment – Resistant Depression

Effective May 23, 2006

- Active Cooling Therapy (Game Ready System) for Control of Pain, Swelling, and Drainage
- Dynamic Splinting (Dynosplint) for Increasing Range of Motion (does not include use on elbow, wrist or finger)
- Oncotype DX Gene Expression for Profiling and Management of Breast Cancer
- Stand-Up MRI
- Visceral Manipulation

Services for investigational items are not eligible for coverage because there is inadequate evidence demonstrating the safety and effectiveness and/or diagnostic benefit in the published peer reviewed literature.

New in the pharmacy area are three criteria sets: B006 Biologics (Remicade) for Crohn's disease and Ulcerative Colitis, B007 Biologics (Enbrel and Remicade) for Ankylosing Spondylitis, and D001 Diabetic Adjunct Agents (Byetta and Symlin) (**Exhibits C, D & E**).

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# Medical Management

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The following item was added to the investigational list by the Pharmacy and Therapeutics Subcommittee effective May 17, 2006:

- Sildenafil for Treatment of Infertility in Women

This item is not eligible for coverage because there is inadequate evidence demonstrating the safety and effectiveness and/or diagnostic benefit in the published peer-reviewed literature.

Attached are the latest Medical, Pharmacy, and Chiropractic Policy and Criteria indexes indicating new and revised documents approved at recent meetings of the PreferredOne Medical/Surgical, Behavioral Health, and Pharmacy & Therapeutics Quality Management Subcommittees. Please add the attached documents (**Exhibits F, G, H, I & J**) to the Utilization Management section of your Office Procedures Manual and always refer to the on-line 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 Quality@PreferredOne.com.

## Institute for Clinical Systems Improvement (ICSI)

### Health Care Guidelines

- Management of Labor
- Admission for Routine Labor - order set
- Assessment and Management of Chronic Pain
- Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS)
- Diagnosis of Breast Disease
- Hypertension Diagnosis and Treatment
- Management of Initial Abnormal Pap Smear
- Management of Type 2 Diabetes Mellitus
- Prevention and Management of Obesity
- Preventive Services for Adults

- Preventive Services for Children and Adolescents
- Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS) - order set
- Chronic Obstructive Pulmonary Disease
- Diagnosis and Treatment of Headache
- Ankle Sprain
- Assessment and Management of Acute Pain
- Venous Thromboembolism
- Diagnosis and Initial Treatment of Ischemic Stroke
- Admission for Ischemic Stroke for Patients not Receiving tPA - order set
- Postoperative Total Hip, Total Knee Arthroplasty - order set
- Preoperative Total Hip and total Knee Arthroplasty - order set
- Diagnosis and Treatment of Obstructive Sleep Apnea
- ER and Inpatient Management of Asthma
- Admission for Asthma - order set

### Technology Assessment Reports

- HPV DNA Testing for the Screening and Monitoring of Cervical Cancer (Revised)
- Lumbar Artificial Intervertebral Discs
- Antiviral Treatment for Chronic Hepatitis C

### **\*Medication Safety Alert\*** **Incorrect Pediatric Dosing Information for Hydromorphone**



ICSI has discovered an error in Appendix B of its Guideline for the Assessment and Management of Acute Pain, concerning pediatric dosing of hydromorphone. The listed dosing guideline of .3-.8 mg/kg/dose was overstated by a factor of ten. Page 5...

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**The correct dosing for pediatric hydromorphone is .03-.08 mg/kg/dose.**

Acute overdosage with hydromorphone can be manifested by **respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, bradycardia, hypotension, and death.** Hydromorphone is a potent Schedule II opioid agonist. **Schedule II opioid agonists (which include hydromorphone, fentanyl, methadone, morphine, oxycodone, and oxymorphone), have the highest risk of fatal overdoses due to respiratory depression.** For more information on hydromorphone overdosage, please consult the manufacturer's prescribing information.

**IMPORTANT:** Immediately delete any downloaded copies and destroy all paper printouts of this guideline obtained from the ICSI Web site before May 19, 2006.

Please alert clinicians and staff who may have downloaded this guideline between the above dates and notify them of the availability of the corrected guideline. If your organization makes the electronic version of guidelines available through its own server, please be sure to replace the existing Acute Pain Guideline with the new version.

**NOTE:** The incorrect dosing information does not appear in the PDA or Pocket Guideline versions of the Acute Pain Guideline.

For more information, please call Cally Vinz, Director, Evidence Based Health Care, 952-814-7068.

## **Pharmacy Update**

### **Prior Authorization now Required for Erectile Dysfunction Drugs**



PreferredOne Community Health Plan (PCHP) now requires Prior Authorization (PA) on all Erectile Dysfunction drugs.

You can access the Erectile Dysfunction medical criteria on the PreferredOne website at [www.PreferredOne.com](http://www.PreferredOne.com). Go to For Providers, Pharmacy Resources – Drug

Formulary, Pharmacy Criteria. Go to the bottom of this page under Quick Links and click on Medical Criteria. There you will find the link to Erectile Dysfunction Treatment (E009).

## **Pharmacy Website Update**

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

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

- 2006 Express Scripts National Preferred Formulary (*This information applies only to those members with Express Scripts as their Pharmacy Benefit Manager*)
- Medication Request Forms
- Pharmacy Policy & Criteria
- Guide for providers interested in learning about our on-line Medication Request Form

Providers are able to request hard copies of this information by contacting the pharmacy department from the email link at the top of the pharmacy information page on the website. That address is [Pharmacy@PreferredOne.com](mailto:Pharmacy@PreferredOne.com).

## **Medication Request Forms Now Available Online**

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

Accessing the form is as easy as logging into the PreferredOne provider page at [www.PreferredOne.com](http://www.PreferredOne.com). ...Page 6



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

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

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

## **Pharmacy Management Procedure/Program Available Upon Request**

A paper copy of any pharmaceutical management procedure/program posted on the PreferredOne Provider website is available upon request by contacting the Pharmacy Department online at [Pharmacy@PreferredOne.com](mailto:Pharmacy@PreferredOne.com).

## **PreferredOne PPO Members**

PreferredOne **does not** review medication requests for PPO members. Please review the member's PreferredOne identification card to determine if your patient is a PPO member.

## **Quality Management Update**

### **Quality Management (QM) Program**

The mission of the QM Program is to identify and act on opportunities that improve the quality, safety and value of care provided to PreferredOne members both independently and/or collaboratively with contracted practitioners and community efforts, and also improve service provided to PreferredOne members and other customers.

