

Update
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Affected Programs: BadgerCare Plus, Medicaid, SeniorCare

**To:** Blood Banks, Dentists, Federally Qualified Health Centers, Hospital Providers, Nurse Practitioners, Nursing Homes, Pharmacies, Physician Assistants, Physician Clinics, Physicians, Podiatrists, Rural Health Clinics, HMOs and Other Managed Care Programs

## January 2016 Preferred Drug List Review and Other Pharmacy Policy Changes

This ForwardHealth Update provides information for prescribers and pharmacy providers about changes to the Preferred Drug List and other pharmacy policy changes effective for dates of service on and after January 1, 2016, unless otherwise noted.

This ForwardHealth Update provides information for prescribers and pharmacy providers about changes to the Preferred Drug List (PDL) and other pharmacy policy changes effective for dates of service (DOS) on and after January 1, 2016, unless otherwise noted.

This *Update* provides an overview of the major changes to certain PDL drug classes for BadgerCare Plus, Medicaid, and SeniorCare programs but does not address all of the changes made in PDL drug classes. For additional information about covered drugs on the PDL for BadgerCare Plus, Medicaid, and SeniorCare, providers may refer to the Preferred Drug List Quick Reference on the Pharmacy Resources page of the Providers area of the ForwardHealth Portal at *mmw.forwardhealth.wi.gov*/.

## Changes to Pharmacy-Related Forms and Completion Instructions

Attachment 1 of this *Update* lists the prior authorization (PA) forms and completion instructions that are new or have been revised, renamed, or discontinued as a result of the January 2016 PDL review or as a result of other pharmacy policy changes. Providers should refer to the Forms page of the

Portal for current copies of all PA forms and completion instructions. Unless otherwise noted, all forms listed in Attachment 1 are effective January 1, 2016. Additional information regarding changes to clinical criteria or submission options is noted in the applicable drug class section of this *Update*.

## Archive Page for Pharmacy-Related Forms and Completion Instructions

Providers may reference the Pharmacy-Related Forms and Completion Instructions link under the Archives section on the Pharmacy Resources page of the Portal for old versions of pharmacy-related forms and completion instructions. These archives are provided for reference purposes only. Providers should refer to the ForwardHealth Online Handbook for current policy and procedures and to the Forms page of the Portal for current forms and completion instructions.

## A Brief Overview of the Preferred Drug List

ForwardHealth makes recommendations to the Wisconsin Medicaid Pharmacy PA Advisory Committee on whether certain PDL drugs should be preferred or non-preferred. These recommendations are based primarily on objective evaluations of a drug's relative safety, effectiveness of the drug, clinical outcomes, and the relative cost of the drug (to Wisconsin Medicaid) in comparison with other

therapeutically interchangeable alternative agents in the same drug class.

New drugs are usually added to existing drug classes on the PDL as non-preferred drugs until their next scheduled class review by the Pharmacy PA Advisory Committee.

The PDL is not a drug formulary and is not a comprehensive list of covered drugs.

Most drugs and drug classes included on the PDL are covered by BadgerCare Plus, Medicaid, and SeniorCare, but certain drugs may have restrictions (e.g., diagnosis, quantity limits, age limits). Prescribers are encouraged to write prescriptions for preferred drugs if medically appropriate. Non-preferred drugs may be covered with an approved PA request. Most preferred drugs do not require PA except in designated classes identified on the Preferred Drug List Quick Reference. Noncovered drugs (e.g., drugs used for hair loss or cosmetic purposes) are not reimbursed, even with PA.

#### Prescribers' Responsibilities for Prior Authorization for Preferred Drug List Drugs

Prescribers are encouraged to write prescriptions for preferred drugs.

Prescribers are encouraged to prescribe more than one preferred drug before a non-preferred drug is prescribed.

Prescribers are required to provide clinical information so that pharmacy providers can request and obtain PA.

Prescribers are required to complete the Prior

Authorization/Preferred Drug List (PA/PDL) Exemption

Request form, F-11075 (09/13), for non-preferred drugs that do not require a drug- or drug class-specific PA form.

#### Clinical Criteria for Non-preferred Drugs

Clinical criteria for approval of a PA request for a nonpreferred drug are **at least one** of the following, unless drug class-specific clinical criteria have been established and published by ForwardHealth:

- The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with at least one of the preferred drugs from the same PDL drug class as the drug being requested.
- There is a clinically significant drug interaction between another drug the member is taking and at least one of the preferred drugs from the same PDL drug class as the drug being requested.
- The member has a medical condition(s) that prevents the use of at least one of the preferred drugs from the same PDL drug class as the drug being requested.

## Alternate Clinical Criteria for Non-preferred Drugs in Eligible Drug Classes Only

The following drug classes have alternate clinical criteria that may be considered if the member does not meet the previously listed clinical criteria for non-preferred drugs:

- Alzheimer's agents drug class (excluding memantine and Namenda XR® for members who are 44 years of age or younger)
- Anticonvulsants drug class
- Antidepressants, other drug class
- Antidepressants, selective serotonin reuptake inhibitor (SSRI) drug class
- Antiparkinson's agents drug class
- Antipsychotics drug class
- Pulmonary arterial hypertension drug class

Alternate clinical criteria may be considered if a member does not meet the previously listed clinical criteria for nonpreferred drugs. Alternate clinical criteria are **one** of the following:

- The member is new to ForwardHealth (i.e., the member has been granted eligibility for ForwardHealth within the past month) and has taken the requested nonpreferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.
- The member had an approved PA request issued by ForwardHealth that recently expired for the non-

preferred drug, and the member has taken the requested non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.

 The member was recently discharged from an inpatient stay in which the member was stabilized on the nonpreferred drug being requested.

*Note:* Starting a member on a medication by using manufacturer-provided samples or manufacturer patient assistance programs will not be considered as previous medication history for PA review.

#### Completing a Prior Authorization Form

If a non-preferred drug or a preferred drug that requires clinical PA is medically necessary for a member, the prescriber is required to do the following:

- Complete the appropriate PA form for the drug.
- Send the PA form to the pharmacy where the prescription will be filled.
- Include accurate and complete answers and clinical information about the member's medical history on the PA form.
- Provide his or her handwritten signature and date on the form.

The PA form may be faxed or mailed to the pharmacy, or the member may carry the form with the prescription to the pharmacy. The pharmacy provider will use the completed PA form to submit a PA request to ForwardHealth. Prescribers should **not** submit the PA form to ForwardHealth.

Prescribers are required to retain a completed, signed, and dated copy of the PA form and any supporting documentation. Pharmacy providers may not reuse PA forms from previously approved PA requests for subsequent PA request submissions.

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet, F-01176 (12/11), which is available on the Forms page of the

Portal, or to the Additional Information section available on most PA forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

#### Pharmacy Providers' Responsibilities for Prior Authorization for Preferred Drug List Drugs

Pharmacy providers should review the Preferred Drug List Quick Reference for the most current list of preferred and non-preferred drugs.

If a member presents a prescription for a non-preferred drug, the pharmacy provider is encouraged to contact the prescriber to discuss preferred drug options. The prescriber may choose to change the prescription to a preferred drug, if medically appropriate for the member, or the prescriber may complete the appropriate PA form.

Pharmacy providers are required to do the following:

- Submit the PA request using the PA form received from the prescriber and using the PA request submission option most appropriate for the drug. Pharmacy providers may submit PA requests using the Specialized Transmission Approval Technology-Prior Authorization (STAT-PA) system (when applicable), on the Portal, by fax, or by mail.
- Retain a completed, signed, and dated copy of the PA form and any supporting documentation received from the prescriber.

Pharmacy providers may not reuse PA forms from previously approved PA requests for subsequent PA request submissions.

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet, which is available on the Forms page of the Portal, or to the Additional Information section available on most PA forms.

The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

Changes to the Preferred or Nonpreferred Status of Drugs on the Preferred Drug List

On November 11, 2015, the Pharmacy PA Advisory Committee met to review new and existing therapeutic drug classes on the PDL.

