



**Update**  
**December 2016**  
**No. 2016-54**

**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 2017 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, 2017, 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, 2017, 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 [www.forwardhealth.wi.gov/](http://www.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 2017 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, 2017. 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.

### ***A Prescriber's 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 non-preferred 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
- Anticonvulsants drug class
- Antidepressants, other drug class
- Antidepressants, selective serotonin reuptake inhibitor 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 non-preferred 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 non-preferred 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 non-preferred 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.

## ***A Pharmacy Provider's 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 Non-Preferred Status of Drugs on the Preferred Drug List**

On November 2, 2016, 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, 2017. 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 2, 2016, meeting are effective January 1, 2017, 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*.

## **Alzheimer's Agents**

Memantine products and Namenda XR® will be diagnosis restricted. 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.

As a reminder, the following policy for clinical information for diagnosis-restricted drug requests will now apply to memantine products and Namenda XR®.

## ***Clinical Information for Diagnosis-Restricted Drug Requests***

If the prescriber writes a prescription with a diagnosis outside the ForwardHealth-allowed diagnoses for a drug, the prescriber is required to include peer-reviewed medical literature to support the proven efficacy and safety of the requested use of the drug. Documentation of previous treatments and detailed reasons why other covered drug treatments were discontinued or not used are required. Medical records should be provided as necessary to support the PA request. This information should be documented in Section V (Clinical Information for Diagnosis-Restricted Drug Requests) of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016).

When completing the PA/DGA form, prescribers should provide the diagnosis code and description, complete Section V (Clinical Information for Diagnosis-Restricted Drug Requests), and use Section VIII (Additional Information), if needed. Prescribers are reminded to provide a handwritten signature and date on the form before submitting it to the pharmacy provider where the prescription will be filled. The pharmacy provider is required to complete a Prior Authorization Request Form (PA/RF), F-11018 (05/13), before submitting the forms and supporting documentation to ForwardHealth. Prescribers should not submit PA/DGA forms to ForwardHealth.

For more information about diagnosis-restricted drugs, providers may refer to the Prior Authorization/Drug Attachment topic (topic #15937) in the Forms and Attachments chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

Prior authorization requests for drugs with a diagnosis outside the ForwardHealth-allowed diagnoses may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

Previously, BadgerCare Plus, Medicaid, and SeniorCare members who were 44 years of age or younger and were taking Namenda (as identified from claims history) prior to February 15, 2013, were allowed to continue receiving memantine, Namenda, or Namenda XR® products without

PA. Effective for DOS on and after January 1, 2017, current PA policies and diagnosis code restrictions will apply for these members if **one** of the following is true:

- They do **not** have other primary insurance on file with ForwardHealth and have no claim activity for any memantine, Namenda, or Namenda XR® products for DOS in the last six months of 2016.
- They have other primary insurance on file with ForwardHealth and have no claim activity for any memantine, Namenda, or Namenda XR® products for any DOS in 2016.

### **Memantine**

Memantine tablets will remain a preferred drug.

Prior authorization was previously required for all memantine products for members who were 44 years of age or younger, regardless of a drug's preferred or non-preferred status. For members 44 years of age or younger with an allowable diagnosis code, PA will no longer be required for preferred memantine products.

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

### **Memantine Solution and Namenda XR®**

Memantine solution and Namenda XR® will remain non-preferred drugs requiring PA.

Currently, all PA requests for memantine solution and Namenda XR® for members who are 44 years of age or younger have to be submitted using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form and the PA/RF. Effective for DOS on and after January 1, 2017, PA requests for memantine solution and Namenda XR® for members 44 years of age or younger with an allowable diagnosis code will no longer have to be submitted on the PA/DGA form. These PA requests must be submitted on the PA/PDL Exemption Request form.

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 may submit PA requests for memantine solution and Namenda XR® with an allowable diagnosis code using the STAT-PA system, on the Portal, by fax, or by mail.

## **Antipsychotics**

### **Generic Quetiapine Fumarate ER**

Generic quetiapine fumarate ER, an antipsychotic drug, requires PA. All established clinical criteria for non-preferred drugs and, if applicable, all PA policy for antipsychotic drugs for children 7 years of age and younger will apply. In addition, the following PA criteria also apply to generic quetiapine fumarate ER.

#### *Clinical Criteria for Generic Quetiapine Fumarate ER*

In addition to the member meeting established clinical criteria for non-preferred drugs and, if applicable, PA policy for antipsychotic drugs for children 7 years of age and younger, the prescriber is required to submit detailed clinical justification for prescribing generic quetiapine fumarate ER instead of brand name Seroquel XR®. This clinical information must document why the member cannot use brand name Seroquel XR®, including why it is medically necessary that the member receive generic quetiapine fumarate ER instead of brand name Seroquel XR®.

#### *Submitting Prior Authorization Requests for Generic Quetiapine Fumarate ER*

Prior authorization requests for generic quetiapine fumarate ER for members 8 years of age and older 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 PA/DGA form
- The PA/PDL Exemption Request form
- The PA/RF

Prior authorization requests for generic quetiapine fumarate ER for children 7 years of age and younger 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 PA/DGA form
- The Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form, F-00556 (01/2016)
- The PA/RF

Prior authorization requests for generic quetiapine fumarate ER may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

## **Cytokine and Cell Adhesion Molecule Antagonist Drugs**

ForwardHealth has revised the following terms:

- “Plaque psoriasis” has been changed to “psoriasis.”
- “Polyarticular juvenile rheumatoid arthritis (RA)” has been changed to “juvenile idiopathic arthritis (JIA).”

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

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)
- Psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis and JIA

- Ulcerative colitis
- Uveitis

Prior authorization requests for cytokine and CAM antagonist drugs will only be approved for **one cytokine and CAM antagonist drug per member**. ForwardHealth does not cover treatment with more than one cytokine and CAM antagonist drug.

As a reminder, the following policy for obtaining provider-administered drugs will continue to apply to all cytokine and CAM antagonist 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.

For more information about provider-administered drugs, providers may refer to the Provider-Administered Drugs topic (topic #5697) in the Covered Services and Requirements chapter of the Covered and Noncovered Services section of the Online Handbook.

## ***Non-Preferred Oral Agents***

The following will **not** be considered for PA requests 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 Ankylosing Spondylitis form, F-11304 (01/2017)
- Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Hidradenitis Suppurativa form, F-01674 (01/2017)

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, 2017, 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.

## ***Revised and Renamed Prior Authorization/Preferred Drug List for Cytokine and CAM Antagonist Drugs for Plaque Psoriasis Form***

ForwardHealth has revised and renamed the 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 form has been renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Psoriasis form, F-11306 (01/2017).

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, 2017, 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 Forms for Cytokine and CAM Antagonist Drugs***

ForwardHealth has created 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 and Ulcerative Colitis form, F-01950 (01/2017)
- Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), and Psoriatic Arthritis form, F-01951 (01/2017)
- Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Uveitis and Neonatal Onset Multisystem Inflammatory Disease (NOMID) form, F-01952 (01/2017)

Prior authorization requests submitted on and after January 1, 2017, must be submitted on the appropriate new form or they will be returned to the provider.

## ***Discontinued Prior Authorization Forms for Cytokine and CAM Antagonist Drugs***

Effective for PA requests submitted on and after January 1, 2017, the following PA/PDL for Cytokine and CAM Antagonist Drugs forms will no longer be accepted:

- 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 Psoriatic Arthritis form, F-11307 (12/12)
- 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)

- Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Ulcerative Colitis form, F-00694 (12/13)

The previously listed forms are being discontinued. They 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.

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

### ***Clinical Criteria for Cytokine and CAM 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.

Clinical criteria for approval of a PA request for preferred cytokine and CAM antagonist drugs used 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 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) inhibitors

- Sulfasalazine

- The prescriber has indicated what other drug therapies the member has attempted for ankylosing spondylitis (e.g., glucocorticoids or IV immunomodulators such as infliximab).

Cimzia®, Cosentyx®, and Simponi® are non-preferred drugs used to treat ankylosing spondylitis.