PreferredOne Community Health Plan's physician website will be updated to offer the following program documents by July 1, 2006:

- 2006 PreferredOne QM Program Description, Executive Summary
- 2005 Year-End QM Program Evaluation, Executive Summary

Log onto the Provider site, click on the Quality Management Program link under the Information heading.

If you would like to request a paper copy of either of these documents, please call Heather Kamrath at 763-847-3562 or e-mail us at [Quality@PreferredOne.com](mailto:Quality@PreferredOne.com).

## **Clinic Contacts/Quality Improvement Collaboration**

At times, the PreferredOne Quality Management Committee structure requests that we provide information to network physicians. PreferredOne understands how busy physicians are and the magnitude of mail they receive. In order to improve this process we would like to start contacting the clinic manager or quality contact person at clinic sites instead of physicians. Please submit office contact information for your clinic/clinic system to [Quality@PreferredOne.com](mailto:Quality@PreferredOne.com).

# PreferredOne®

<b>Department of Origin:</b> Medical Management	<b>Approved by:</b> Medical-Surgical Quality Management Subcommittee	<b>Date approved:</b> 03/28/06
<b>Department(s) Effected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 03/28/06	
<b>Medical Criteria Document:</b> Erectile Dysfunction Treatment	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> MC/E009	<b>Page:</b>	1 of 4

## PRODUCT APPLICATION:

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

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

This criteria set applies to PAS enrollees only when the employer group has elected to provide benefits for the service/procedure/device. Check benefits or verify with the appropriate account manager the availability of benefits when not specifically addressed in the plan document.

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:

### Medically Necessary:

Diagnostic testing, *preventive health care* services, and medical treatment consistent with the diagnosis of a prescribed course of treatment for *enrollee's* condition, which PCHP/Plan Administrator determines (using its discretion on a case-by-case basis) are consistent with the medical standards and accepted practice parameters of the community and considered necessary for the enrollee's condition; and

1. help to restore or maintain the enrollee's health; or
2. prevent deterioration of the enrollee's condition; or
3. prevent the reasonably likely onset of a health problem or detect a problem that has no or minimal symptoms.

## BACKGROUND:

This criteria set is based on expert professional practice guidelines.

Not all plans have benefits for sexual dysfunction treatment, be sure to check plans for benefits

Vascular surgery is considered investigational when done to treat impotence (does not include traumatic arterial injuries), see [investigational list](#)

Compounded transdermal administration of Verapamil for treatment of Peyronies Disease (this does not include Verapamil injections) is considered investigational, see [investigational list](#).

## GUIDELINES:

Must have both of the following I and II

- I. Comprehensive history and physical evaluation of erectile dysfunction documenting, A or B :

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A. Organic causes – must have 1 or 2:

1. History of radical prostatectomy or radiation therapy to prostate
2. Other organic causes – must have all of the following a-c:
  - a. Documentation of any comorbid diseases and appropriate testing obtained for potential causes of impotence (e.g. diabetes mellitus, cardiovascular disease, peripheral neuropathy or bladder dysfunction, vascular indications such as intermittent claudication, symptoms of penile disease such as priapism or penile curvature, history of previous surgery)
  - b. Laboratory tests – both of the following (1) & (2):
    - (1.) Serum testosterone (if testosterone level is low testing may include luteinizing hormone, follicle stimulating hormone, and prolactin levels)
    - (2.) Thyroid function studies
  - c. Complete drug history obtained noting any drugs that may be associated with erectile dysfunction

B. Psychological factors – Formal psychological evaluation

II. Treatment of erectile dysfunction

A. Medications - one of the following 1 or 2:

1. Oral medications (Table 1) – all of the following a-c:
  - a. Documented erectile dysfunction for at least 6 months;
  - b. Documentation that erectile dysfunction is still present despite active treatment of underlying organic or psychological condition (e.g. psychotherapy, adjustment of medications);
  - c. Patient is not taking organic nitrates or alpha blockers per FDA restrictions
2. Injectable (Table 2) or intraurethral medications (Table 3)–both of the following a and b:
  - a. Documented erectile dysfunction for at least 6 months
  - b. Documentation that erectile dysfunction is still present despite active treatment of underlying organic or psychological condition (e.g. psychotherapy, adjustment of medications)

Note: coverage of medications for the treatment of erectile dysfunction is subject to the terms of the member's pharmacy benefits. Please refer to the enrollee's benefit document for specific information.

B. Implantable Devices - all of the following,

1. Documented erectile dysfunction for at least 6 months duration
2. Documented organic cause of erectile dysfunction
3. Erectile dysfunction still present despite adequate treatment of underlying organic condition (e.g. psychotherapy, adjustment of medications)



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4. Patient has not responded to, is intolerant to, or a poor candidate for oral, injectable or intraurethral medications for erectile dysfunction

C. Surgical Revascularization – all of the following:

1. Arterial blockage at base of the penis due to blunt trauma or pelvic fracture;
1. Patient is under 45 years of age;
2. Duplex scan documents blockage of arterial inflow;
3. No risk factors for atherosclerosis;
4. Patient does not have insulin dependent diabetes; and
5. Patient does not smoke

D. Excision of plaque and venous patch grafting for Peyronie’s Disease – both of the following 1&2:

1. Symptoms have progressed over a 1 year period of time; and
2. Patient has not responded to, is intolerant to, or a poor candidate for verapamil intralesional injection

Table 1, Oral Medications:

Generic Name	Generics available	Brand Name
sildenafil citrate	N	Viagra
tadalafil	N	Cialis
verdenafil hydrochloride	N	Levitra

Note: This criteria set does not cover requests for Revatio

Table 2, Injectable Medications:

Generic Name	Generics available	Brand Name
alprostadil injection	N	Edex
alprostadil injection	N	Caverject
papaverine HCL	Y	none
phenotolamine mesylate	Y	none
prostaglandin E1 (alprostadil)	Y	none

Table 3, Intraurethral Medications:

Generic Name	Generics available	Brand Name
alprostadil pellets	N	Muse

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## REFERENCES:

1. Chun SS, Fenemore J, Heaton JP, Johnston B, Morales A. Enhancement of ertile responses to vasoactive drugs by a variable amplitude oscillation device. Int J Impot Res. 1996 Dec;8(4):221-5.
2. Erdogru T, Kadioglu A, Cayan S, Tellaloglu S. Does the positive intracavernous papaverine test always indicate a normal penile vascular system? Eur Urol. 1997;31(3):323-8.
3. Harrison's Principles of Internal Medicine Thirteenth Edition. McGrall Hill . New York, NY 1994. P 262-265.
4. National Guideline Clearinghouse. The management of erectile dysfunction: an update. American Urological Association Education and Research, Inc.; 2005.  
[http://www.guideline.gov/summary/summary.aspx?doc\\_id=7261&nbr=004323&string=erectile+AND+dysfunction](http://www.guideline.gov/summary/summary.aspx?doc_id=7261&nbr=004323&string=erectile+AND+dysfunction) Accessed December 13, 2005
5. Park K, Ku JH, Kim SW, Paick JS. Risk factors in predicting a poor response to sildenafil citrate in elderly men with erectile dysfunction. BJU Int. 2005 Geb;95(3):366-70.
6. Peyronie's Disease. <http://www.urologyhealth.org/adult/index.cfm?cat=11&topic=50> Accessed December 13, 2005.
7. Sadovsky, R. Selecting patients appropriate for treatment. Supplement to The Journal of Family Practice. December 2005:5-13.
8. Surgical Management of Erectile Dysfunction.  
<http://www.urologyhealth.org/adult/index.cfm?cat=11&topic=50> Accessed December 13, 2005.

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<b>Medical Policy Document:</b> Physician Directed Weight Loss Programs	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> MP/W001	<b>Page:</b>	1 of 4

## PRODUCT APPLICATION:

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

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

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

## PURPOSE:

The intent of this policy is to provide coverage guidelines for *physician directed weight loss programs*.

## DEFINITIONS:

### Obesity:

For adults body mass index (BMI) greater than or equal to 30

In children body fatness changes over the years as they grow. Also, girls and boys differ in their body fatness as they mature. This is why BMI for children, also referred to as BMI-for-age, is gender and age specific. BMI-for-age is plotted on gender specific growth charts by the Center for Disease Control (CDC). These charts are used for children and teens 2 – 20 years of age (Attachment A and B).

### Physician directed weight loss program:

Primary physician is actively directing or providing the comprehensive medical care of the patient including but not limited to nutritional counseling, pharmacological therapy, surgical intervention, and management of comorbid conditions.

## POLICY:

Coverage for medically necessary physician directed weight loss programs will be recommended for payment. Guidelines listed below apply.

## GUIDELINES:

Must have both I and II:

- I. Documentation of obesity – one of the following A – C:
  - A. Adults (over age 20) BMI equal to or greater than 30

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- B. Adults (over age 20) BMI 27-29.9 with symptoms or findings of obesity related diseases (e.g. hypertension [BP greater than 140/90] despite medical management), dyslipidemia, osteoarthritis, coronary heart disease, type 2 diabetes, sleep apnea, or other life threatening cardiovascular diseases
  - C. Children (age 2 to 20) BMI for age greater than or equal to the 90<sup>th</sup> percentile
- III. Physician who is managing primary care of patient is directly involved in the *physician directed weight loss program* including directly managing or referring to other health care professionals for, but not limited to, any of the following:
- A. Nutritional counseling (see medical policy [MP/N002 Nutritional Counseling](#))
  - B. Weight loss medications (see pharmacy criteria [PC/W001 Weight Loss Medications](#))
  - C. Bariatric surgery (see medical criteria [MC/H003 Bariatric Surgery](#))

**EXCLUSIONS/LIMITATIONS** (not limited to):

Commercial weight loss programs.

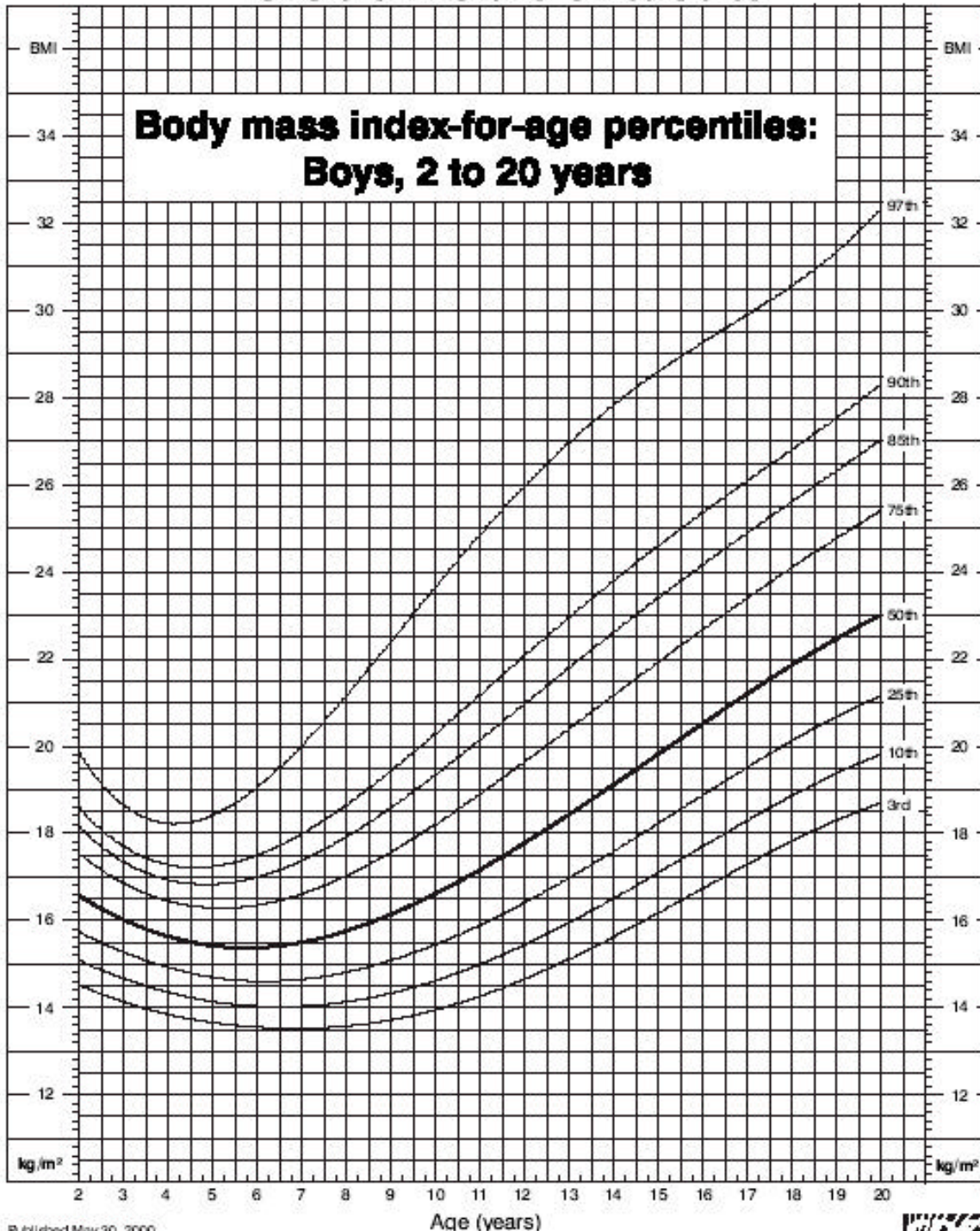
Refer to enrollee's Certificate of Coverage or Summary Plan Description.