Providers may refer to Attachment 2 for a table listing all of the drugs that have had a change in their preferred or non-preferred status as a result of this meeting. The updated statuses are effective January 1, 2016. Providers should review the Preferred Drug List Quick Reference on the Portal for a complete list of preferred and non-preferred drugs.

For drugs that were previously preferred and will become non-preferred, pharmacists should work with prescribers to transition members to a preferred drug or to complete the appropriate PA request forms.

As a reminder, new drugs are usually added to existing drug classes on the PDL as non-preferred drugs until the next scheduled class review by the Pharmacy PA Advisory Committee; therefore, some drugs listed in the table had not been reviewed previously and were added to the PDL with an interim status of non-preferred. These drugs have now been reviewed and their PDL status resulting from the November 11, 2015, meeting are effective January 1, 2016, and are included in Attachment 2.

For some drugs in Attachment 2, additional information is provided in the applicable drug class section of this *Update*.

#### **New Drug Class**

The methotrexate drug class will be added to the PDL on January 1, 2016.

Pharmacy providers should begin working with prescribers to transition members using non-preferred drugs in the drug class or request PA for a non-preferred drug if it is medically appropriate for the member.

#### Methotrexate

The following will be preferred drugs in the methotrexate drug class:

- Methotrexate tablet
- Methotrexate PF vial
- Methotrexate vial

The following will be non-preferred drugs in the methotrexate drug class:

- Otrexup<sup>™</sup> auto injector
- Rasuvo® auto injector
- Rheumatrex® tablet dose pack
- Trexall<sup>™</sup> tablet

#### **Anticonvulsants**

Certain brand name drugs will be preferred over their generic equivalents. Brand name Tegretol® tablets and Tegretol® suspension will become preferred drugs (in addition to other preferred drugs) in the anticonvulsants drug class.

Generic carbamazepine tablets and carbamazepine suspension will become non-preferred drugs.

#### **Antipsychotics**

#### Antipsychotics, Injectable

Antipsychotic injectable formulations will be added to the PDL in the antipsychotics drug class.

Providers may refer to Attachment 2 for the complete list of antipsychotic injectable drugs that were reviewed during the November 11, 2015, Pharmacy PA Advisory Committee meeting.

Note: Recently released antipsychotic injectable formulations not reviewed during the November 11, 2015, meeting will be added to the PDL with an initial status of non-preferred until the next scheduled antipsychotics drug class review by the Pharmacy PA Advisory Committee.

As a reminder, the following policy for obtaining provideradministered drugs will continue to apply to all antipsychotics, injectable drugs.

#### Obtaining Provider-Administered Drugs

To ensure the content and integrity of the drugs administered to members, prescribers are required to obtain all drugs that will be administered in their offices. Prescribers may obtain a provider-administered drug from a pharmacy provider if the drug is delivered directly from the pharmacy to the prescriber's office. Prescribers may also obtain a drug to be administered in the prescriber's office from a drug wholesaler or direct purchase. Pharmacy providers should not dispense a drug to a member if the drug will be administered in the prescriber's office.

## Antipsychotic Drugs for Children 7 Years of Age and Younger

Revised Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger

ForwardHealth has revised the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form, F-00556 (01/2016). The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. Prior authorization requests submitted on and after January 1, 2016, must be submitted on the revised form or the PA request will be returned to the provider.

Prior authorization requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

Pharmacy providers should refer to the Preferred Drug List Quick Reference for a complete list of covered antipsychotic drugs. Prescribers are encouraged to write prescriptions for preferred antipsychotic drugs.

#### Background

ForwardHealth continues to monitor the use of antipsychotic drugs in young children. The PA process is intended to scrutinize the prescribing of antipsychotic drugs for mood disorders and the monitoring of metabolic effects of this class of drugs. ForwardHealth strongly encourages prescribers to earnestly engage in clarifying the differentiation between disruptive mood dysregulation disorder (DMDD) and bipolar disorder, not otherwise specified (NOS).

The increased use of antipsychotic drugs in young children over the past decade has been associated with the frequent use of the diagnosis of bipolar disorder, NOS (F31.9) per the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) in many of these children. A discussion and review of the issues in differentiating bipolar disorder, NOS from DMDD can be found in the *Journal of the American Academy of Child and Adolescent Psychiatry*, Volume 52, Issue 5, May 5, 2013, pp.466-481 (Towbin, K. MD, Axelson, D. MD, Leibenluft, E. MD, Birmaher, B. MD. "Differentiating Bipolar Disorder–Not Otherwise Specified and Severe Mood Dysregulation").

In recent years, there has been some progress in the research of these clinical issues. Specifically, the DSM-5 addresses the inclusion of DMDD (F34.8). This evolved out of the observation that many children with a diagnosis of bipolar disorder do not progress to having bipolar disorder, NOS as adults, thus bringing into question the use of antipsychotic drugs for these children. Many of the children with DMDD (or severe mood dysregulation as referenced in several research studies) respond to stimulants and/or SSRI antidepressants. Although SSRIs may cause mild activation when first administered, this is not necessarily mania. These antidepressants can be very effective for irritability associated with anxiety and depression in young children and they have far fewer side effects than antipsychotic drugs. Clinicians need to be vigilant about target symptoms and strive to clarify persistent irritability as seen in DMDD versus the more classic episodic irritability typical of bipolar spectrum disorders. Clinicians who prescribe antipsychotic drugs to

children with bipolar disorder, NOS diagnoses will need to become familiar with the details of the current research on differentiating DMDD from bipolar disorder, NOS.

#### Prescriber Responsibilities for Antipsychotic Drugs for Children 7 Years of Age and Younger

If a child is 7 years of age or younger and requires an oral antipsychotic drug, the prescriber is required to complete the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form. Prior authorization request forms must be faxed, mailed, or sent with the member to the pharmacy provider.

The pharmacy provider will use the completed form to submit a PA request to ForwardHealth. Prescribers should not submit the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form directly to ForwardHealth. Prescribers are required to retain a completed and signed copy of the PA form.

Prior authorization requests for covered antipsychotic drugs for children 7 years of age and younger are approved at the active ingredient level; therefore, an approved PA request allows any covered National Drug Code with the same active ingredient of the prior authorized drug to be covered with the same PA. For example, if a member has an approved PA request for risperidone 1 mg tablets and the prescriber orders a new prescription for risperidone 2 mg tablets, an amended PA request or new PA request is not required.

#### Clinical Documentation

If the PA request for antipsychotic drugs for children 7 years of age and younger is for a member who is being treated for autism or tics, the only documentation required is the diagnosis information described in the following list. Pharmacy providers are encouraged to submit all PA requests for autism and tics using the STAT-PA system. The following clinical documentation is required on PA requests for members who are being treated for a condition other

than autism or tics and must be submitted on the ForwardHealth Portal, by fax, or by mail:

- Information about the child's diagnoses There are appropriate indications for the use of antipsychotic drugs in young children with certain diagnoses, including autism spectrum disorders, psychotic disorders, and tic disorders. Antipsychotic drugs may also be helpful for severe symptoms of irritability, aggression, anger, or defiance that may accompany severe mood disorders, developmental disorders, or attention-deficit or attention-deficit hyperactivity disorders (ADHD).
- Body Mass Index (BMI) measurements Antipsychotic drugs can have profoundly adverse effects on weight, glucose, and lipids. Because of these welldocumented side effects, the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form requires the submission of a BMI percentile measurement with each PA request. The BMI percentile measurement is required because it is the standard for stratifying individuals as obese or atrisk for obesity and, therefore, requiring closer monitoring and active intervention. Children who have a BMI percentile measurement greater than or equal to 85 percent are at risk for diabetes and the metabolic syndrome associated with many antipsychotic drugs. If the child's BMI percentile is 85 percent or greater, the PA request must include a fasting lipid panel and a fasting glucose drawn within the past six months for the PA request to be approved. A BMI calculator may be found on the Centers for Disease Control and Prevention website at nccd.cdc.gov/dnpabmi/Calculator.aspx.
- Target symptoms The prescriber is required to be very familiar with the criteria for DMDD and to clarify persistent versus episodic irritability as well as to identify the presence, or absence, of comorbid conditions such as ADHD and oppositional defiant disorder.
- Polypharmacy information The Prior Authorization
   Drug Attachment for Antipsychotic Drugs for Children
   7 Years of Age and Younger form requires
   documentation of the child's experience with any

- psychoactive drugs, concurrent drugs, as well as previous drug trials in the preceding 12 months.
- Specialty information ForwardHealth is interested in tracking the prescriber's practice specialty information.
- Documentation for non-preferred antipsychotic drug requests — If the prescriber is requesting a nonpreferred antipsychotic drug, clinical documentation must be provided to support the request and must include detailed reasons why preferred drugs were discontinued or not utilized.