A copy of the member's medical records must be submitted with all PA requests for non-preferred drugs. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

Clinical criteria for approval of a PA request for Cimzia®, Cosentyx®, or Simponi® are **both** of the following:

- The member meets **all** clinical criteria for the preferred cytokine and CAM antagonist drugs listed above.
- The member has 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.

Prior authorization requests for cytokine and CAM antagonist drugs used to treat ankylosing spondylitis must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Ankylosing Spondylitis form.

Prior authorization requests for preferred cytokine and CAM antagonist drugs used to treat ankylosing spondylitis may be submitted using the STAT-PA system, on the Portal, by fax, or by mail. Prior authorization requests for non-preferred cytokine and CAM antagonist drugs used to treat ankylosing spondylitis may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

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

Humira® is a preferred drug used to treat Crohn's disease.



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

- The member has Crohn's disease.
- The prescription is written by a gastroenterologist or through a gastroenterology consultation.
- 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:
  - ✓ 6-mercaptopurine (6MP)
  - ✓ Azathioprine
  - ✓ **Oral aminosalicylates (balsalazide, mesalamine, olsalazine, or sulfasalazine)**
  - ✓ Methotrexate
- The prescriber has indicated what other drug therapies the member has attempted for Crohn's disease (e.g., antibiotics, glucocorticoids, or IV immunomodulators such as infliximab).

Cimzia® and Stelara® are non-preferred drugs used to treat Crohn's disease.

A copy of the member's medical records must be submitted with all PA requests for non-preferred drugs. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

Clinical criteria for approval of a PA request for Cimzia® or Stelara® are **both** of the following:

- The member meets **all** clinical criteria for the preferred cytokine and CAM antagonist drugs listed above.
- The member has 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.

Prior authorization requests for cytokine and CAM antagonist drugs used to treat Crohn's disease must be submitted on the PA/PDL for Cytokine and CAM

Antagonist Drugs for Crohn's Disease and Ulcerative Colitis form.

Prior authorization requests for Humira® used to treat Crohn's disease may be submitted using the STAT-PA system, on the Portal, by fax, or by mail. Prior authorization requests for non-preferred cytokine and CAM antagonist drugs used to treat Crohn's disease may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

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

Humira® is a preferred drug used to treat hidradenitis suppurativa.

Clinical criteria for approval of a PA request for preferred cytokine and CAM antagonist drugs used 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 derroofing 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:
    - Oral antibiotics
    - Oral retinoids
- The prescriber has indicated what other drug therapies the member has attempted for hidradenitis suppurativa (e.g., topicals or IV immunomodulators such as infliximab).

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

Prior authorization requests for Humira® used to treat hidradenitis suppurativa may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

*Clinical Criteria for Cytokine and CAM Antagonist Drugs for Neonatal Onset Multisystem Inflammatory Disease*

Kineret® is a non-preferred drug used to treat NOMID.

Clinical criteria for approval of a PA request for Kineret® used to treat NOMID are **both** of the following:

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

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.

Prior authorization requests for cytokine and CAM antagonist drugs used to treat NOMID must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Uveitis and NOMID form.

Prior authorization requests for Kineret® used to treat NOMID may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

*Clinical Criteria for Cytokine and CAM Antagonist Drugs for Psoriasis*

Enbrel® and Humira® are preferred drugs used to treat psoriasis.

Otezla® will become a preferred drug used to treat psoriasis.

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

- The member has psoriasis.
- The provider has indicated the areas affected and the approximate percent of body surface area involved.
- 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
- The prescriber has indicated what other drug therapies the member has attempted for psoriasis (e.g., topicals, glucocorticoids, or IV immunomodulators such as infliximab).

Cosentyx®, Stelara®, and Taltz® are non-preferred drugs used to treat psoriasis.

A copy of the member's medical records must be submitted with all PA requests for non-preferred drugs. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

Clinical criteria for approval of a PA request for Cosentyx®, Stelara®, or Taltz® are **both** of the following:

- The member meets **all** clinical criteria for the preferred cytokine and CAM antagonist drugs listed above.
- The member has 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.

Prior authorization requests for cytokine and CAM antagonist drugs used to treat psoriasis must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Psoriasis form.

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

submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

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

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

Otezla® will become a preferred drug used to treat psoriatic arthritis.

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

- The member has 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 axial symptoms of psoriatic arthritis.
  - ✓ 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:
    - Azathioprine
    - Hydroxychloroquine
    - Leflunomide
    - Methotrexate
- The prescriber has indicated what other drug therapies the member has attempted for psoriatic arthritis (e.g., NSAIDs, COX-2 inhibitors, glucocorticoids, or IV immunomodulators such as infliximab).

Cimzia®, Cosentyx®, Simponi®, and Stelara® are non-preferred drugs used to treat psoriatic arthritis.

A copy of the member's medical records must be submitted with all PA requests for non-preferred drugs. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

Clinical criteria for approval of a PA request for Cimzia®, Cosentyx®, Simponi®, or Stelara® are **both** of the following:

- The member meets **all** clinical criteria for the preferred cytokine and CAM antagonist drugs listed previously.
- The member has 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.

Prior authorization requests for cytokine and CAM antagonist drugs used to treat psoriatic arthritis must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for RA, JIA, and Psoriatic Arthritis form.

Prior authorization requests for preferred cytokine and CAM antagonist drugs used to treat psoriatic arthritis may be submitted using the STAT-PA system, on the Portal, by fax, or by mail. Prior authorization requests for non-preferred cytokine and CAM antagonist drugs used to treat psoriatic arthritis may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

### *Clinical Criteria for Cytokine and CAM Antagonist Drugs for Rheumatoid Arthritis and Juvenile Idiopathic Arthritis*

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

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

- The member has RA.
- The prescription is written by a rheumatologist or through a rheumatology consultation.
- 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:
  - ✓ Azathioprine
  - ✓ Hydroxychloroquine
  - ✓ Leflunomide
  - ✓ Methotrexate

✓ Sulfasalazine

- The prescriber has indicated what other drug therapies the member has attempted for RA (e.g., NSAIDs, COX-2 inhibitors, glucocorticoids, or IV immunomodulators such as infliximab).

Actemra® subQ solution, Cimzia®, Kineret®, Orencia® subQ solution, Simponi®, and Xeljanz®/Xeljanz® XR are non-preferred drugs used to treat RA.

A copy of the member's medical records must be submitted with all PA requests for non-preferred drugs. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

Clinical criteria for approval of a PA request for Actemra® subQ solution, Cimzia®, Kineret®, Orencia® subQ solution, Simponi®, or Xeljanz®/Xeljanz® XR are **both** of the following:

- The member meets **all** clinical criteria for the preferred cytokine and CAM antagonist drugs listed above.
- At least **one** of the following is true:
  - ✓ The member has 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®.
  - ✓ The member has taken Enbrel® or Humira® along with one or more disease-modifying antirheumatic drugs for **at least three** consecutive months, and the member continues to have moderate to severe disease activity.

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

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

- 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:

✓ Azathioprine  
✓ Leflunomide  
✓ Methotrexate  
✓ Sulfasalazine

- The prescriber has indicated what other drug therapies the member has attempted for JIA (e.g., NSAIDs, COX-2 inhibitors, glucocorticoids, or IV immunomodulators such as infliximab).

Prior authorization requests for cytokine and CAM antagonist drugs used to treat RA and JIA must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for RA, JIA, and Psoriatic Arthritis form.

Prior authorization requests for preferred cytokine and CAM antagonist drugs used to treat RA and JIA may be submitted using the STAT-PA system, on the Portal, by fax, or by mail. Prior authorization requests for non-preferred cytokine and CAM antagonist drugs used to treat RA may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

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

Humira® is a preferred drug used to treat ulcerative colitis.

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

- The member has ulcerative colitis.
- The prescription is written by a gastroenterologist or through a gastroenterology consultation.
- The member has taken **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:
  - ✓ 6-mercaptopurine (6MP)
  - ✓ Azathioprine

- ✓ Oral aminosalicylates (balsalazide, mesalamine, olsalazine, or sulfasalazine)
- The prescriber has indicated what other drug therapies the member has attempted for ulcerative colitis (e.g., antibiotics, glucocorticoids, or IV immunomodulators such as infliximab).