**DOCUMENT HISTORY:**

<b>Created Date:</b> 03/06
<b>Reviewed Date:</b>
<b>Revised Date:</b>

<b>Department of Origin:</b> Medical Management	<b>Approved by:</b> Medical-Surgical Quality Management Subcommittee	<b>Date approved:</b> 03/28/06
<b>Department(s) Effected:</b> Medical Management	<b>Effective Date:</b> 03/28/06	
<b>Medical Policy Document:</b> Physician Directed Weight Loss Programs	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> MP/W001	<b>Page:</b>	3 of 4

## CDC Growth Charts: United States



Published May 30, 2000.

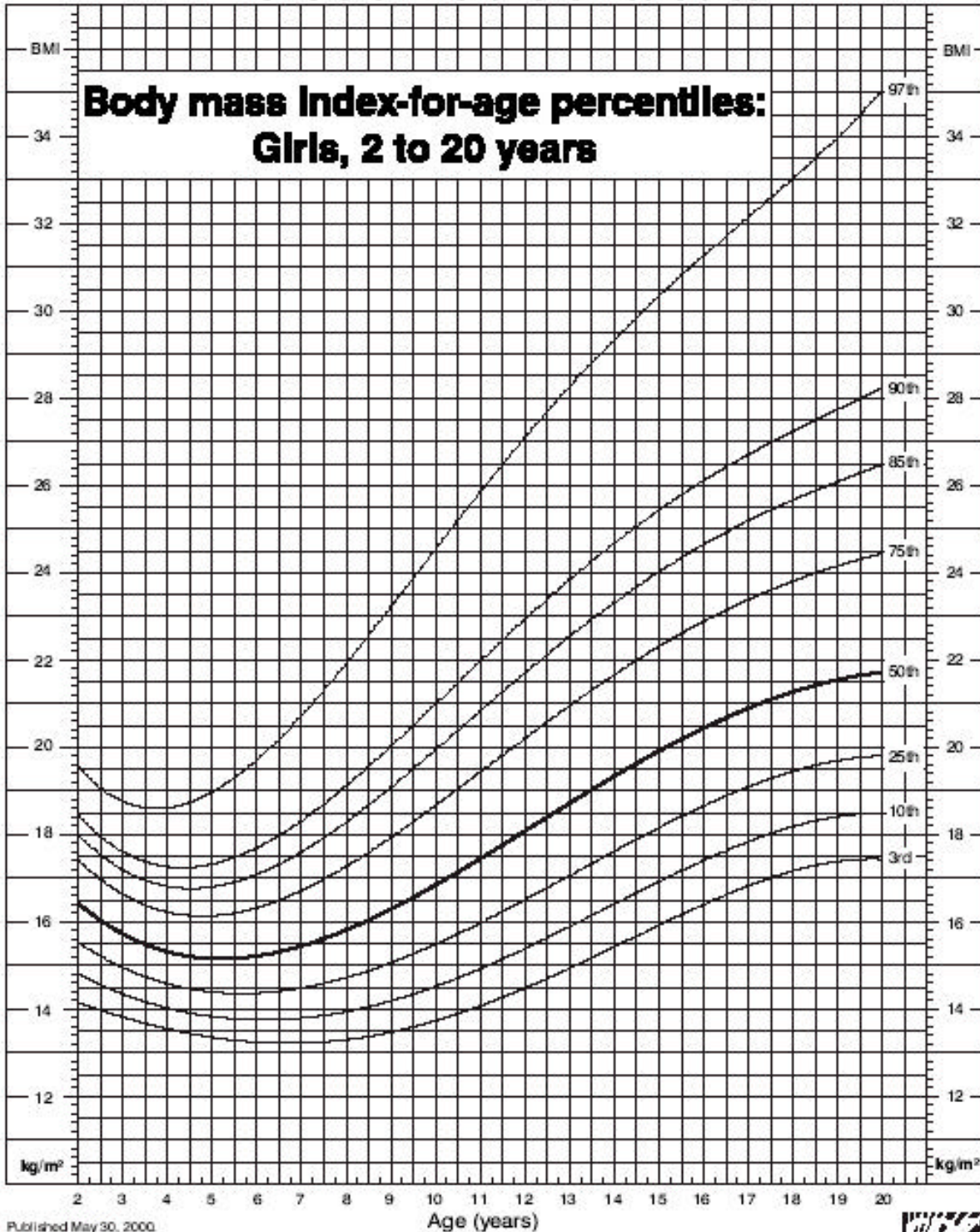
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).





<b>Department of Origin:</b> Medical Management	<b>Approved by:</b> Medical-Surgical Quality Management Subcommittee	<b>Date approved:</b> 03/28/06
<b>Department(s) Effected:</b> Medical Management	<b>Effective Date:</b> 03/28/06	
<b>Medical Policy Document:</b> Physician Directed Weight Loss Programs	<b>Replaces Effective Policy Dated:</b> N/A	
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## CDC Growth Charts: United States



Published May 30, 2000.

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).



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<b>Department of Origin:</b> Pharmacy	<b>Approved by:</b> Pharmacy and Therapeutics Quality Management Subcommittee	<b>Date approved:</b> 05/17/06
<b>Department(s) Affected:</b> Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Biologics (Remicade) for Crohn's Disease and Ulcerative Colitis	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> PC/B006	<b>Page:</b>	1 of 3

## PRODUCT APPLICATION:

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

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

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

## PURPOSE:

The intent of this criteria set is to require a trial of a first line therapy before a second line therapy.

## DEFINITIONS:

### Step Therapy:

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

## BACKGROUND:

### Drugs Affected:

Generic Name	Generics available	Brand Name
infliximab	N	Remicade

Infliximab should be used during pregnancy only if clearly needed.