#### Pharmacy Responsibilities for Antipsychotic Drugs for Children 7 Years of Age and Younger

Pharmacy providers should ensure that they have received the completed Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form from the prescriber.

For BadgerCare Plus and Medicaid members, pharmacy providers should review the Preferred Drug List Quick Reference for the most current list of preferred and non-preferred drugs.

If a BadgerCare Plus or Medicaid member presents a prescription for a non-preferred antipsychotic drug, the pharmacy provider is encouraged to contact the prescriber to discuss preferred drug options. The prescriber may choose to change the prescription to a preferred antipsychotic drug if medically appropriate for the member.

It is important that pharmacy providers work with prescribers to ensure that members are given appropriate assistance regarding coverage information and the PA request submission process for antipsychotic drugs. Pharmacy providers are responsible for the submission of the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form to ForwardHealth. Pharmacy providers are required to retain a completed and signed copy of the PA form.

Brand name antipsychotic drugs prescribed to children 7 years of age and younger that are brand medically necessary

(BMN) require that a Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form be submitted on the Portal, by fax, or by mail with the Prior Authorization/Brand Medically Necessary Attachment (PA/BMNA) form, F-11083 (01/15), and the Prior Authorization Request Form (PA/RF), F-11018 (05/13).

Two unique PA numbers will be assigned for a BMN antipsychotic drug. One PA number will be assigned to the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form, and the other will be assigned to the PA/BMNA form.

#### Prior Authorization Request Submission Methods

Pharmacy providers are encouraged to use the STAT-PA system to submit PA requests for antipsychotic drugs for children who have one of the following conditions:

- Autism
- Tics

If the prescriber indicates on the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form that the child has autism or tics, no additional clinical information is required on the form and the pharmacy may submit the request using the STAT-PA system.

Prior authorization requests cannot be submitted using the STAT-PA system if **any** of the following are true:

- The child has a condition other than autism or tics.
- The drug being requested is a non-preferred antipsychotic drug.
- The child is 2 years of age or younger.
- The PA request is for a BMN antipsychotic drug.

If the PA request is not approved through the STAT-PA system, pharmacy providers are required to submit the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form, a PA/RF, and any supporting documentation from the prescriber on the Portal, by fax, or by mail.

#### Approved Prior Authorization Requests for Antipsychotic Drugs for Children 7 Years of Age and Younger

Neither a new PA request nor a PA amendment is needed if the antipsychotic drug the child is taking has changed and the new drug contains the same active ingredient as the original drug approved or if the child is taking multiple strengths of the same drug.

Prior authorization decision notice letters for antipsychotic drugs for children 7 years of age and younger will include a message stating: "The prior authorization for this drug has been approved at the active ingredient level instead of the drug strength and dosage form level. Additional PAs are not needed for a different strength of this same drug."

#### Expedited Emergency Supply for Antipsychotic Drugs for Children 7 Years of Age and Younger

ForwardHealth strongly encourages pharmacy providers to utilize the expedited emergency supply process for antipsychotic drugs for children 7 years of age and younger when it is determined that the member should begin taking the medication immediately, but the PA request submission and adjudication process would delay dispensing the medication to the member. This may occur if a child 7 years of age or younger receives a prescription for an antipsychotic covered drug and the prescriber has not completed the necessary PA form or the PA request is still in process.

Expedited emergency supply requests for antipsychotic drugs will be granted for up to a 14-day supply. Members will be limited to receiving two expedited emergency supply requests of the same drug in 30 days from one pharmacy provider within a six-month time period. A PA request is not required to be in process when the first expedited emergency supply request is submitted; however, before a second expedited emergency supply request for the same drug is submitted, a PA request must be submitted to ForwardHealth and be in the process of being adjudicated. Requests for a second expedited emergency supply must be submitted either on day 15 or day 16 after the initial request was submitted.

Refer to the Emergency Medication Dispensing topic (topic #1399) of the Covered Services and Requirements chapter of the Covered and Noncovered Services section of the ForwardHealth Online Handbook for detailed information regarding expedited emergency medication supply and emergency medication supply options.

#### **COPD Agents**

#### **Daliresp**®

Daliresp® will become a non-preferred drug.

Daliresp® continues to be a diagnosis restricted drug. Providers may refer to the Diagnosis Restricted Drugs data table on the Pharmacy Resources page of the Providers area of the Portal for the most current list of allowable diagnosis codes.

#### **Cytokine and CAM Antagonist Drugs**

Cimzia® and Cosentyx® will become non-preferred drugs.

Note: Members currently taking Cimzia® who have had previous PA requests for that agent approved by ForwardHealth will be allowed to continue to receive PA approval as long as they continue to meet the PA criteria for the member's clinical condition. Members are also required to have been adherent with treatment.

Clinical PA is required for all cytokine and cell adhesion molecule (CAM) antagonist drugs, including preferred cytokine and CAM antagonist drugs.

Prior authorization requests for preferred cytokine and CAM antagonist drugs may be submitted using STAT-PA, on the Portal, by fax, or by mail.

Prior authorization requests for non-preferred cytokine and CAM antagonist drugs must be submitted on the Portal, by fax, or by mail. Prior authorization requests for non-preferred cytokine and CAM antagonist drugs may **not** be submitted using the STAT-PA system.

Initial PA requests for non-preferred cytokine and CAM antagonist drugs may be approved for up to 183 days. Renewal PA requests for non-preferred cytokine and CAM antagonist drugs may be approved for up to 365 days.

Prior authorization requests for cytokine and CAM antagonist drugs will only be approved for use to treat the following identified clinical conditions:

- Ankylosing spondylitis
- Crohn's disease
- Hidradenitis suppurativa
- Neonatal Onset Multisystem Inflammatory Disease (NOMID)
- Plaque psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis (RA) and polyarticular juvenile RA
- Ulcerative colitis

#### Non-preferred Oral Agents

ForwardHealth has established that the following will **not** be considered as criteria for use of a non-preferred oral agent:

- Non-adherence to previous cytokine and CAM antagonist drug treatment
- The member's fear of needles
- Member or prescriber preference for the use of an oral agent

#### Revised Prior Authorization Forms for Cytokine and CAM Antagonist Drugs

ForwardHealth has revised the following PA/PDL for Cytokine and CAM Antagonist Drugs forms:

- Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM)
   Antagonist Drugs for Crohn's Disease form, F-11305 (01/2016)
- Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Plaque Psoriasis form, F-11306 (01/2016)

The previous versions will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. Prior authorization requests submitted on and after January 1, 2016, must be submitted on the revised form or the PA request will be returned to the provider.

Prior authorization requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

#### New Prior Authorization Form for Cytokine and CAM Antagonist Drugs for Hidradenitis Suppurativa

ForwardHealth has created the Prior Authorization/
Preferred Drug List (PA/PDL) for Cytokine and Cell
Adhesion Molecule (CAM) Antagonist Drugs for
Hidradenitis Suppurativa form, F-01674 (01/2016), and
established clinical criteria for coverage of cytokine and
CAM antagonist drugs for hidradenitis suppurativa. Prior
authorization requests submitted on and after January 1,
2016, must be submitted on the new form or they will be
returned to the provider.

#### Clinical Criteria for Cytokine and Cell Adhesion Molecule Antagonist Drugs

ForwardHealth has revised the clinical criteria for cytokine and CAM antagonist drugs.