Simponi™ is a non-preferred drug used to treat ulcerative colitis.

A copy of the member's medical records must be submitted with all PA requests for non-preferred drugs. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

Clinical criteria for approval of a PA request for Simponi™ are **both** of the following:

- The member meets **all** clinical criteria for the preferred cytokine and CAM antagonist drugs listed above.
- The member has 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.

Prior authorization requests for cytokine and CAM antagonist drugs used to treat ulcerative colitis must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Crohn's Disease and Ulcerative Colitis form.

Prior authorization requests for Humira® used to treat ulcerative colitis may be submitted using the STAT-PA system, on the Portal, by fax, or by mail. Prior authorization requests for non-preferred cytokine and CAM antagonist drugs used to treat ulcerative colitis may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

### *Clinical Criteria for Cytokine and CAM Antagonist Drugs for Uveitis*

Humira® is a preferred drug used to treat uveitis.

Clinical criteria for approval of a PA request for Humira® used to treat uveitis are **all** of the following:

- The member has noninfectious uveitis.
- The prescription is written by an ophthalmologist or rheumatologist or through an ophthalmology or rheumatology consultation.
- **At least one** of the following is true:
  - ✓ The member has received glucocorticoid eye drops for **at least three** consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.
  - ✓ The member has received oral glucocorticoid therapy for **at least three** consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.

Prior authorization requests for cytokine and CAM antagonist drugs used to treat uveitis must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Uveitis and NOMID form.

Prior authorization requests for Humira® used to treat uveitis may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

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 Online Handbook.

## **Hepatitis C Agents**

Epclusa® will become a preferred drug for members who have chronic hepatitis C virus (HCV) genotype 2 or 3 infection.

Daklinza™ will become a non-preferred drug.

## ***Revised Prior Authorization Drug Attachment for Hepatitis C Agents***

ForwardHealth has revised the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (01/2017). 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, 2017, 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.

Clinical PA is required for all hepatitis C agents, including preferred drugs.

Viekira Pak™/Viekira XR™ and Zepatier™ are the preferred drugs for members who have chronic HCV genotype 1 infection. Prior authorization requests for other hepatitis C agents for members who have chronic HCV genotype 1 infection will not be considered unless the member is clinically ineligible for treatment with Viekira Pak™/Viekira XR™ and Zepatier™ due to a medical or medication contraindication.

Epclusa® is the preferred drug for members who have chronic HCV genotype 2 or 3 infection. Prior authorization requests for other hepatitis C agents for members who have chronic HCV genotype 2 or 3 infection will not be considered unless the member is clinically ineligible for treatment with Epclusa® due to a medical or medication contraindication.

Technivie™ and Zepatier™ are the preferred drugs for members who have chronic HCV genotype 4 infection. Prior authorization requests for other hepatitis C agents for members who have chronic HCV genotype 4 infection will not be considered unless the member is clinically ineligible for treatment with Technivie™ and Zepatier™ due to a medical or medication contraindication.

Prior authorization requests for hepatitis C agents must be completed and signed by prescribers. Initial PA requests for hepatitis C agents must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents form. Renewal PA requests for hepatitis C agents must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form, F-01248 (08/2016).

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

Prior authorization requests for hepatitis C agents may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

*Note:* When two or more hepatitis C agents are used as a **combined** treatment (e.g., Daklinza™ as a combined treatment with Sovaldi®), providers should not submit a separate PA request form for each drug. For initial PA requests, hepatitis C agents that are used for a combined treatment must be submitted on **one** Prior Authorization Drug Attachment for Hepatitis C Agents form and one completed PA/RF. For renewal PA requests, hepatitis C agents that are used for a combined treatment must be submitted on one Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form. A PA/RF should not be submitted for hepatitis C agents renewal requests. Amendment PA requests for hepatitis C agents that are used for a combined treatment must be submitted on **one** Prior Authorization Amendment Request form, F-11042 (07/12).

Only HCV treatment prescribed by a board-certified gastroenterologist or a board-certified infectious disease provider for a member who is 18 years of age or older will be considered for review. If the prescriber is a mid-level practitioner, he or she must have a collaborative relationship with a physician board-certified in gastroenterology or a physician board-certified in infectious disease.

### ***Clinical Information That Must Be Documented on All Initial Prior Authorization Requests for Hepatitis C Agents***

For initial PA requests for hepatitis C agents, prescribers are required to complete and sign the Prior Authorization Drug Attachment for Hepatitis C Agents form and submit the form to the pharmacy where the prescription will be filled. Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for Hepatitis C Agents form and a completed PA/RF to ForwardHealth.

The clinical information that must be submitted with all initial PA requests for hepatitis C agents are **all** of the following:

- Lab data (within the last six months), including the following:
  - ✓ Albumin test
  - ✓ Complete blood count
  - ✓ Hepatitis C virus genotype
  - ✓ Hepatitis C virus-ribonucleic acid (HCV-RNA) level
  - ✓ International normalized ratio
  - ✓ Liver function test
  - ✓ Serum creatinine test
- Tests (if performed), including the following:
  - ✓ Liver computed tomography (CT) scan, ultrasound, or MRI results
  - ✓ Liver biopsy results
  - ✓ Transient ultrasound elastography (FibroScan®) results
  - ✓ Magnetic resonance elastography (MRE) results
  - ✓ Shear wave elastography (SWE) results
- Hepatitis C virus clinical data, including the following:
  - ✓ Likely source of the HCV infection and date diagnosed
  - ✓ Current medical records for HCV assessment and treatment
  - ✓ History of coinfection with hepatitis A, hepatitis B, or HIV
  - ✓ History of liver transplant or on liver transplant wait list
- If cirrhotic, documentation of the following clinical assessments:
  - ✓ Child-Turcotte-Pugh (CTP) score
  - ✓ Hepatocellular carcinoma status based on liver CT, ultrasound, or MRI performed within the last six months
  - ✓ Presence and treatment of any of the following:
    - Ascites
    - Esophageal varices
    - Hepatic encephalopathy
    - Jaundice
    - Portal hypertension
- Hepatitis C medication treatment history, including the following:
  - ✓ Details of when treatment occurred
  - ✓ Medications taken and compliance
  - ✓ Treatment results (e.g., null response, partial response, or relapse)
- From the member's primary care provider, a current history and physical, including complete problem list and medication list
- Current and past psychosocial history including alcohol and illicit drug use
- Planned HCV treatment regimen

ForwardHealth requires the following to confirm a Metavir score of F2 (portal fibrosis with a few septa) or greater:

- Magnetic resonance elastography of 3.66 kPa or greater
- Shear wave elastography demonstrating a Metavir score of F2 (portal fibrosis with a few septa) or greater (Documentation of the specific SWE device used and the manufacturer literature regarding proper interpretation of the test result value, based on the device used, must be included to support the test results.)
- FibroScan® of 7.1 kPa or greater
- Liver biopsy

If the required documentation is not included on or with the Prior Authorization Drug Attachment for Hepatitis C Agents form, the PA request will be considered incomplete and will be returned to the provider or denied.

Initial PA requests for hepatitis C agents may be approved for up to a maximum of eight weeks.

Depending on the treatment course that has been approved, PA requests may be renewed for additional weeks if the member's HCV-RNA is less than 25 IU/mL.

For renewal PA requests, a copy of the member's HCV-RNA level lab results needs to be submitted with each renewal request for treatment weeks 4 and 12, as applicable.

Prior authorization requests for retreatment of members due to reinfection will be denied.

### ***Pharmacy Provider-Specific Prior Authorization Requests for Hepatitis C Agents***

Prior authorization requests for hepatitis C agents included in the hepatitis C agents drug class on the PDL are approved as pharmacy provider-specific. This approach is used to ensure continuity of care for members approved for treatment with these complex drug therapies. When a PA request is approved for drugs in this class, the pharmacy provider will be notified of the pharmacy provider-specific PA status via the decision notice letter. ForwardHealth recommends that the pharmacy provider inform the member of the pharmacy provider-specific PA requirement. The provider should explain to the member that the drug therapy authorized must be dispensed by the pharmacy provider approved under the PA request.