## GUIDELINES:

### Step Therapy Requirements for:

- I. Crohn's disease – one of the following A or B:
  - A. Ordered by a board certified gastroenterologist
  - B. Not ordered by a board certified gastroenterologist – must have 1 & 2:
    1. Symptomatic disease (e.g. fever, abdominal distention, pain, diarrhea, bleeding, weight loss, intestinal fistula, intestinal obstruction)

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<b>Pharmacy Criteria Document:</b> Biologics (Remicade) for Crohn's Disease and Ulcerative Colitis	<b>Replaces Effective Policy Dated:</b> N/A	
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2. The patient has not responded to, or responds to but can not taper off corticosteroids without recurrent symptoms, is intolerant to, or a poor candidate for corticosteroids (Table 1), 6-mercaptopurine (6MP), or azathioprine (Imuran).

II. Ulcerative Colitis – one of the following A or B:

- A. Ordered by a board certified gastroenterologist
- B. Not ordered by a board certified gastroenterologist – must have all of the following 1 - 3:
  1. Moderate to severely active ulcerative colitis
  2. The patient has not responded to, is intolerant to, or a poor candidate for one aminosalicylate (Table 2):
  3. The patient has not responded to, is intolerant to, responds to but can not taper off drug without recurrent symptoms, or is a poor candidate for one oral or intravenous therapy for ulcerative colitis [e.g. a corticosteroid (Table 1), 6-mercaptopurine (6MP), or azathioprine (Imuran), cyclosporine].

Table 1: Corticosteroids

Generic Name	Generics Available	Brand Name
hydrocortisone acetate (25mg suppositories)	N	Anusol
hydrocortisone (susp, tabs)	N	Cortef
hydrocortisone acetate (10% aerosol foam)	N	Cortifoam
dexamethasone (inj, soln, tabs)	Y	Decadron
prednisone (soln, tbs)	Y	Deltasone
budesonide (oral capsules)	N	Entocort
methylprednisolone	Y	Medrol/Medrol does pack
prednisolone (soln)	N	Orapred/Prelone/Pediapred
hydrocortisone acetate (30mg suppositories)	N	Protocort

Table 2: Aminosalicylates

Generic Name	Generics Available	Brand Name
mesalamine	N	Asacol, Pentasa, Rowasa
sulfasalazine	Y	Azulfidine, Sulfazine
olsalazine	N	Dipentum
balsalazide	N	Colazal

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<b>Reference #:</b> PC/B006	<b>Page:</b>	3 of 3

## REFERENCES:

1. Cross RD, Wilson KT, Binion DG. Polypharmacy and Crohn's disease. Aliment Pharmacol Ther. 2005 May 15;21(10):1211-6.
2. Express Scripts Prior Authorization Policy: infliximab recombinant for IV injection (Remicade® – Centocor, Inc) Date Revised: 10/05/2005 to revise ankylosing spondylitis.
3. Rutgeerts MD, Sandborn WJ, Feagan BG et al. Infliximab for induction and maintenance therapy for ulcerative colitis. N Engl J Med. 2005 Dec 8;353:2462-76.
4. Yoshida EM. The Crohn's Disease Activity Index, its derivatives and the Inflammatory Bowel Disease Questionnaire: a review of instruments to assess Crohn's disease.

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<b>Department(s) Affected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Biologics (Enbrel & Remicade) for Ankylosing Spondylitis	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> PC/B007	<b>Page:</b>	1 of 6

## PRODUCT APPLICATION:

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

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

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

## PURPOSE:

The intent of this criteria set is to require the use of generic and branded NSAID's for peripheral Ankylosing Spondylitis before the use of a biologic agent, and the use of Enbrel before Remicade.

## DEFINITIONS:

### Ankylosing Spondylitis (AS):

AS is a chronic inflammatory progressive form of spinal arthritis but it can also effect peripheral joints, eye, and rarely other organs.

### BASDAI Score:

The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) is a tool to assess disease severity in Ankylosing Spondylitis. The tool is composed of six questions, which relate to measures of disease activity (Attachment A).

### BASFI Score:

Bath Ankylosing Spondylitis functional index measures physical function through ten questions about daily functions, a visual analogue to measure pain and a patient and physician global assessment (Attachment B).

### NSAIDs:

Non Steroidal Anti-Inflammatory Drugs (NSAIDs) are medications which, as well as having pain-relieving (analgesic) effects, have the effect of reducing inflammation when used over a period of time.

### DMARDs:

Disease Modifying Antirheumatic Drugs (DMARDs).

### Step Therapy:

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

<b>Department of Origin:</b> Pharmacy	<b>Approved by:</b> Pharmacy and Therapeutics Quality Management Subcommittee	<b>Date approved:</b> 05/17/06
<b>Department(s) Affected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Biologics (Enbrel & Remicade) for Ankylosing Spondylitis	<b>Replaces Effective Policy Dated:</b> N/A	
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**BACKGROUND:**

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

Drugs Affected:

Generic Name	Generics Available	Brand Name
etanercept	N	Enbrel
infliximab	N	Remicade

**GUIDELINES:**

Medical Necessity Criteria and Step Therapy Requirements:

One of the following:

- I. Requests for Enbrel – one of the following A or B:
  - A. Ordered by a board certified rheumatologist
  - B. Not ordered by a board certified rheumatologist – must have 1 and 2:
    - 1. Documentation of active disease demonstrated by BASDAI score greater than or equal to 4 on two visits over a two- month period
    - 2. Axial skeletal disease: The patient has not responded to, is intolerant to, or a poor candidate for at least 2 different generic NSAIDs (Table 1) and one Branded NSAID (Table 2)

Note: If the patient has only peripheral symptoms of disease refer to criteria set B004 Biologics for Arthritic Conditions B004 Biologics for Arthritic Conditions.

- II. Requests for Remicade – one of the following A or B:
  - A. Ordered by a board certified rheumatologist
  - B. Not ordered by a board certified rheumatologist – must have 1 and 2:
    - 1. Documentation of active disease demonstrated by BASDAI score greater than or equal to 4 on two visits over a two- month period:
    - 2. Axial skeletal disease – the patient has not responded to, is intolerant to, or a poor candidate for both of the following:
      - a. At least 2 different generic NSAIDs (Table 1) and one Branded NSAID (Table 2)
      - b. Enbrel

<b>Department of Origin:</b> Pharmacy	<b>Approved by:</b> Pharmacy and Therapeutics Quality Management Subcommittee	<b>Date approved:</b> 05/17/06
<b>Department(s) Affected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Biologics (Enbrel & Remicade) for Ankylosing Spondylitis	<b>Replaces Effective Policy Dated:</b> N/A	
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Note: If the patient has only peripheral symptoms of disease refer to criteria set B004 Biologics for Arthritic Conditions B004 Biologics for Arthritic Conditions.