Clinical Criteria for Cytokine and CAM Antagonist Drugs for Ankylosing Spondylitis

Enbrel® and Humira® are preferred drugs used to treat ankylosing spondylitis. Cimzia® and Simponi™ are non-preferred drugs used to treat ankylosing spondylitis. For PA requests for Cimzia® and Simponi™, the member must meet all clinical criteria below and have taken two preferred cytokine and CAM antagonist drugs for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat ankylosing spondylitis are **all** of the following:

- The member has ankylosing spondylitis.
- The prescription is written by a rheumatologist or through a rheumatology consultation.
- At least **one** of the following is true:
  - ✓ The member has moderate to severe axial symptoms of ankylosing spondylitis.
  - ✓ The member has received **one or more** of the following drugs and taken each drug for **at least three** consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
    - Leflunomide
    - Methotrexate
    - Non-steroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase (COX-2) inhibitor drugs
    - o Oral corticosteroids
    - o Sulfasalazine

Prior authorization requests for drugs for ankylosing spondylitis must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Ankylosing Spondylitis form, F-11304 (12/12).

#### Clinical Criteria for Cytokine and CAM Antagonist Drugs for Crohn's Disease

Humira<sup>®</sup> is a preferred drug used to treat Crohn's disease. Cimzia<sup>®</sup> is a non-preferred drug used to treat Crohn's disease. For PA requests for Cimzia<sup>®</sup>, the member must meet **all** clinical criteria below and have taken one preferred cytokine and CAM antagonist drug for **at least three** consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat Crohn's disease are **all** of the following:

- The member has Crohn's disease.
- The member has moderate to severe symptoms of Crohn's disease.
- The prescription is written by a gastroenterologist or through a gastroenterology consultation.
- The member has received two or more of the following drugs and taken each drug for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
  - ✓ 5-aminosalicylic (5-ASA)
  - ✓ 6-mercaptopurine (6MP)
  - ✓ Azathioprine
  - ✓ Methotrexate
  - ✓ Oral corticosteroids
  - ✓ Sulfasalazine

Prior authorization requests for drugs for Crohn's Disease must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Crohn's Disease form.

#### Clinical Criteria for Cytokine and CAM Antagonist Drugs for Hidradenitis Suppurativa

Humira<sup>®</sup> is a preferred drug used to treat hidradenitis suppurativa.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat hidradenitis suppurativa are all of the following:

- The member has hidradenitis suppurativa.
- The prescription is written by a dermatologist or through a dermatology consultation.
- The member has recurrent abscesses with sinus tracts and scarring.
- At least one of the following is true:
  - ✓ The member has had laser therapy, excision, or deroofing surgery to treat hidradenitis suppurativa.
  - ✓ The member has received **one or more** of the following drug therapies and received each drug

therapy for **at least three** consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:

- Antibiotics
- Retinoids

Prior authorization requests for drugs for hidradenitis suppurativa must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Hidradenitis Suppurativa form.

#### Clinical Criteria for Cytokine and CAM Antagonist Drugs for NOMID

Kineret<sup>®</sup> is a non-preferred drug used to treat NOMID. For PA requests for Kineret<sup>®</sup>, the member must meet **all** clinical criteria below.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat NOMID are **both** of the following:

- The member has NOMID.
- The prescription is written by a rheumatologist or through a rheumatology consultation.

Prior authorization requests for drugs to treat NOMID must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Rheumatoid Arthritis (RA) and Polyarticular Juvenile RA form, F-11308 (12/12).

Clinical documentation and medical records must be submitted with the PA request to support the member's condition of NOMID and outline the member's current treatment plan for NOMID.

#### Clinical Criteria for Cytokine and CAM Antagonist Drugs for Plaque Psoriasis

Enbrel® and Humira® are preferred drugs used to treat plaque psoriasis. Cosentyx®, Otezla®, and Stelara® are non-preferred drugs used to treat plaque psoriasis.

For PA requests for Cosentyx<sup>®</sup>, Otezla<sup>®</sup>, or Stelara<sup>®</sup>, the member must meet **all** clinical criteria below and have taken **two** preferred cytokine and CAM antagonist drugs for **at least three** consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat plaque psoriasis are **all** of the following:

- The member has plaque psoriasis and at least one of the following is true:
  - ✓ The member has moderate to severe symptoms of plaque psoriasis involving greater than or equal to 10 percent or more of his or her body surface area.
  - ✓ The member has palmoplantar psoriasis.
- The prescription is written by a dermatologist or through a dermatology consultation.
- The member has received one or more of the following treatments and received each treatment for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
  - ✓ Cyclosporine
  - ✓ Methotrexate
  - ✓ Phototherapy
  - ✓ Soriatane

Prior authorization requests for drugs for plaque psoriasis must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Plaque Psoriasis form.

#### Clinical Criteria for Cytokine and CAM Antagonist Drugs for Psoriatic Arthritis

Enbrel® and Humira® are preferred drugs used to treat psoriatic arthritis.

Cimzia®, Otezla®, Simponi®, and Stelara® are non-preferred drugs used to treat psoriatic arthritis. For PA requests for Cimzia®, Otezla®, Simponi®, or Stelara®, the member must meet all clinical criteria below and have taken two preferred cytokine and CAM antagonist drugs for at least three

consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat psoriatic arthritis are **all** of the following:

- The member has psoriatic arthritis.
- The member has moderate to severe symptoms of psoriatic arthritis.
- The prescription is written by a dermatologist or rheumatologist or through a dermatology or rheumatology consultation.
- At least **one** of the following is true:
  - ✓ The member has moderate to severe axial symptoms of psoriatic arthritis.
  - ✓ The member has received two or more of the following drugs and taken each drug for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
    - o Azathioprine
    - Cyclosporine
    - o Hydroxychloroquine
    - o Leflunomide
    - Methotrexate
    - Non-steroidal anti-inflammatory drugs or COX-2 inhibitor drugs
    - o Oral corticosteroids

Prior authorization requests for drugs for psoriatic arthritis must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Psoriatic Arthritis form, F-11307 (12/12).

Clinical Criteria for Cytokine and CAM Antagonist Drugs for Rheumatoid Arthritis and Polyarticular Juvenile Rheumatoid Arthritis

Enbrel® and Humira® are preferred drugs used to treat RA and polyarticular juvenile RA.

Actemra® subQ solution, Cimzia®, Kineret®, Orencia® subQ solution, Simponi™, and Xeljanz are non-preferred drugs used to treat RA. For PA requests for Actemra® subQ solution, Cimzia®, Kineret®, Orencia® subQ solution, Simponi™, or Xeljanz, the member must meet all clinical criteria below and have taken two preferred cytokine and CAM antagonist drugs for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction. For PA requests for Simponi™, members must also continue to take methotrexate in combination with Simponi™.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat RA are **all** of the following:

- The member has RA.
- The member has moderate to severe symptoms of RA.
- The prescription is written by a rheumatologist or through a rheumatology consultation.
- The member has received two or more of the following drugs and taken each drug for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
  - ✓ Azathioprine
  - ✓ Cyclosporine
  - ✓ Hydroxychloroquine
  - ✓ Leflunomide
  - ✓ Methotrexate
  - ✓ Non-steroidal anti-inflammatory drugs or COX-2 inhibitor drugs
  - ✓ Oral corticosteroids
  - ✓ Penicillamine
  - ✓ Sulfasalazine

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat polyarticular juvenile RA are **all** of the following:

- The member has polyarticular juvenile RA.
- The prescription is written by a rheumatologist or through a rheumatology consultation.

- The member has received two or more of the following drugs and taken each drug for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
  - ✓ Azathioprine
  - ✓ Cyclosporine
  - ✓ Hydroxychloroquine
  - ✓ Leflunomide
  - ✓ Methotrexate
  - ✓ Non-steroidal anti-inflammatory drugs or COX-2 inhibitor drugs
  - ✓ Oral corticosteroids
  - ✓ Penicillamine
  - ✓ Sulfasalazine

Prior authorization requests for drugs for RA and polyarticular juvenile RA must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Rheumatoid Arthritis (RA) and Polyarticular Juvenile RA form, F-11308 (12/12).

#### Clinical Criteria for Cytokine and CAM Antagonist Drugs for Ulcerative Colitis

Humira® is a preferred drug in the cytokine and CAM antagonist drug class used to treat ulcerative colitis.