Pharmacy providers should not submit PA requests for hepatitis C agents if they do not intend to also dispense the entire drug therapy approved under the PA to the member. If the member needs to discontinue receiving the drug from the approved pharmacy provider once the approved treatment has begun, the pharmacy provider is required to contact Provider Services. Provider Services will work with the pharmacy provider on the approved PA request to ensure the member does not experience a disruption of therapy, and if necessary, will facilitate the transfer of the PA to a new pharmacy provider.

### ***Renewal Prior Authorization Requests for Hepatitis C Agents***

For renewal PA requests for hepatitis C agents, prescribers should complete and sign the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form and submit the form to the pharmacy where the prescription will be filled. The member's HCV-RNA levels and a copy of the actual laboratory report are required to be submitted with each renewal PA request for hepatitis C agents. Pharmacy providers are required to submit to ForwardHealth the completed Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form and a completed Prior Authorization Amendment Request form. A PA/RF should **not** be submitted.

### ***Hepatitis C Agents, Epclusa®***

Epclusa® is a preferred drug that requires clinical PA for members who have chronic HCV genotype 2 or 3 infection.

Epclusa® is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 4, 5, or 6 infection.

### ***Prior Authorization Requests That Will Be Considered for Review***

Only PA requests for Epclusa® for members with genotype 1, 2, 3, 4, 5, or 6 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Moderate decompensated cirrhosis (i.e., CTP class B)
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

*Note:* For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak™/Viekira XR™ and Zepatier™ due to a medical or medication contraindication. For moderate decompensated cirrhosis (i.e., CTP class B) HCV genotype 1 infection, the member must be clinically ineligible for treatment with Harvoni® due to a



medical or medication contraindication. For HCV genotype 4 infection, the member must be clinically ineligible for treatment with Technivie™ and Zepatier™ due to a medical or medication contraindication. For HCV genotype 5 or 6 infection, the member must be clinically ineligible for treatment with Harvoni® due to a medical or medication contraindication.

Epclusa® treatment regimens will only be approved for a maximum of 12 weeks of treatment.

### *Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied*

Prior authorization requests for Epclusa® will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™/Viekira XR™ and Zepatier™.
- The member has chronic HCV genotype 1 infection with moderate decompensated cirrhosis (i.e., CTP class B) and does not have a medical or medication contraindication for treatment with Harvoni®.
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie™ and Zepatier™.
- The member has chronic HCV genotype 5 or 6 infection and does not have a medical or medication contraindication for treatment with Harvoni®.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has received a liver transplant.
- The member has HCV infection and cirrhosis with severe liver functional compromise (i.e., CTP class C). Currently, there is no evidence to support that HCV treatment of members with end-stage liver disease impacts morbidity or mortality. The severity of liver damage present in decompensated liver disease makes it unlikely that treating the underlying infection would lead to meaningful liver function improvement. The only

definitive treatment for end-stage liver disease is a liver transplant.

- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Harvoni®, Sovaldi®, or a sofosbuvir-containing product.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

### ***Hepatitis C Agents, Technivie™***

Technivie™ is a preferred drug that requires clinical PA for members who have chronic HCV genotype 4 infection.

### *Prior Authorization Requests That Will Be Considered for Review*

Only PA requests for Technivie™ for members with genotype 4 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

### *Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied*

Prior authorization requests for Technivie™ will be denied in the following circumstances:

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life

expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).

- The member has cirrhosis.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Technivie™ or Viekira Pak™/Viekira XR™.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

### ***Hepatitis C Agents, Viekira Pak™/Viekira XR™***

Viekira Pak™ and Viekira XR™ are preferred drugs that require clinical PA for members who have chronic HCV genotype 1 infection.

#### ***Prior Authorization Requests That Will Be Considered for Review***

Only PA requests for Viekira Pak™/Viekira XR™ for members with genotype 1 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)
- Liver transplant recipients with or without fibrosis or liver transplant recipients with compensated cirrhosis (i.e., CTP class A)

#### ***Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied***

Prior authorization requests for Viekira Pak™/Viekira XR™ will be denied in the following circumstances:

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Technivie™ or Viekira Pak™/Viekira XR™.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

### ***Hepatitis C Agents, Zepatier™***

Zepatier™ is a preferred drug that requires clinical PA for members who have chronic HCV genotype 1 or 4 infection.

#### ***Prior Authorization Requests That Will Be Considered for Review***

Only PA requests for Zepatier™ for members with genotype 1 or 4 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative

glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

Members with genotype 1a infection must be tested for the presence of HCV with NS5A resistance-associated polymorphisms prior to initiating a PA request for Zepatier™.

### *Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied*

Prior authorization requests for Zepatier™ will be denied in the following circumstances:

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Zepatier™.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

## ***Hepatitis C Agents, Daklinza™***

Daklinza™ (combined with Sovaldi® with or without ribavirin) is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 3 infection.

### *Prior Authorization Requests That Will Be Considered for Review for Use of Daklinza™ as a Combined Treatment with Sovaldi® with or Without Ribavirin*

Only PA requests for the use of Daklinza™ as a combined treatment with Sovaldi® with or without ribavirin for members with genotype 1 or 3 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Moderate decompensated cirrhosis (i.e., CTP class B)
- Liver transplant recipients with or without fibrosis or liver transplant recipients with compensated cirrhosis (i.e., CTP class A)
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

*Note:* For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak™/Viekira XR™ and Zepatier™ due to a medical or medication contraindication. For moderate decompensated cirrhosis (i.e., CTP class B) HCV genotype 1 infection, the member must be clinically ineligible for treatment with Harvoni® due to a medical or medication contraindication. For HCV genotype 3 infection, the member must be clinically ineligible for treatment with Epclusa® due to a medical or medication contraindication.

Members with genotype 1a infection with cirrhosis must be screened for the presence of NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93. If the presence of NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93 is detected, treatment will not be considered for review.

Daklinza™ treatment regimens will only be approved for a maximum of 12 weeks of treatment unless the member is ribavirin ineligible or intolerant.

*Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied for Use of Daklinza™ as a Combined Treatment with Sovaldi® with or Without Ribavirin*

Prior authorization requests for the use of Daklinza™ as a combined treatment with Sovaldi® with or without ribavirin will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™/Viekira XR™ and Zepatier™.
- The member has chronic HCV genotype 1 infection with moderate decompensated cirrhosis (i.e., CTP class B) and does not have a medical or medication contraindication for treatment with Harvoni®.
- The member has chronic HCV genotype 3 infection and does not have a medical or medication contraindication for treatment with Epclusa®.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis with severe liver functional compromise (i.e., CTP class C). Currently, there is no evidence to support that HCV treatment of members with end-stage liver disease impacts morbidity or mortality. The severity of liver damage present in decompensated liver disease makes it unlikely that treating the underlying infection would lead to meaningful liver function improvement. The only definitive treatment for end-stage liver disease is a liver transplant.
- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Daklinza™, Sovaldi®, or a sofosbuvir-containing product.

- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

***Hepatitis C Agents, Harvoni®***

Harvoni® is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 4, 5, or 6 infection.

*Prior Authorization Requests That Will Be Considered for Review*

Only PA requests for Harvoni® for members with genotype 1, 4, 5, or 6 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Moderate decompensated cirrhosis (i.e., CTP class B) for members who have chronic HCV genotype 1 infection
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)
- Liver transplant recipients with or without fibrosis or liver transplant recipients with compensated cirrhosis (i.e., CTP class A)

*Note:* For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak™/Viekira XR™ and Zepatier™ due to a medical or medication contraindication. For HCV genotype 4 infection, the member must be clinically ineligible for treatment with

Technivie™ and Zepatier™ due to a medical or medication contraindication.

For treatment-naïve members who have HCV genotype 1 infection without cirrhosis, an HCV-RNA level less than 6 million IU/mL, and meet the above criteria for PA review consideration, only eight weeks of Harvoni® treatment will be considered for review.