III. Continued use of Enbrel or Remicade – assessment made after 6-12 weeks on medication with both of the following – both of the following A and B:

- A. Improvement documented by a decrease of at least 50% or 2 units (on a 1-10 scale) of the BASDI<sup>1</sup>
- B. Documentation from the physician that treatment should be continued<sup>1</sup>

Table 1: Generic NSAIDs

Generic Name	Generics Available	Brand Name	Drug Class
diclofenac potassium	Y	Cataflam®	acetic acids
indomethacin	Y	Indocin®, Indocin SR	acetic acids
sulindac	Y	Clinoril®	acetic acids
tolmetin	Y	Tolectin®	acetic acids
diclofenac sodium	Y	Voltaren® ,	acetic acids
meclofenamate	Y	Meclomen®	fenamates
nabumetone	Y	Relafen®	naphthylalkanomes
piroxicam	Y	Feldene®	oxicams
naproxen sodium	Y	Anaprox®, Anaprox	propionic acids
flurbiprofen	Y	Ansaid®	propionic acids
oxaprozin	Y	Daypro®	propionic acids
ibuprofen	Y	Motrin®, Advil	propionic acids
EC naproxen	Y	Naprelan®	propionic acids
naproxen	Y	Naprosyn®	propionic acids
ketoprofen	Y	Orudis®, Orudis KT	propionic acids
ketoprofen SR	Y	Oruvail®	propionic acids
fenoprofen	Y	Nalfon®	propionic acids
etodolac	Y	Lodine®, LodineXL®	pyranocarboxylic acids
ketorolac	Y	Toradol®	pyrrolizine carboxylic

Adopted from Express Scripts Coverage Rule Criteria: Cyclooxygenase-2 (COX-2) Inhibitor Step Therapy Program 2002

Table 2: Brand Name NSAIDs

Generic Name	Generics Available	Brand Name
diclofenac sodium/misoprostol	N	Arthrotec®
meloxicam	N	Mobic®
mefenamic acid	N	Ponstel®

Adopted from Express Scripts Coverage Rule Criteria: Branded Nonsteroidal Anti- Inflammatory Drug (NSAID) Step Therapy Program October 30, 2002



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<b>Department(s) Affected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Biologics (Enbrel & Remicade) for Ankylosing Spondylitis	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> PC/B007	<b>Page:</b>	4 of 6

## REFERENCES:

1. Braun J, Pham T, Sieper J, et al. International ASAS consensus statement for the use of anti-tumour necrosis factor agents in patients with ankylosing spondylitis. <http://www.annrheumdis.com> Accessed Dec. 13, 2005.
2. Express Scripts Prior Authorization Policy: infliximab recombinant for IV injection (Remicade® – Centocor, Inc) Date Revised: 10/05/2005 to revise ankylosing spondylitis
3. Express Scripts Prior Authorization or Step Therapy Policy Subject: Etanercept (Enbrel® – Immunex) Date Revised: 11/24/2004
4. Van der Heijde D, Dijkmans B, Geusens P, Sieper J, DeWoody K, Williamson P, Braun J; Ankylosing Spondylitis Study for the Evaluation of Recombinant Infliximab Therapy Study Group. Efficacy and safety of infliximab in patients with ankylosing spondylitis: results of a randomized, placebo-controlled trial (ASSERT). Arthritis Rheum. 2005 Feb;52(2):582-91. Abstract available April 14, 2005 @:  
[http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=15692973&query\\_hl=1](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15692973&query_hl=1).

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<b>Pharmacy Criteria Document:</b> Biologics (Enbrel & Remicade) for Ankylosing Spondylitis	<b>Replaces Effective Policy Dated:</b> N/A	
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Attachment A

## Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

PLEASE PLACE A MARK ON EACH LINE BELOW TO INDICATE YOUR ANSWER TO EACH QUESTION, RELATING TO THE PAST WEEK.

(1) How would you describe the overall level of fatigue/tiredness you have experienced?

NONE \_\_\_\_\_ VERY SEVERE

(2) How would you describe the overall level of AS neck, back or hip pain you have had?

NONE \_\_\_\_\_ VERY SEVERE

(3) How would you describe the overall level of pain/swelling in joints other than neck, back or hips you have had?

NONE \_\_\_\_\_ VERY SEVERE

(4) How would you describe the overall level of discomfort you have had from any areas tender to touch or pressure?

NONE \_\_\_\_\_ VERY SEVERE

(5) How would you describe the overall level of morning stiffness you have had from the time you wake up?

NONE \_\_\_\_\_ VERY SEVERE

(6) How long does your morning stiffness last from the time you wake up?

0      1/2      1      1 1/2      2 or more hours

Garrett S, Jenkinson T, Kennedy LG, et al. A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. *J Rheumatol.* 1994;21:2286-2291.

<b>Department of Origin:</b> Pharmacy	<b>Approved by:</b> Pharmacy and Therapeutics Quality Management Subcommittee	<b>Date approved:</b> 05/17/06
<b>Department(s) Affected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Biologics (Enbrel & Remicade) for Ankylosing Spondylitis	<b>Replaces Effective Policy Dated:</b> N/A	
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Attachment B

## Bath Ankylosing Spondylitis Functional Index (BASFI)

PLEASE DRAW A MARK ON EACH LINE BELOW TO INDICATE YOUR LEVEL OF ABILITY WITH EACH OF THE FOLLOWING ACTIVITIES DURING THE LAST WEEK:

EXAMPLE:

EASY \_\_\_\_\_ IMPOSSIBLE

(1) Putting on your socks or tights without help or aids (e.g. sock aid)

EASY \_\_\_\_\_ IMPOSSIBLE

(2) Bending forward from the waist to pick up a pen from the floor without an aid

EASY \_\_\_\_\_ IMPOSSIBLE

(3) Reaching up to a high shelf without help or aids (e.g. helping hand)

EASY \_\_\_\_\_ IMPOSSIBLE

(4) Getting up out of an armless dining room chair without using your hands or any other help

EASY \_\_\_\_\_ IMPOSSIBLE

(5) Getting up off the floor without help from lying on your back

EASY \_\_\_\_\_ IMPOSSIBLE

(6) Standing unsupported for 10 minutes without discomfort

EASY \_\_\_\_\_ IMPOSSIBLE

(7) Climbing 12 – 15 steps without using a handrail or walking aid  
**One foot on each step**

EASY \_\_\_\_\_ IMPOSSIBLE

(8) Looking over your shoulder without turning your body

EASY \_\_\_\_\_ IMPOSSIBLE

(9) Doing physically demanding activities (e.g. physiotherapy exercises, gardening or sports)

EASY \_\_\_\_\_ IMPOSSIBLE

(10) Doing a full day's activities whether it be at home or at work

EASY \_\_\_\_\_ IMPOSSIBLE

Calin A, Garrett S, Whitelock H, et al. A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index. *J Rheumatol.* 1994;21:2281-2285.