Simponi<sup>™</sup> is a non-preferred drug used to treat ulcerative colitis. For PA requests for Simponi<sup>™</sup>, the member must meet **all** clinical criteria below and have taken **one** preferred cytokine and CAM antagonist drug for **at least two** consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.

Clinical criteria for approval of a PA request for cytokine and CAM antagonist drugs to treat ulcerative colitis are **all** of the following:

- The member has ulcerative colitis.
- The member has moderate to severe symptoms of ulcerative colitis.

- The prescription is written by a gastroenterologist or through a gastroenterology consultation.
- The member has taken two or more of the following drugs and taken each drug for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
  - ✓ 6-mercaptopurine (6MP)
  - ✓ Azathioprine
  - ✓ Oral aminosalicylates (balsalazide, mesalamine, olsalazine, or sulfasalazine)
  - ✓ Oral corticosteroids

Prior authorization requests for cytokine and CAM antagonist drugs to treat ulcerative colitis must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Ulcerative Colitis form, F-00694 (12/13).

Prior authorization requests for Humira® to treat ulcerative colitis may be initially approved for up to three months. Prior authorization requests may be approved for up to one year if the member has been using Humira® for ulcerative colitis for **at least two** consecutive months and the member has shown signs of clinical remission. Prior authorization requests for Simponi™ to treat ulcerative colitis may be initially approved for up to six months. Prior authorization requests may be approved for up to one year if the member has been using Simponi™ for ulcerative colitis and the member has shown evidence of clinical remission.

For more information about cytokine and CAM antagonist drugs, providers may refer to the Cytokine and Cell Adhesion Molecule Antagonist Drugs topic (topic #16217) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the ForwardHealth Online Handbook.

#### Glucocorticoids, Inhaled

Aerospan® will become a preferred drug.

Arnuity<sup>™</sup> Ellipta<sup>®</sup>, budesonide 1 mg respules, Flovent<sup>®</sup> Diskus<sup>®</sup>, and Flovent<sup>®</sup> HFA will become non-preferred drugs.

Pulmicort Respules® are preferred drugs (in addition to other preferred drugs) in the glucocorticoids, inhaled drug class and are preferred over their generic equivalent, budesonide respules.

For Pulmicort Respules®, ForwardHealth will automatically apply a generic copayment. Providers do not need to indicate a National Council for Prescription Drug Programs (NCPDP) Dispense as Written (DAW) code on claims to ensure the generic copayment deduction. In addition, ForwardHealth will automatically apply a generic dispensing fee to claims for Pulmicort Respules®.

#### **Sedative Hypnotics**

Belsomra® will become a non-preferred drug.

### New Prior Authorization Form for Belsomra®

ForwardHealth has created the Prior Authorization/Preferred Drug List (PA/PDL) for Belsomra® form, F-01673 (01/2016), and established clinical criteria for coverage of Belsomra®. Prior authorization requests submitted on and after January 1, 2016, must be submitted on the new form or they will be returned to the provider.

Prior authorization requests for Belsomra® may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

#### Clinical Criteria for Belsomra®

Clinical criteria for approval of a PA request for Belsomra® are all of the following:

- The member is at least 18 years of age.
- The member does not have narcolepsy.
- At least one of the following is true:
  - ✓ The member has experienced an unsatisfactory therapeutic response or experienced a clinically

- significant adverse drug reaction with **at least two** preferred sedative hypnotics.
- ✓ The member has a medical history of substance abuse or misuse.

If clinical criteria for Belsomra<sup>®</sup> are met, PA requests may be approved for up to 365 days.

#### **Stimulants and Related Agents**

Changes have been made to the preferred and non-preferred status of drugs in the stimulants and related agents drug class. Providers should refer to Attachment 2 for a table listing all of the drugs that have had a change in their preferred or non-preferred status as a result of the November 11, 2015, Pharmacy PA Advisory Committee meeting. The updated statuses are effective January 1, 2016. Providers should review the Preferred Drug List Quick Reference for the most current list of preferred and non-preferred drugs.

Providers should pay particular attention to the PA and policy changes noted below.

Note: The Prior Authorization Drug Attachment for Modafinil and Nuvigil® form, F-00079 (01/15), and clinical criteria for modafinil and Nuvigil® have not changed.

Zenzedi<sup>®</sup> will remain a non-preferred drug and Procentra<sup>®</sup> will become a non-preferred drug; however, effective for DOS on and after January 1, 2016, PA will not be required for members who are 6 years of age or younger for Zenzedi<sup>®</sup> or Procentra<sup>®</sup>.

#### **Grandfathering Overview**

If a BadgerCare Plus, Medicaid, or SeniorCare member is grandfathered on a brand name drug and a generic equivalent is available, grandfathering of the brand name drug for the member will be discontinued once the brand name drug is added to the State Maximum Allowed Cost (SMAC) List pharmacy data table.

If medically appropriate for the member, providers should request BMN PA for the member to continue taking the brand name drug.

If a BadgerCare Plus, Medicaid, or SeniorCare member is grandfathered on a generic drug, PA is not required until further notice.

### Grandfathering for Stimulants and Related Agents — Amphetamine Formulations

BadgerCare Plus, Medicaid, and SeniorCare members who were taking amphetamine formulations (as identified from claims history) during the six months prior to January 1, 2016, and are still actively taking an amphetamine formulation will be grandfathered. For these members, PA is not required until further notice.

When a pharmacy claim is submitted real-time for a member who is not eligible to be grandfathered on an amphetamine product, the pharmacy will receive an explanation of benefits code and an NCPDP reject code indicating a denial in the claim response, which informs the pharmacy that the drug requires PA.

For complete grandfathering information for amphetamine formulations, providers should refer to Attachment 3 for a table listing all of the amphetamine formulations that will be eligible for grandfathering and the applicable grandfathering details.

Note: Brand name Adderall® (immediate release) will continue to require BMN PA. Members will not be grandfathered. In addition to meeting established BMN criteria, PA requests for Adderall® that are submitted on and after January 1, 2016, must also meet the clinical criteria for amphetamine formulations.

Drugs in this class are diagnosis restricted. A ForwardHealth-allowed diagnosis code must be indicated on claims (and PA requests when applicable) for all stimulant and related agent drugs, except for guanfacine ER, Kapvay®, modafinil, and Nuvigil®.

Providers may refer to the Diagnosis Restricted Drugs data table on the Pharmacy Resources page of the Providers area of the Portal for the most current list of allowable diagnosis codes.

#### New Prior Authorization Form for Amphetamine Formulations

ForwardHealth has created the Prior Authorization/Preferred Drug List (PA/PDL) for Amphetamine Formulations form, F-01672 (01/2016), and established clinical criteria that must be documented on PA requests for non-preferred amphetamine formulations. Prior authorization requests submitted on and after January 1, 2016, must be submitted on the new form or they will be returned to the provider.

#### Clinical Criteria for Amphetamine Formulations

The clinical criteria for approval of a PA request for amphetamine formulations are that the member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with **at least two** preferred drugs from the stimulants and related agents drug class, and that one of these preferred drugs was Vyvanse<sup>®</sup>.

#### Submitting Prior Authorization Requests for Amphetamine Formulations

Prior authorization requests for amphetamine formulations must be completed and signed by the prescriber and must be submitted using the PA/PDL for Amphetamine Formulations form.

Prior authorization requests for amphetamine formulations (except for generic amphetamine salt combo ER requests and brand name Adderall®) may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

#### Clinical Criteria for Generic Amphetamine Salt Combo ER

In addition to the member meeting the previously listed clinical criteria for amphetamine formulations, the prescriber also is required to submit detailed clinical justification for prescribing generic amphetamine salt combo ER instead of brand name Adderall XR<sup>®</sup>. This clinical information must document why the member cannot use brand name Adderall XR<sup>®</sup>, including why it is medically necessary that the member receive generic amphetamine salt combo ER instead of brand name Adderall XR<sup>®</sup>.