Harvoni® treatment regimens will only be approved for a maximum of 12 weeks of treatment unless the member is ribavirin ineligible or intolerant.

### *Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied*

Prior authorization requests for Harvoni® will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™/Viekira XR™ and Zepatier™.
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie™ and Zepatier™.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has HCV genotype 4, 5, or 6 infection and cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has HCV genotype 1 infection and cirrhosis with severe liver functional compromise (i.e., CTP class C). Currently, there is no evidence to support that HCV treatment of members with end-stage liver disease impacts morbidity or mortality. The severity of liver damage present in decompensated liver disease makes it unlikely that treating the underlying infection would lead to liver function improvement. The only definitive treatment for end-stage liver disease is a liver transplant.

- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has HCV genotype 5 or 6 infection and has received a liver transplant.
- The member has taken a prior course of therapy with Harvoni®, Sovaldi®, or a sofosbuvir-containing product.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

### ***Hepatitis C Agents, Olysio®***

Olysio® is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1 or 4 infection.

### *Prior Authorization Requests That Will Be Considered for Review for Use of Olysio® with Pegylated Interferon and Ribavirin*

Only PA requests for the use of Olysio® with pegylated interferon and ribavirin for members with genotype 1 or 4 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

*Note:* For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak™/Viekira XR™ and Zepatier™ due to a medical or medication contraindication. For HCV genotype 4 infection, the

member must be clinically ineligible for treatment with Technivie™ and Zepatier™ due to a medical or medication contraindication.

Members with HCV genotype 1a infection must be screened for the NS3 Q80K polymorphism. If the NS3 Q80K polymorphism is detected, the PA request will not be considered for review.

*Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied for Use of Olysio® with Pegylated Interferon and Ribavirin*

Prior authorization requests for the use of Olysio® with pegylated interferon and ribavirin will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™/Viekira XR™ and Zepatier™.
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie™ and Zepatier™.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with a treatment regimen that includes Olysio® or any other HCV protease inhibitor.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the

member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

*Prior Authorization Requests That Will Be Considered for Review for Use of Olysio® as a Combined Treatment with Sovaldi®*

Only PA requests for the use of Olysio® as a combined treatment with Sovaldi® for members with genotype 1 infection whose HCV liver disease has advanced to **any** of the following stages and who are clinically ineligible for treatment with Viekira Pak™/Viekira XR™ and Zepatier™ due to a medical or medication contraindication may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

Members with HCV genotype 1a infection must be screened for the NS3 Q80K polymorphism. If the NS3 Q80K polymorphism is detected, the PA request will not be considered for review.

*Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied for Use of Olysio® as a Combined Treatment with Sovaldi®*

Prior authorization requests for the use of Olysio® as a combined treatment with Sovaldi® will be denied in the following circumstances:

- The member does not have a medical or medication contraindication for treatment with Viekira Pak™/Viekira XR™ and Zepatier™.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular

disease, cancer, depression, diabetes, pulmonary disease).

- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Harvoni®, Olysio®, Sovaldi®, a sofosbuvir-containing product, or any other HCV protease inhibitor.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

Prior authorization requests for use of Olysio® as a combined treatment with Sovaldi® will only be considered for members who have contraindications to the use of Daklinza™, Harvoni®, ribavirin, Viekira Pak™/Viekira XR™, and Zepatier™. Providers are required to clearly document why the member is unable to take Daklinza™, Harvoni®, ribavirin, Viekira Pak™/Viekira XR™, and Zepatier™.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

### ***Hepatitis C Agents, Sovaldi®***

Sovaldi® is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 2, 3, or 4 infection.

#### ***Prior Authorization Requests That Will Be Considered for Review***

Only PA requests for Sovaldi® for members with genotype 1, 2, 3, or 4 infection whose HCV liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)

- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

*Note:* For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak™/Viekira XR™ and Zepatier™ due to a medical or medication contraindication. For HCV genotype 2 or 3 infection, the member must be clinically ineligible for treatment with Epclusa® due to a medical or medication contraindication. For HCV genotype 4 infection, the member must be clinically ineligible for treatment with Technivie™ and Zepatier™ due to a medical or medication contraindication.

Sovaldi® treatment regimens for genotype 1 infection will only be approved for a maximum of 12 weeks of treatment with pegylated interferon and ribavirin unless the member is interferon ineligible or intolerant. Sovaldi® treatment regimens for genotype 2 infection will only be approved for a maximum of 12 weeks of treatment with ribavirin. Sovaldi® treatment regimens for genotype 4 infection will only be approved for a maximum of 12 weeks of treatment with pegylated interferon and ribavirin.

#### ***Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied***

Prior authorization requests for Sovaldi® will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™/Viekira XR™ and Zepatier™.
- The member has chronic HCV genotype 3 infection and does not have a medical or medication contraindication for treatment with Epclusa®.
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie™ and Zepatier™.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life

expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).

- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Harvoni®, Sovaldi®, or a sofosbuvir-containing product.
- The member is non-compliant with an approved HCV treatment regimen.

In addition, members with a history of a substance use disorder must no longer be abusing drugs or alcohol for at least six months prior to and during HCV treatment. If a member has a recent history of a substance use disorder, the member must also be an active participant in a recovery program.

*Note:* The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

### **Intranasal Rhinitis Agents**

Nasonex® will become a non-preferred drug in the intranasal rhinitis agents drug class. However, PA for Nasonex® will not be required for members 6 years of age or younger. Once a member reaches 7 years of age, PA is required.

### **Otic Antibiotics**

Ciprodex® and ofloxacin will remain non-preferred drugs in the otic antibiotics drug class.

Ciprodex® and ofloxacin are non-preferred drugs; however, PA for Ciprodex® or ofloxacin is not required for members who are 6 years of age or younger. Once a member reaches 7 years of age, PA is required.

### **Stimulants and Related Agents**

Due to the variability of drugs contained within the stimulants and related agents PDL drug class, the stimulants and related agents drug class will be split into two individual

drug classes on the Preferred Drug List Quick Reference. ForwardHealth will monitor the individual drug classes separately.

The individual drug classes will be named stimulants and stimulants – related agents.

### **Stimulants**

Changes have been made to the preferred and non-preferred status of drugs in the stimulants drug class. 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 the November 2, 2016, Pharmacy PA Advisory Committee meeting. The updated statuses are effective January 1, 2017. Providers should review the Preferred Drug List Quick Reference on the Portal for a complete list of preferred and non-preferred drugs.

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

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 drugs. 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.

Amphetamine salt combo, Dexedrine® tablets, dextroamphetamine solution, dextroamphetamine tablets, Evekeo®, Procentra®, and Zenzedi® are non-preferred drugs; however, PA for amphetamine salt combo, Dexedrine® tablets, dextroamphetamine solution, dextroamphetamine tablets, Evekeo®, Procentra®, or Zenzedi® is not required for members who are 6 years of age or younger. Once a member reaches 7 years of age, PA is required.

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



For renewal PA requests, members who are currently taking a non-preferred drug and are not grandfathered are not exempt from meeting the revised PA approval criteria.

### ***Revised and Renamed Prior Authorization/Preferred Drug List for Amphetamine Formulations***

ForwardHealth has revised and renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Amphetamine Formulations form, F-01672 (01/2016). The form has been renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Non-Preferred Stimulants form, F-01672 (01/2017). 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 for non-preferred stimulants, which are currently submitted on the PA/PDL Exemption Request form, and amphetamine formulations, which are currently submitted on the PA/PDL for Amphetamine Formulations form, submitted on and after January 1, 2017, 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.

#### ***Clinical Criteria for Non-Preferred Stimulants***

Non-preferred stimulants require PA.

Clinical criteria for approval of a PA request for a non-preferred stimulant are **both** of the following:

- At least **one** of the following is true:
  - ✓ The member took Vyvanse® for at least 60 consecutive days with a minimum of one dosage adjustment and experienced an unsatisfactory therapeutic response.
  - ✓ The member took Vyvanse® and experienced a clinically significant adverse drug reaction.
- At least **one** of the following is true:
  - ✓ The member took a methylphenidate stimulant for at least 60 consecutive days with a minimum of one

dosage adjustment and experienced an unsatisfactory therapeutic response.