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<b>Department of Origin:</b> Pharmacy	<b>Approved by:</b> Pharmacy and Therapeutics Quality Management Subcommittee	<b>Date approved:</b> 05/17/06
<b>Department(s) Affected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Diabetic Adjunct Agents (Byetta and Symlin)	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> PC/D001	<b>Page:</b> 1 of 3	

## PRODUCT APPLICATION:

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

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

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

## PURPOSE:

The intent of this criteria set is to ensure appropriate use of the diabetic adjunct agents of Byetta (exenatide) or Symlin.

## BACKGROUND:

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

Byetta/Symlin is indicated as adjunctive therapy in patients with diabetes mellitus (DM) who are unable to achieve adequate glycemic control despite taking appropriate medication.

Exenatide injection (Byetta<sup>®</sup>), the first incretin mimetic agent, and pramlintide acetate SC injection (Symlin<sup>®</sup>), an amylinomimetic agent, are the two newest hormone agents approved for the management of DM.

## Drugs Affected

Generic Name	Generics available	Brand Name
exenatide	N	Byetta
pramlintide	N	Symlin

## GUIDELINES:

### Medical Necessity and Step Therapy Criteria Requirements:

One of the following I or II:

- I. Requests for the use of Byetta – one of the following A or B:
  - A. Ordered by a board certified endocrinologist
  - B. Not ordered by a board certified endocrinologist – must have 1 and 2:
    1. Must have type II diabetes with documented inadequate glycemic control despite trial of a Biguanides (Table 1), a sulfonylureas (Table 2), and both in combination

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<b>Department(s) Affected:</b> Medical Management and Pharmacy	<b>Effective Date:</b> 05/17/06	
<b>Pharmacy Criteria Document:</b> Diabetic Adjunct Agents (Byetta and Symlin)	<b>Replaces Effective Policy Dated:</b> N/A	
<b>Reference #:</b> PC/D001	<b>Page:</b> 2 of 3	

2. Must be on a biguanide (Table 1), a sulfonylurea (Table 2) or both

Note: This product is not indicated for weight loss and would not be approved for that diagnosis

II. Requests for the use of Symlin - one of the following A or B:

- A. Ordered by a board certified endocrinologist
- B. Not ordered by a board certified endocrinologist – must have 1 and 2:
  1. Must have type I or II diabetes with documented inadequate glycemic control
  2. Must be on insulin therapy

Table 1: Biguanides

Generic Name	Generics available	Brand Name
metformin	Y	Glucophage
metformin ext-rel	N	Glucophage XR
metformin ext-rel	N	Fortamet

Table 2: Sulfonylureas

Generic Name	Generics available	Brand Name
glimepiride	N	Amaryl
glyburide	Y	Diabeta
glyburide	Y	Micronase
glyburide	Y	Glynase
glipizide	Y	Glucotrol
glipizide ext-rel	N	Glucotrol XL

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<b>Pharmacy Criteria Document:</b> Diabetic Adjunct Agents (Byetta and Symlin)	<b>Replaces Effective Policy Dated:</b> N/A	
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## REFERENCES:

1. Express Scripts, Place in Therapy: Subject exenatide injection (Byetta™ - Amylin), June 1, 2005.
2. D'Alessio DA, Vahl TP. Utilizing the GLP-1 signaling system to treat diabetes: sorting through the pharmacologic approaches. Current Diabetes Reports 2005, 5:346-352.
3. Deacon CF. Therapeutic strategies based on glucagon-like peptide 1. Diabetes. 2004 Sep;53(9):2181-9.
4. Institute for Clinical Systems Improvement. Health care guidelines, Management of Diabetes Mellitus, Type 2; released 11/2004. <http://www.icsi.org/index.asp> Accessed May 23, 2006.
5. Kendall DM, Riddle MC, Rosenstock J, Zhuang D, Kim DD, Fineman MS, Baron AD. Effects of exenatide (exendin-4) on glycemic control over 30 weeks in patients with type 2 diabetes treated with metformin and a sulfonylurea. Diabetes Care. 2005 May;28(5):1083-91.

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D002	Diabetic Supplies <i>Revised</i>
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H005	Home Health Care <i>Revised</i>
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N002	Nutritional Counseling <i>Revised</i>
P004	Private Room <i>Revised</i>
P007	Preparatory/Preoperative Blood Donation <i>Revised</i>
R002	Reconstructive Surgery <i>Revised</i>
S006	Screening Tests
S008	Scar Revision <i>Revised</i>
T002	Transition of Care for Continuity and Safety <i>Revised</i>
T004	Therapeutic Overnight Pass <i>Revised</i>
T005	Transfers to a Lower Level of Care for Rehabilitation from an Acute Care Facility <i>Revised</i>
W001	Physician Directed Weight Loss Programs <i>New</i>