#### Submitting Prior Authorization Requests for Generic Amphetamine Salt Combo ER

Prior authorization requests for generic amphetamine salt combo ER must be completed and signed by the prescriber and must be submitted using **all** of the following forms:

- Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (10/13)
- Prior Authorization/Preferred Drug List (PA/PDL) for Amphetamine Formulations form
- Prior Authorization Request Form

Prior authorization requests for generic amphetamine salt combo ER may be submitted on the Portal, by fax, or by mail. Prior authorization requests for generic amphetamine salt combo ER may **not** be submitted using the STAT-PA system.

Clinical Criteria for Non-preferred Stimulants and Related Agents, Except for Amphetamine Formulations, Modafinil, and Nuvigil®

Effective for PA requests submitted on and after January 1, 2016, the clinical criteria for non-preferred stimulants and related agents, except for amphetamine formulations, modafinil, and Nuvigil®, will be the clinical criteria for non-preferred drugs.

For more information about the clinical criteria for nonpreferred drugs, refer to the Prescribers' Responsibilities for Prior Authorization for Preferred Drug List Drugs section of this *Update*.

#### Submitting Prior Authorization Requests for Nonpreferred Stimulants and Related Agents

Providers will be required to use the PA/PDL Exemption Request form for PA requests for non-preferred stimulants and related agents, except for amphetamine formulations, modafinil, and Nuvigil<sup>®</sup>. Prior authorization requests submitted on and after January 1, 2016, must be submitted on the PA/PDL Exemption Request form or the PA request will be returned to the provider. Prior authorization requests for non-preferred stimulants and related agents (except for modafinil and Nuvigil<sup>®</sup>) may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

Prior authorization requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

#### Prior Authorization/Preferred Drug List for Stimulants and Related Agents Form Being Discontinued

Effective for PA requests submitted on and after January 1, 2016, the Prior Authorization/Preferred Drug List (PA/PDL) for Stimulants and Related Agents form, F-11097 (12/12), will no longer be accepted. This form is being discontinued. It will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal.

#### **Pharmacy Policy Changes**

#### **Xyrem**®

Xyrem® requires clinical PA.

Quantity limits apply to Xyrem<sup>®</sup>. Members are limited to a maximum nightly dose of 18 ml (9 g) of Xyrem<sup>®</sup>, which is equivalent to 540 ml (270 g) of Xyrem<sup>®</sup> per month. Providers may refer to the Quantity Limit Drugs and Diabetic Supplies data table on the Pharmacy Resources page of the Providers area of the Portal for the most current quantity limits.

## Revised Prior Authorization Drug Attachment Form for Xyrem®

Prior authorization requests for Xyrem® must be submitted on the Prior Authorization Drug Attachment for Xyrem®, F-01430 (01/2016). This form has been revised. The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. Prior authorization requests submitted on and after January 1, 2016, must be submitted on the revised form or the PA request will be returned to the provider.

Prior authorization requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

Prior authorization requests for Xyrem® may be submitted on the Portal, by fax, or by mail. Prior authorization requests for Xyrem® may **not** be submitted using the STAT-PA system.

ForwardHealth has revised the clinical criteria for Xyrem®.

#### Clinical Criteria for Xyrem®

Prior authorization requests for Xyrem® will only be approved for use to treat the following identified clinical conditions:

- Narcolepsy with cataplexy
- Narcolepsy without cataplexy

#### Narcolepsy with Cataplexy

Clinical criteria for approval of a PA request for Xyrem® to treat narcolepsy with cataplexy are **all** of the following:

- The member has narcolepsy with cataplexy.
- The member is at least 16 years of age.
- The member does not have a succinic semialdehyde dehydrogenase deficiency.
- The prescriber has counseled the member on the contraindication between Xyrem® and alcohol.
- The member has agreed to be abstinent from alcohol while being treated with Xyrem<sup>®</sup>.

- The member does not have a history of substance abuse, addiction, or diversion.
- The member is not currently taking any sedative hypnotics.
- The member is not currently taking central nervous system (CNS) depressants (i.e., anxiolytics, barbiturates, opioids) that could significantly impact daytime sleepiness.
- An overnight polysomnogram (PSG) sleep study and multiple sleep latency test (MSLT) have been performed for the member using standard protocols, confirming the member has narcolepsy. (Note: Test results for the PSG and MSLT, along with provider interpretation, must be submitted with the PA request.)
- At least one of the following is true:
  - ✓ The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with a stimulant.
  - ✓ The member has a medical condition that prevents treatment with a stimulant.
  - ✓ There is a clinically significant drug interaction with another medication the member is taking and a stimulant.
- At least one of the following is true:
  - ✓ The member has experienced an unsatisfactory therapeutic response that occurred after the medication had been titrated to a maximum recommended daily dose or experienced a clinically significant adverse drug reaction with modafinil or Nuvigil®.
  - ✓ The member has a medical condition that prevents treatment with modafinil or Nuvigil®.
  - ✓ There is a clinically significant drug interaction with another medication the member is taking and modafinil or Nuvigil®.
- The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction to at least one of the following:
  - ✓ Tricyclic antidepressant (TCA)
  - ✓ Selective serotonin reuptake inhibitor
  - ✓ Serotonin norepinephrine reuptake inhibitor (SNRI)

Initial PA requests for Xyrem® to treat narcolepsy with cataplexy may be approved for up to a maximum of 183 days.

In addition to documenting the previously listed clinical information on the Prior Authorization Drug Attachment for Xyrem®, medical records must be submitted with the PA request to support the member's condition of narcolepsy with cataplexy.

Renewal PA requests may be approved for up to a maximum of 365 days. Medical records must be submitted demonstrating clinical improvement, including a decrease in cataplexy or a decrease in the member's excessive daytime sleepiness (EDS). A decrease in a member's EDS must be supported by an Epworth sleepiness scale (ESS), maintenance of wakefulness test (MWT), or MSLT. Medical records must also reflect patient compliance with medication use and safety precautions for Xyrem®.

#### Narcolepsy Without Cataplexy

Clinical criteria for approval of a PA request for Xyrem® to treat narcolepsy without cataplexy are **all** of the following:

- The member has narcolepsy without cataplexy.
- The member is at least 16 years of age.
- The member does not have a succinic semialdehyde dehydrogenase deficiency.
- The prescriber has counseled the member on the contraindication between Xyrem<sup>®</sup> and alcohol.
- The member has agreed to be abstinent from alcohol while being treated with Xyrem<sup>®</sup>.
- The member does not have a history of substance abuse, addiction, or diversion.
- The member is not currently taking any sedative hypnotics.
- The member is not currently taking CNS depressants (i.e., anxiolytics, barbiturates, opioids) that could significantly impact daytime sleepiness.
- An overnight PSG sleep study and MSLT have been performed for the member using standard protocols, confirming the member has narcolepsy. (Note: Test

- results for the PSG and MSLT, along with provider interpretation, must be submitted with the PA request.)
- The member has EDS that interferes with normal activities on a daily basis.
- An ESS questionnaire, MWT, or MSLT has been performed for the member, confirming that the member has EDS. (*Note:* Test results for the ESS, MWT, and/or MSLT must be submitted with the PA request.)
- The prescriber ruled out or treated the member for other causes of EDS, including:
  - ✓ Other sleep disorders including sleep apnea.
  - Chronic pain or illness that disrupts normal sleep patterns.
  - ✓ Mood disorders such as depression.
  - Caffeine or nicotine use causing poor quality of nighttime sleep.
- At least one of the following is true:
  - ✓ The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with a stimulant.
  - ✓ The member has a medical condition that prevents treatment with a stimulant.
  - ✓ There is a clinically significant drug interaction with another medication the member is taking and a stimulant.
- At least one of the following is true:
  - ✓ The member has experienced an unsatisfactory therapeutic response that occurred after the medication had been titrated to a maximum recommended daily dose or experienced a clinically significant adverse drug reaction with modafinil or Nuvigil®.
  - ✓ The member has a medical condition that prevents treatment with modafinil or Nuvigil®.
  - ✓ There is a clinically significant drug interaction with another medication the member is taking and modafinil or Nuvigil®.

Initial PA requests for Xyrem® to treat narcolepsy without cataplexy may be approved for up to a maximum of 183 days.