- ✓ The member took a methylphenidate stimulant and experienced a clinically significant adverse drug reaction.
- ✓ The member took a dexamethylphenidate stimulant for at least 60 consecutive days with a minimum of one dosage adjustment and experienced an unsatisfactory therapeutic response.
- ✓ The member took a dexamethylphenidate stimulant and experienced a clinically significant adverse drug reaction.

#### ***Submitting Prior Authorization Requests for Non-Preferred Stimulants***

Prior authorization requests for non-preferred stimulants must be completed and signed by the prescriber and must be submitted using the PA/PDL for Non-Preferred Stimulants form.

Prior authorization requests for non-preferred stimulants (except for generic amphetamine salt combo ER requests) 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 non-preferred stimulants, the prescriber is also required to submit detailed clinical justification for prescribing generic amphetamine salt combo ER instead of brand name Adderall XR®. This clinical information must document why the member cannot use brand name Adderall XR®, including why it is medically necessary that the member receive generic amphetamine salt combo ER instead of brand name Adderall XR®.

### *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 PA/DGA form
- The PA/PDL for Non-Preferred Stimulants form
- The PA/RF

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

### **Grandfathering for Stimulants**

BadgerCare Plus, Medicaid, and SeniorCare members who were grandfathered on amphetamine formulations for DOS on and after January 1, 2016, will no longer be grandfathered for DOS on and after January 1, 2017, if **one** of the following is true:

- For members without other primary insurance on file with ForwardHealth, they have no claim activity for grandfathered amphetamine formulations for DOS in the last six months of 2016.
- For members with other primary insurance on file with ForwardHealth, they have no claim activity for grandfathered amphetamine formulations for DOS in all of 2016.

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 a National Council for Prescription Drug Programs reject code indicating a denial in the claim response, informing the pharmacy that the drug requires PA.

For more information about grandfathering in this drug class, providers may refer to the Grandfathering for Stimulants topic (topic #10662) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

### **Vyvanse® for the Treatment of Binge Eating Disorder**

The use of Vyvanse® for the treatment of binge eating disorder (BED) requires clinical PA.

Prior authorization requests for Vyvanse® should be submitted using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form and the PA/RF.

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

### *Clinical Criteria for Vyvanse® for the Treatment of Binge Eating Disorder*

Clinical criteria that must be documented for approval of a PA request for Vyvanse® for the treatment of BED are **all** of the following:

- The member is 18 years of age or older.
- The member has experienced at least three binge days per week for the last two weeks.
- The member is participating in at least one weekly intervention, including, but not limited to:
  - ✓ Psychotherapy (individual or group).
  - ✓ Nutritional counseling.
  - ✓ Monitored exercise program. (*Note:* The name and telephone number of the individual monitoring the intervention[s] must be included on the PA request form.)
- The member is not currently taking an anti-obesity drug.
- The member does not have a history of drug abuse or drug diversion.

Prior authorization requests should also include clinical documentation of the diagnostic work-up for BED, as well as all past and current BED treatments that have been attempted (both pharmacologic and non-pharmacologic).

If clinical criteria for Vyvanse® for the treatment of BED are met, PA requests will be approved for up to a maximum of 183 days.

Once the member has completed 183 days of Vyvanse® for the treatment of BED, the member must wait six months before PA can be requested for a second trial.

ForwardHealth allows only two approvals for Vyvanse® for the treatment of BED during a member's lifetime. Additional PA requests will not be approved. ForwardHealth will return additional PA requests to the provider as noncovered services. Members do not have appeal rights for noncovered services.

For more information about stimulants, providers may refer to the Stimulants topic (topic #16357) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

## **Stimulants – Related Agents**

Drugs in this class **are not** diagnosis restricted.

### ***Revised Prior Authorization Drug Attachment for Modafinil and Nuvigil®***

Providers are required to submit PA requests for modafinil and Nuvigil® on the Prior Authorization Drug Attachment for Modafinil and Nuvigil® form, F-00079 (01/2017). 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, 2017, 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 may submit PA requests for modafinil and Nuvigil® on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

### ***Conditions for Which Prior Authorization Requests for Use of Modafinil Will Be Considered for Review***

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

- Narcolepsy with cataplexy
- Narcolepsy without cataplexy
- Obstructive sleep apnea/hypopnea syndrome (OSAHS)
- Shift work sleep disorder
- Attention deficit disorder (ADD)
- Attention deficit hyperactivity disorder (ADHD)

### ***Clinical Criteria for Modafinil for Members with Narcolepsy with or Without Cataplexy***

Clinical criteria for approval of a PA request for modafinil for members with narcolepsy with or without cataplexy are **all** of the following:

- The member is at least 16 years of age.
- An overnight polysomnogram (PSG) sleep study and multiple sleep latency test (MSLT) have been performed for the member using standard protocols, and the prescribing provider has submitted medical record documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy.
- The overnight PSG test results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ Total sleep time documented is at least 360 minutes.
  - ✓ The member experienced minimal sleep interruptions (e.g., respiratory events, periodic leg movements).
  - ✓ Provider interpretation indicates an adequate night's sleep was achieved.
- The MSLT results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ The MSLT was conducted the morning after the overnight PSG.
  - ✓ Average sleep latency for all naps is eight minutes or less.
  - ✓ The member achieved at least two sleep onset rapid eye movement periods (SOREMPs). A SOREMP within 15 minutes of sleep onset on the preceding

nocturnal PSG may replace one of the SOREMPs on the MSLT.

- The member is not currently taking any sedative hypnotics.
- For members currently taking central nervous system (CNS) depressants (i.e., anxiolytics, barbiturates, opioids), the prescriber has evaluated the CNS depressants and determined they are not contributing to the member's daytime sleepiness.

If clinical criteria for modafinil for members with narcolepsy with or without cataplexy are met, initial PA requests may be approved for up to 183 days. Renewal PA requests for modafinil for members with narcolepsy with or without cataplexy may be approved for up to a maximum of 365 days.

#### *Clinical Criteria for Modafinil for Members with Obstructive Sleep Apnea/Hypopnea Syndrome*

Clinical criteria for approval of a PA request for modafinil for members with OSAHS are **all** of the following:

- The member is at least 16 years of age.
- An overnight PSG sleep study has been performed for the member, confirming the member has OSAHS.
- Test results and provider interpretation for the PSG have been submitted with the PA request.
- The member's apnea-hypopnea index (AHI) measures more than five events per hour.
- The member has tried a continuous positive airway pressure (CPAP) machine.
- The member is not currently taking any other stimulants or related agents.

If clinical criteria for modafinil for members with OSAHS are met, initial PA requests may be approved for up to 183 days. Renewal PA requests for modafinil for members with OSAHS may be approved for up to a maximum of 365 days.

#### *Clinical Criteria for Modafinil for Members with Shift Work Sleep Disorder*

Clinical criteria for approval of a PA request for modafinil for members with shift work sleep disorder are **all** of the following:

- The member is at least 16 years of age.

- The member is a night shift worker. (*Note:* The member's employer information and weekly work schedule need to be documented to support shift work sleep disorder.)
- The member is not currently taking any sedative hypnotics.
- For members currently taking CNS depressants (i.e., anxiolytics, barbiturates, opioids), the prescriber has evaluated the CNS depressants and determined they are not significantly contributing to the member's daytime sleepiness.
- The member is not currently taking any other stimulants or related agents.

If clinical criteria for modafinil for members with shift work sleep disorder are met, initial PA requests may be approved for up to 183 days. Renewal PA requests for modafinil for members with shift work sleep disorder may be approved for up to a maximum of 365 days.

#### *Clinical Criteria for Modafinil for Members with Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder*

Clinical criteria for approval of a PA request for modafinil for members with ADD or ADHD are **all** of the following:

- The member is at least 16 years of age.
- The member is not currently taking any other stimulants or related agents.
- **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 stimulants.
  - ✓ The member has a medical history of a substance use disorder.
  - ✓ The member has a serious risk of drug diversion.
- The member has experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction with Strattera®.