*Revised 05/23/06*

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

Reference #	Category	Description
A006	Cardiac/Thoracic	Ventricular Assist Devices (VAD)
A007	Cardiac/Thoracic	Lung Volume Reduction <i>Revised</i>
B002	Dental and Oral Maxillofacial	Orthognathic Surgery <i>Revised</i>
C001	Eye, Ear, Nose, and Throat	Nasal Reconstructive Surgery
C007	Eye, Ear, Nose, and Throat	Uvulopalatopharyngoplasty (UPPP) <i>Revised</i>
C008	Eye, Ear, Nose, and Throat	Strabismus Repair (Adult and pediatric) <i>Revised</i>
C009	Eye, Ear, Nose, and Throat	Cochlear Implant <i>Revised</i>
C010	Eye, Ear, Nose, and Throat	Otoplasty
E008	Obstetrical, Gynecological & Urological	Uterine Artery Embolization (UAE) <i>Revised</i>
E009	Obstetrical, Gynecological & Urological	Erectile Dysfunction Treatment <i>New</i>
F014	Orthopaedic/Musculoskeletal	Percutaneous Vertebroplasty & Kyphoplasty <i>Revised</i>
G001	Skin and Integumentary	Eyelid Surgery (Blepharoplasty & Ptosis Repair) <i>Revised</i>
G002	Skin and Integumentary	Reduction Mammoplasty <i>Revised</i>
G003	Skin and Integumentary	Panniculectomy/Abdominoplasty <i>Revised</i>
G004	Skin and Integumentary	Breast Reconstruction
G006	Skin and Integumentary	Gynecomastia Procedures <i>Revised</i>
G007	Skin and Integumentary	Prophylactic Mastectomy
G008	Skin and Integumentary	Hyperhidrosis Treatment <i>Revised</i>
H003	Gastrointestinal/Nutritional	Bariatric Surgery <i>Revised</i>
J001	Vascular	Treatment of Varicose Veins <i>Revised</i>
L001	Diagnostic	Positron Emission Tomography (PET) Scan
L002	Diagnostic	Coronary Artery Evaluation (EBCT, UFCT, MSCT, Spiral CT, Helical CT)
M001	BH/Substance Related Disorders	Inpatient Treatment for Mental Disorders <i>Revised</i>

M002	BH/Substance Related Disorders	<b>Electroconvulsive Treatment (ECT): Inpatient Treatment</b>
M004	BH/Substance Related Disorders	<b>Day Treatment Program-Mental Health Disorder</b>
M005	BH/Substance Related Disorders	<b>Eating Disorders-Level of Care Criteria</b>
M006	BH/Substance Related Disorders	<b>Partial Hospitalization Program (PHP)-Mental Health Disorder</b>
M007	BH/Substance Related Disorders	<b>Residential Treatment</b>
M008	BH/Substance Related Disorders	<b>Outpatient Psychotherapy <i>Revised</i></b>
M009	BH/Substance Related Disorders	<b>Outpatient Chronic Pain Program Criteria <i>Revised</i></b>
M010	BH/Substance Related Disorders	<b>Substance Related Disorders: Inpatient Primary Treatment</b>
M014	BH/Substance Related Disorders	<b>Detoxification: Inpatient Treatment</b>
M019	BH/Substance Related Disorders	<b>Pathological Gambling Outpatient Treatment</b>
M020	BH/Substance Related Disorders	<b>Autism Spectrum Disorders Treatment</b>
N001	Rehabilitation	<b>Acute Inpatient Rehabilitation <i>Revised</i></b>
N002	Rehabilitation	<b>Skilled Nursing Facilities</b>
N003	Rehabilitation	<b>Outpatient Occupational, Physical and Speech Therapy</b>
T001	Transplant	<b>Bone Marrow Transplantation/Stem Cell Harvest (Autologous and Fetal Cord Blood)</b>
T002	Transplant	<b>Kidney/Pancreas Transplantation</b>
T003	Transplant	<b>Heart Transplantation</b>
T004	Transplant	<b>Liver Transplantation</b>
T005	Transplant	<b>Lung Transplantation</b>
T006	Transplant	<b>Intestinal Transplant <i>Revised</i></b>

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## Pharmacy Policy Table of Contents

<b>Reference #</b>	<b>Description</b>
C001	Coordination of Benefits
C002	Combination Drugs
D001	Drugs with Potential Adverse Effects or Interactions <i>Revised</i>
D002	Dosing Optimizing Programs
F001	Formulary Overrides
L001	Long Acting Medications
N001	National Formulary Exceptions
O001	Off-Label Drug Use
P001	Prior Authorization of Medications Ordered by a Specialist
Q001	Quantity Limits per Prescription per Copayment
S001	Step Therapy <i>Revised</i>
U001	Urgent Pharmacy Situations

*Revised 05/18/06*

## Pharmacy Criteria Table of Contents

<b>Reference #</b>	<b>Category</b>	<b>Description</b>
A001	Pharmacy	<b>ACE Inhibitors Step Therapy</b> <i>Revised</i>
A002	Pharmacy	<b>Oral Antifungal Treatment</b>
B003	Pharmacy	<b>Botulinum Toxin</b> <i>Revised</i>
B004	Pharmacy	<b>Biologics for Arthritic Conditions: Enbrel (etanercept), Humira (adalimumab), &amp; Remicade (infliximab)</b>
B005	Pharmacy	<b>Biologics for Psoriasis: Amevive (alefacept) Enbrel (etanercept) and Raptiva (efalizumab)</b>
B006	Pharmacy	<b>Biologics (Remicade) for Crohn's Disease and Ulcerative Colitis</b> <i>New</i>
B007	Pharmacy	<b>Biologics (Enbrel &amp; Remicade) for Ankylosing Spondylitis</b> <i>New</i>
C002	Pharmacy	<b>Cyclooxygenase-2 (COX-2) Inhibitors (Celebrex)</b> <i>Revised</i>
D001	Pharmacy	<b>Diabetic Adjunct Agents (Byetta and Symlin)</b> <i>New</i>
D002	Pharmacy	<b>Dihydropyridine Step Therapy</b>
G001	Pharmacy	<b>Growth Hormone Therapy</b>
I001	Pharmacy	<b>Topical Immunomodulators</b> <i>Revised</i>
L002	Pharmacy	<b>Leukotriene Pathway Inhibitors Step Therapy</b>
N001	Pharmacy	<b>Branded Nonsteroidal Anti-Inflammatory Drug (NSAID) Step Therapy</b> <i>Revised</i>
P001	Pharmacy	<b>Proton Pump Inhibitor (PPI) Step Therapy</b>
R002	Pharmacy	<b>RSV Prophylaxis - American Academy of Peds</b>
S002	Pharmacy	<b>Selective Serotonin Reuptake Inhibitors (SSRIs) Step Therapy</b> <i>Revised</i>
W001	Pharmacy	<b>Weight Loss Medications</b>
X001	Pharmacy	<b>Xolair</b>

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### Chiropractic Policy Table of Contents

<b>Reference #</b>	<b>Description</b>
B005	<b>Electrical Stimulation</b> <i>Revised</i>
H001	<b>Hot N Cold Packs</b> <i>Revised</i>
I001	<b>Experimental, Investigational or Unproven Services</b> <i>Revised</i>
P001	<b>Passive Rx Therapies beyond six weeks</b> <i>Revised</i>
P002	<b>Plain films within first 30 days of care</b> <i>Revised</i>

*Revised 02/28/06*