In addition to documenting the previously listed clinical information on the Prior Authorization Drug Attachment for Xyrem®, medical records must be submitted with the PA request to support the member's condition of narcolepsy without cataplexy.

Renewal PA requests may be approved for up to a maximum of 365 days. Medical records must be submitted demonstrating clinical improvement, including a decrease in the member's EDS. A decrease in a member's EDS must be supported by an ESS, MWT, or MSLT. Medical records must also reflect patient compliance with medication use and safety precautions for Xyrem<sup>®</sup>.

#### **Quantity Limits**

Generally, ForwardHealth follows Food and Drug Administration-labeled dose and administration guidelines to establish quantity limits. The quantity limit allowed for a specific drug and drug strength is established to encourage prescribing and dispensing of the most cost-effective strength and quantity of a drug.

When a claim is submitted with a quantity that exceeds the limit, the claim will be denied.

For more information about quantity limit policy overrides, providers may refer to the Quantity Limits topic (topic #3444) in the Submission chapter of the Claims section of the Pharmacy service area of the Online Handbook.

#### Short-Acting Opioids Quantity Limits

Effective for DOS on and after January 1, 2016, ForwardHealth is changing the quantity limits for certain short-acting opioid products for which a quantity limit currently applies. This change is an effort to reduce the number of different quantity limits in the short-acting opioids drug category and to reduce the total number of short-acting opioids a member can receive per month. Most short-acting opioid products will now have a single quantity limit of 360 units per month. For a complete list of all quantity limits, refer to the Quantity Limit Drugs and

Diabetic Supplies data table on the Pharmacy Resources page of the Providers area of the Portal.

#### Copayment and Dispensing Fee for Brand Name Drugs Preferred Over Generic Drugs

ForwardHealth generally applies a generic copayment and dispensing fee to a brand name drug when a drug that previously required BMN PA moves to a preferred drug on the PDL and the available generic equivalents are non-preferred drugs.

This does not include brand name drugs that were preferred over generic equivalents because the generic equivalents are new to the marketplace and are not yet cost-effective when compared with brand pricing (i.e., a SMAC rate has not been established).

For drugs determined to be included in this policy,
ForwardHealth will automatically apply the generic
copayment when a specific brand name drug is preferred
over a generic equivalent. Providers do not need to indicate a
NCPDP DAW code on claims to ensure the generic
copayment deduction. In addition, ForwardHealth will
automatically apply a generic dispensing fee to claims for
which a specific brand name drug is preferred over the
generic equivalent.

The following table includes the most current list of drugs for which this policy applies. Drugs shown in bold letters are drugs that have been added to this list. This list is available on the Preferred Drug List Quick Reference Pharmacy Resources page of the Providers area of the Portal. Providers are encouraged to review the list closely to identify future changes.

Drug Class	Drug Name	Effective Date
Acne Agents,	Differin® 0.1%	01/01/2012
Topical	gel	
	Differin® cream	01/01/2012
Anticonvulsants	Depakote®	01/01/2012
	Sprinkles	
	Tegretol®	01/01/2016
	suspension	
	Tegretol®	01/01/2016
	tablets	
	Tegretol® XR	01/01/2012
	200mg	
	Tegretol® XR	01/01/2012
	400mg	
Antihypertensives,	Catapres-TTS®	01/01/2014
Sympatholytics		
Glucorticoids,	Pulmicort	01/01/2016
Inhaled	Respules®	
Immunomodulators,	Aldara®	01/01/2014
Topical		
Lipotropics, Fibric	TriCor <sup>®</sup>	07/01/2015
Acids		
Migraine Agents,	Imitrex <sup>®</sup>	07/01/2012
Injectable	Injection	
Migraine Agents,	Imitrex® Nasal	07/01/2012
Other		
Ophthalmics,	Tobradex <sup>®</sup>	01/01/2012
Anitbiotic-Steroid	suspension	
Combinations		
Opthalmics,	Alphagan® P	01/01/2012
Glaucoma-Other	0.15%	
Stimulants and	Adderall XR®	01/01/2012
Related Agents	1	

Noncovered Services section of the Pharmacy service area of the Online Handbook includes more information about dispensing an emergency supply of medication.

#### For More Information

Providers should refer to the Pharmacy service area of the Online Handbook on the Portal for more information about PDL policies.

## Information Regarding Managed Care Organizations

This *Update* contains fee-for-service policy for members enrolled in Medicaid and BadgerCare Plus who receive pharmacy services on a fee-for-service basis only. Pharmacy services for Medicaid members enrolled in the Program of All Inclusive Care for the Elderly (PACE) and the Family Care Partnership are provided by the member's managed care organization. Medicaid and BadgerCare Plus HMOs must provide at least the same benefits as those provided under fee-for-service.

The ForwardHealth Update is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Health Care Access and Accountability, Wisconsin Department of Health Services (DHS). The Wisconsin AIDS Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, Wisconsin DHS.

For questions, call Provider Services at 800-947-9627 or visit our website at www.forwardhealth.wi.gov/.
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#### **Expedited Emergency Supply**

As a result of changes made during the January 2016 PDL review, the Expedited Emergency Supply Request Drugs data table on the Pharmacy Resources page of the Providers area of the Portal has been updated. The Emergency Medication Dispensing topic (topic #1399) of the Covered Services and Requirements chapter of the Covered and

# ATTACHMENT 1 Changes to Pharmacy Prior Authorization Forms and Completion Instructions

The table below lists the pharmacy prior authorization forms and completion instructions that are new or have been revised, renamed, or discontinued as a result of the January 2016 Preferred Drug List review or as a result of other pharmacy policy changes. Providers should refer to the Forms page of the ForwardHealth Portal at www.forwardhealth.wi.gov/ for current copies of these forms and completion instructions. Unless otherwise noted, all form changes listed are effective January 1, 2016. The old versions of these forms and completion instructions will be moved to the Pharmacy-Related Forms and Completion Instructions archive page that is linked under the Archives section on the Pharmacy Resources page of the Portal. Additional information regarding changes to clinical criteria or submission options is noted under the applicable drug classes in this ForwardHealth Update.

Form Name	Form Number	Revised, Discontinued, or New	Effective Date
Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger	F-00556	Revised	01/01/2016
Completion Instructions	F-00556A	Revised	01/01/2016
Prior Authorization Drug Attachment for Xyrem®	F-01430	Revised	01/01/2016
Completion Instructions	F-01430A	Revised	01/01/2016
Prior Authorization/Preferred Drug List (PA/PDL) for Amphetamine Formulations	F-01672	New	01/01/2016
Completion Instructions	F-01672A	New	01/01/2016
Prior Authorization/Preferred Drug List (PA/PDL) for Belsomra®	F-01673	New	01/01/2016
Completion Instructions	F-01673A	New	01/01/2016
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Crohn's Disease	F-11305	Revised	01/01/2016
Completion Instructions	F-11305A	Revised	01/01/2016
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Hidradenitis Suppurativa	F-01674	New	01/01/2016
Completion Instructions	F-01674A	New	01/01/2016

Form Name	Form Number	Revised, Discontinued, or New	Effective Date
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Plaque Psoriasis	F-11306	Revised	01/01/2016
Completion Instructions	F-11306A	Revised	01/01/2016
Prior Authorization/Preferred Drug List (PA/PDL) for Stimulants and Related Agents	F-11097	Discontinued	01/01/2016
Completion Instructions	F-11097A	Discontinued	01/01/2016

#### **ATTACHMENT 2**

## Changes to the Preferred or Non-preferred Status of Drugs on the Preferred Drug List

The following table lists drugs that have had a change in their preferred or non-preferred status as a result of the January 2016 Preferred Drug List (PDL) review. The updated statuses are effective January 1, 2016. Drugs that have not been previously reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee are marked with an asterisk (\*). The complete Preferred Drug List Quick Reference is located on the Pharmacy Resources page of the Providers area of the ForwardHealth Portal at www.forwardhealth.wi.gov/.