If clinical criteria for modafinil for members with ADD or ADHD are met, initial PA requests may be approved for up to 183 days. Renewal PA requests for modafinil for members

with ADD or ADHD may be approved for up to a maximum of 365 days.

### *Dose Limit for Modafinil*

A dose limit applies to modafinil. The dose limit for modafinil is 200 mg per day.

ForwardHealth will only consider modafinil dose limit overrides up to 400 mg per day for members who meet the following criteria:

- The member has narcolepsy with or without cataplexy.
- 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.
- The member has experienced a partial response to modafinil 200 mg per day.

For members with an existing approved PA request for modafinil, a dose limit override may be requested using the Prior Authorization Amendment Request form. For members without an existing PA request for modafinil, the Prior Authorization Drug Attachment for Modafinil and Nuvigil® must be submitted.

The following documentation must be submitted with all modafinil dose limit override requests:

- A list of the medications the member is currently taking or has previously taken for narcolepsy
- A history of the member's modafinil use and justification for why the member needs a dose above the Food and Drug Administration-approved dose of 200 mg per day

### *Conditions for Which Prior Authorization Requests for Use of Nuvigil® Will Be Considered for Review*

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

- Narcolepsy with cataplexy
- Narcolepsy without cataplexy
- Obstructive sleep apnea/hypopnea syndrome
- Shift work sleep disorder

### *Clinical Criteria for Nuvigil® for Members with Narcolepsy with or Without Cataplexy*

Clinical criteria for approval of a PA request for Nuvigil® for members with narcolepsy with or without cataplexy are **all** of the following:

- The member is at least 16 years of age.
- An overnight PSG sleep study and MSLT have been performed for the member using standard protocols, and the prescribing provider has submitted medical record documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy.
- The overnight PSG test results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ Total sleep time documented is at least 360 minutes.
  - ✓ The member experienced minimal sleep interruptions (e.g., respiratory events, periodic leg movements).
  - ✓ Provider interpretation indicates an adequate night's sleep was achieved.
- The MSLT results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ The MSLT was conducted the morning after the overnight PSG.
  - ✓ Average sleep latency for all naps is eight minutes or less.
  - ✓ The member achieved at least two SOREMPs. A SOREMP within 15 minutes of sleep onset on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.
- The member is not currently taking any sedative hypnotics.
- For members currently taking CNS depressants (i.e., anxiolytics, barbiturates, opioids), the prescriber has evaluated the CNS depressants and determined they are not contributing to the member's daytime sleepiness.

Initial PA requests for Nuvigil® for members with narcolepsy with or without cataplexy may be approved for up to 183 days. Renewal PA requests for Nuvigil® for members with narcolepsy with or without cataplexy may be approved for up to a maximum of 365 days.

### *Clinical Criteria for Nuvigil® for Members with Obstructive Sleep Apnea/Hypopnea Syndrome*

Clinical criteria for approval of a PA request for Nuvigil® for members with OSAHS are **all** of the following:

- The member is at least 16 years of age.
- An overnight PSG sleep study has been performed for the member, confirming the member has OSAHS.
- Test results and provider interpretation for the PSG have been submitted with the PA request.
- The member's AHI measures more than five events per hour.
- The member has tried a CPAP machine.
- The member is not currently taking any other stimulants or related agents.

Initial PA requests for Nuvigil® for members with OSAHS may be approved for up to 183 days. Renewal PA requests for Nuvigil® for members with OSAHS may be approved for up to a maximum of 365 days.

### *Clinical Criteria for Nuvigil® for Members with Shift Work Sleep Disorder*

Clinical criteria for approval of a PA request for Nuvigil® for members with shift work sleep disorder are **all** of the following:

- The member is at least 16 years of age.
- The member is a night shift worker. (*Note:* The member's employer information and weekly work schedule need to be documented to support shift work sleep disorder.)
- The member is not currently taking any sedative hypnotics.
- For members currently taking CNS depressants (i.e., anxiolytics, barbiturates, opioids), the prescriber has evaluated the CNS depressants and determined they are not significantly contributing to the member's daytime sleepiness.
- The member is not currently taking any other stimulants or related agents.

Initial PA requests for Nuvigil® for members with shift work sleep disorder may be approved for up to 183 days. Renewal PA requests for Nuvigil® for members with shift work sleep disorder may be approved for up to a maximum of 365 days.

### *Dose Limit for Nuvigil®*

A dose limit applies to Nuvigil®. The dose limit for Nuvigil® is 250 mg per day.

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

On and after January 3, 2017, providers will be able to refer to the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook for more information about the stimulants – related agents drug class.

## **Pharmacy Policy Changes**

### ***Orkambi®***

ForwardHealth has revised the clinical criteria for Orkambi® to allow consideration of PA requests for members 6 years of age or older.

For complete clinical criteria for Orkambi®, providers may refer to the Orkambi® topic (topic # 18757) in the Services Requiring Prior Authorization chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

### ***Strensiq®***

Strensiq® requires clinical PA. Prior authorization requests for Strensiq® must be submitted using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form and the PA/RF.

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

### *Clinical Criteria for Prior Authorization Requests for Strensiq®*

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

- Perinatal/infantile-onset hypophosphatasia (HPP)
- Juvenile-onset HPP

Clinical criteria that must be documented for approval of a PA request for Strensiq® are **all** of the following:

- The member has perinatal/infantile-onset HPP or juvenile-onset HPP.
- The member was 18 years of age or younger at the onset of signs/symptoms of HPP.
- The member's current weight is provided.
- The member has clinical manifestations consistent with HPP (e.g., skeletal abnormalities, respiratory problems, hypercalcemia, seizures).
- Findings on radiographic imaging support the diagnosis of HPP (e.g., infantile rickets, alveolar bone loss, osteoporosis, low bone mineral content for age).
- The prescription is written by an endocrinologist or a provider who specializes in HPP.
- The member has a documented history of HPP-related skeletal abnormalities.
- The member has a serum alkaline phosphatase below the age-adjusted normal range.
- The member has a plasma pyridoxal-5'-phosphate level above the upper limit of normal.
- The member has a documented tissue-nonspecific alkaline phosphatase gene mutation.

Medical records must be provided to demonstrate the member meets the clinical criteria listed above.

*Note:* A copy of the gene mutation testing must be included with an initial PA request.

Initial PA requests for Strensiq® may be approved for up to 183 days.

Renewal PA requests for Strensiq® may be approved for up to a maximum of 365 days. Renewals require medical records to be submitted that demonstrate that the member has

responded to treatment with Strensiq® as evidenced by improvement in respiratory status, growth, or radiographic findings.

### ***Xyrem®***

Xyrem® requires clinical PA.

Quantity limits apply to Xyrem®. Members are limited to a maximum nightly dose of 18 ml (9 g) of Xyrem®, which is equivalent to 540 ml (270 g) of Xyrem® 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 for Xyrem®*

Providers are required to submit PA requests for Xyrem® on the Prior Authorization Drug Attachment for Xyrem® form, F-01430 (01/2017). 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, 2017, 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 (but **not** 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 symptoms of narcolepsy:

- Cataplexy
- Excessive daytime sleepiness (EDS)

## *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®.
- The member does not have a history of substance abuse, addiction, or diversion.
- The member is not currently taking any sedative hypnotics.
- For members currently taking CNS depressants (i.e., anxiolytics, barbiturates, opioids), the prescriber has evaluated the CNS depressants and determined they are not contributing to the member's daytime sleepiness.
- An overnight PSG sleep study and MSLT have been performed for the member using standard protocols, and the prescribing provider has submitted medical record documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy with cataplexy.
- The overnight PSG test results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ Total sleep time documented is at least 360 minutes.
  - ✓ The member experienced minimal sleep interruptions (e.g., respiratory events, periodic leg movements).
  - ✓ Provider interpretation indicates an adequate night's sleep was achieved.
- The MSLT results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ The MSLT was conducted the morning after the overnight PSG.
  - ✓ Average sleep latency for all naps is eight minutes or less.
  - ✓ The member achieved at least two SOREMPs. A SOREMP within 15 minutes of sleep onset on the

preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.