Drug Class	Drug Name	Status Effective January 1, 2016
Alzheimer's Agents	memantine dose pack*	Preferred
	memantine tablet*	Preferred
	Namenda dose pack	Non-preferred
	Namzaric <sup>™</sup> *	Non-preferred
	rivastigmine transdermal*	Non-preferred
Anticonvulsants	carbamazepine suspension	Non-preferred
	carbamazepine tablet	Non-preferred
	felbamate suspension	Preferred
	felbamate tablet	Preferred
	Felbatol® suspension	Non-preferred
	Felbatol® tablet	Non-preferred
	lamotrigine ODT*	Non-preferred
	Tegretol® suspension*	Preferred
	Tegretol® tablet*	Preferred
	Trileptal® suspension	Non-preferred
Antihyperuricemics	colchicine capsule*	Non-preferred
	colchicine tablet*	Non-preferred
Antiparkinson's Agents	carbidopa/levodopa/entacapone	Preferred
	Rytary <sup>™</sup> *	Non-preferred
	Stalevo®	Non-preferred
Antipsoriatics, Topical	calcipotriene ointment	Preferred
	Taclonex® ointment	Non-preferred

Drug Class	Drug Name	Status Effective January 1, 2016
Antipsychotics	Abilify Maintena®*	Preferred
	aripipirazole*	Non-preferred
	fluphenazine decanoate*	Preferred
	Haldol® decanoate*	Preferred
	haloperidol deconoate*	Preferred
	Invega® Sustenna®*	Preferred
	Invega Trinza™*	Preferred
	Rexulti®*	Non-preferred
	Risperdal® Consta®*	Preferred
	Zyprexa® Relprevv <sup>™</sup> *	Preferred
Bile Salts	Cholbam™*	Non-preferred
Bronchodilators, Beta Agonist	ProAir® Respiclick*	Non-preferred
	Serevent Diskus	Preferred
COPD Agents	Daliresp <sup>®</sup>	Non-preferred
	Incruse® Ellipta®*	Non-preferred
	Spiriva® Respimat®*	Non-preferred
	Stiolto® Respimat®*	Non-preferred
Cough and Cold, Narcotic	Flowtuss <sup>™</sup> solution*	Non-preferred
	Hycofenix <sup>™</sup> solution*	Non-preferred
	Ninjacof-XG liquid OTC*	Non-preferred
Cytokine and CAM Antagonists	Cosentyx® pen injector*	Non-preferred
	Cosentyx® syringe*	Non-preferred
	Cimzia® syringe	Non-preferred
	Cimzia® kit	Non-preferred
Epinephrine, Self-Injected	Adrenaclick®*	Non-preferred
Glucocorticoids, Inhaled	Aerospan®	Preferred
	Arnuity™ Ellipta®*	Non-preferred
	budesonide 1mg respules*	Non-preferred
	Flovent® Diskus®	Non-preferred
	Flovent® HFA	Non-preferred
Glucocorticoids, Oral	prednisolone sodium phosphate ODT*	Non-preferred
Immunomodulators, Atopic Dermatitis	tacrolimus*	Non-preferred
Intranasal Rhinitis Agents	Astepro®	Non-preferred
<del>-</del>	olopatadine*	Non-preferred

Drug Class	Drug Name	Status Effective January 1, 2016
Methotrexate	methotrexate tablet*	Preferred
	methotrexate vial*	Preferred
	methotrexate PF vial*	Preferred
	Otrexup <sup>™</sup> auto injector*	Non-preferred
	Rasuvo® auto injector*	Non-preferred
	Rheumatrex® tablet dose pack*	Non-preferred
	Trexall™ tablet*	Non-preferred
Neuropathic Pain	duloxetine 40mg*	Non-preferred
	Irenka <sup>™</sup> *	Non-preferred
NSAIDs	celecoxib*	Non-preferred
	naproxen CR*	Non-preferred
	Tivorbex™*	Non-preferred
Ophthalmic Antibiotic-Steroid Combinations	Blephamide S.O.P.	Non-preferred
Ophthalmics for Allergic Conjunctivitis	Pazeo®*	Preferred
Ophthalmics, Glaucoma Agents	betaxolol	Non-preferred
	Cosopt® PF	Non-preferred
	metipranolol	Non-preferred
Otic Antibiotics	ofloxacin	Non-preferred
Sedative Hypnotics	Belsomra®*	Non-preferred
Steroids, Topical High	fluocinonide cream	Non-preferred
	fluocinonide emollient	Non-preferred
	fluocinonide gel	Non-preferred
	fluocinonide ointment	Non-preferred
	fluocinonide solution	Non-preferred
	triamciniolone acetonide aerosol*	Non-preferred
Stimulants and Related Agents	Adderall XR®	Non-preferred
	amphetamine salt combo (immediate release)	Non-preferred
	Aptsensio XR <sup>™</sup>	Non-Preferred
	Dexedrine® tablet*	Non-preferred
	Dexedrine® Spansule	Non-preferred
	dextroamphetamine capsule ER	Non-preferred
	dextroamphetamine tablet	Non-preferred
	Evekeo™*	Non-preferred
	guanfacine ER*	Preferred
	methylphenidate chewable tablets*	Non-preferred
	Procentra®	Non-preferred

<sup>\*</sup> Drug was not previously reviewed. For more information, refer to the Changes to the Preferred or Non-preferred Status of Drugs on the Preferred Drug List section of this *ForwardHealth Update*.

# ATTACHMENT 3 Grandfathering for Stimulants and Related Agents — Amphetamine Formulations

Drugs Eligible for Grandfathering	Details
DEXEDRINE® SPANSULE DEXTROAMPHETAMINE TABLET DEXEDRINE® TABLET	Members identified to be taking any one of these four products will be grandfathered to allow any one of these formulations.
DEXTROAMPHETAMINE CAPSULE ER	Note: Dexedrine® Spansule will no longer qualify for the generic copayment and dispensing fee that ForwardHealth applies to brand name drugs that are preferred over their generic equivalents.
AMPHETAMINE SALT COMBO (IMMEDIATE RELEASE)	Members identified to be taking this product will be grandfathered to <b>allow brand</b> name Adderall XR® or generic immediate release amphetamine salt combo only.
	<i>Note:</i> For members approved to receive brand name Adderall XR®, ForwardHealth will continue to automatically apply a generic copayment and a generic dispensing fee to claims for brand name Adderall XR®.
AMPHETAMINE SALT COMBO ER	Members identified to be taking this product will be grandfathered to <b>allow brand</b> name Adderall XR® or generic immediate release amphetamine salt combo only.
	Members will not be grandfathered on generic amphetamine salt combo ER.
	Prior authorization requests that have already been approved for generic amphetamine salt combo ER will be honored until they expire or until the approved days' supply is used up.
	If it is medically necessary for a member to remain on generic amphetamine salt combo ER, the provider is required to obtain PA. The member must meet the clinical criteria for amphetamine formulations and the clinical criteria for amphetamine salt combo ER.
	<i>Note:</i> For members approved to receive brand name Adderall XR®, ForwardHealth will continue to automatically apply a generic copayment and a generic dispensing fee to claims for brand name Adderall XR®.
ADDERALL XR®	Members identified to be taking this product will be grandfathered to allow brand name Adderall XR® or generic immediate release amphetamine salt combo only.
	<i>Note:</i> For members approved to receive brand name Adderall XR®, ForwardHealth will continue to automatically apply a generic copayment and a generic dispensing fee to claims for brand name Adderall XR®.

Drugs Eligible for Grandfathering	Details
ZENZEDI®	Members identified to be taking this product will be grandfathered to allow this
	formulation only.
	Note: An approved PA request is not required for any child 6 years of age or
	younger.
PROCENTRA®	Members identified to be taking this product will be grandfathered to allow this
	formulation only.
	Note: An approved PA request is not required for any child 6 years of age or
	younger.
EVEKEO™	Members identified to be taking this product will be grandfathered to allow this
	formulation only.
DESOXYN®	Members identified to be taking this product will be grandfathered to allow this
	formulation only.
DEXTROAMPHETAMINE SOLUTION	Members identified to be taking this product will be grandfathered to allow this
(ORAL)	formulation only.
METHAMPHETAMINE	Members identified to be taking this product will be grandfathered to allow this
	formulation only.