- **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 drugs:
  - ✓ Tricyclic antidepressant
  - ✓ Selective serotonin reuptake inhibitor
  - ✓ Serotonin norepinephrine reuptake inhibitor

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 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® and alcohol.
- The member has agreed to be abstinent from alcohol while being treated with Xyrem®.
- The member does not have a history of substance abuse, addiction, or diversion.
- The member is not currently taking any sedative hypnotics.
- For members currently taking CNS depressants (i.e., anxiolytics, barbiturates, opioids), the prescriber has evaluated the CNS depressants and determined they are not contributing to the member's daytime sleepiness.
- An overnight PSG sleep study and MSLT have been performed for the member using standard protocols, and the prescribing provider has submitted medical record documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy without cataplexy.
- The overnight PSG test results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ Total sleep time documented is at least 360 minutes.
  - ✓ The member experienced minimal sleep interruptions (e.g., respiratory events, periodic leg movements).
  - ✓ Provider interpretation indicates an adequate night's sleep was achieved.
- The MSLT results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - ✓ The MSLT was conducted the morning after the overnight PSG.
  - ✓ Average sleep latency for all naps is eight minutes or less.
  - ✓ The member achieved at least two SOREMPs. A SOREMP within 15 minutes of sleep onset on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.
- 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 the following:
  - ✓ 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®.

## Expedited Emergency Supply

As a result of changes made during the January 2017 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 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/](http://www.forwardhealth.wi.gov/).

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# 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 that have been revised, renamed, or discontinued as a result of the January 2017 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/](http://www.forwardhealth.wi.gov/) for current copies of these forms and completion instructions. Unless otherwise noted, all form changes listed are effective January 1, 2017. 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, Renamed, Discontinued, or New	Effective Date
Prior Authorization Drug Attachment for Hepatitis C Agents	F-01247	Revised	01/01/2017
Completion Instructions	F-01247A	Revised	01/01/2017
Prior Authorization Drug Attachment for Modafinil and Nuvigil®	F-00079	Revised	01/01/2017
Completion Instructions	F-00079A	Revised	01/01/2017
Prior Authorization Drug Attachment for Xyrem®	F-01430	Revised	01/01/2017
Completion Instructions	F-01430A	Revised	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Amphetamine Formulations	F-01672	Revised and Renamed: Prior Authorization/Preferred Drug List (PA/PDL) for Non-Preferred Stimulants	01/01/2017
Completion Instructions	F-01672A	Revised and Renamed	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Ankylosing Spondylitis	F-11304	Revised	01/01/2017
Completion Instructions	F-11304A	Revised	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Crohn's Disease	F-11305	Discontinued	01/01/2017
Completion Instructions	F-11305A	Discontinued	01/01/2017

<b>Form Name</b>	<b>Form Number</b>	<b>Revised, Renamed, Discontinued, or New</b>	<b>Effective Date</b>
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Crohn's Disease and Ulcerative Colitis	F-01950	New	01/01/2017
Completion Instructions	F-01950A	New	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Hidradenitis Suppurativa	F-01674	Revised	01/01/2017
Completion Instructions	F-01674A	Revised	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Uveitis and Neonatal Onset Multisystem Inflammatory Disease (NOMID)	F-01952	New	01/01/2017
Completion Instructions	F-01952A	New	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Plaque Psoriasis	F-11306	Revised and Renamed: Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Psoriasis	01/01/2017
Completion Instructions	F-11306A	Revised and Renamed	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Psoriatic Arthritis	F-11307	Discontinued	01/01/2017
Completion Instructions	F-11307A	Discontinued	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Rheumatoid Arthritis (RA) and Polyarticular Juvenile RA	F-11308	Discontinued	01/01/2017
Completion Instructions	F-11308A	Discontinued	01/01/2017

<b>Form Name</b>	<b>Form Number</b>	<b>Revised, Renamed, Discontinued, or New</b>	<b>Effective Date</b>
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), and Psoriatic Arthritis	F-01951	New	01/01/2017
Completion Instructions	F-01951A	New	01/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Ulcerative Colitis	F-00694	Discontinued	01/01/2017
Completion Instructions	F-00694A	Discontinued	01/01/2017

# 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 2017 Preferred Drug List review. The updated statuses are effective January 1, 2017. 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 can be referenced on the Pharmacy Resources page of the Providers area of the ForwardHealth Portal at [www.forwardhealth.wi.gov/](http://www.forwardhealth.wi.gov/).

Drug Class	Drug Name	Status Effective January 1, 2017
Alzheimer's Agents	memantine solution*	Non-Preferred
Anticonvulsants	Banzel <sup>®</sup> tablet*	Non-Preferred
	Briviact <sup>®</sup> solution*	Non-Preferred
	Briviact <sup>®</sup> tablet*	Non-Preferred
	ethosuximide capsule*	Preferred
	Fycompa <sup>®</sup> suspension*	Non-Preferred
	lamotrigine ODT dose pack*	Non-Preferred
	Spritam <sup>®</sup> *	Non-Preferred
Antidepressants, Other	Pristiq <sup>®</sup>	Preferred
Antipsoriatics, Topical	Enstilar <sup>®</sup> *	Non-Preferred
Antipsychotics	aripiprazole ODT*	Preferred
	Aristada <sup>®</sup> *	Non-Preferred
	Nuplazid <sup>™</sup> *	Non-Preferred
	olanzapine ODT	Preferred
	paliperidone*	Non-Preferred
	pimozide*	Non-Preferred
	Vraylar <sup>®</sup> *	Non-Preferred
Bronchodilators, Beta Agonist	albuterol nebulizer solution 0.63 mg, 1.25 mg	Preferred
COPD Agents	Seebri <sup>®</sup> Neohaler <sup>®</sup> *	Non-Preferred
	Utibron <sup>™</sup> Neohaler <sup>®</sup> *	Non-Preferred
Cytokine and CAM Antagonists	Orencia <sup>®</sup> ClickJect <sup>™</sup> *	Non-Preferred
	Otezla <sup>®</sup>	Preferred
	Taltz <sup>®</sup> autoinjector*	Non-Preferred
	Taltz <sup>®</sup> syringe*	Non-Preferred
	Xeljanz <sup>®</sup> XR*	Non-Preferred
Epinephrine, Self-Injected	epinephrine 0.15 mg	Preferred
	epinephrine 0.3 mg	Preferred

<b>Drug Class</b>	<b>Drug Name</b>	<b>Status Effective January 1, 2017</b>
Glucocorticoids, Inhaled	Aerospan <sup>®</sup>	Non-Preferred
Hepatitis C Agents	Daklinza <sup>™</sup>	Non-Preferred
	Epclusa <sup>®</sup>	Preferred
Intranasal Rhinitis Agents	Nasonex <sup>®</sup>	Non-Preferred
NSAIDS	diclofenac gel*	Non-Preferred
	naproxen sodium	Non-Preferred
	Vivlodex <sup>®</sup> *	Non-Preferred
Ophthalmics for Allergic Conjunctivitis	olopatadine*	Non-Preferred
Ophthalmics, Anti-Inflammatories	Ilevro <sup>®</sup>	Preferred
Sedative Hypnotics	zolpidem (sublingual)*	Non-Preferred
Steroids, Topical Medium	flurandrenolide cream*	Non-Preferred
Steroids, Topical High	Sernivo <sup>™</sup> spray*	Non-Preferred
Steroids, Topical Very High	Ultravate <sup>®</sup> Lotion*	Non-Preferred
Stimulants	Adzenys XR-ODT <sup>™</sup> *	Non-Preferred
	methylphenidate ER capsule (generic Ritalin LA <sup>®</sup> )	Preferred
	methylphenidate solution	Preferred
	QuilliChew ER <sup>™</sup> *	Preferred
Stimulants – Related Agents	Kapvay <sup>®</sup>	Preferred

\* 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*.