ForwardHealth
Wisconsin serving you

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

January 2018 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 (PDL) and other pharmacy policy changes effective for dates of service (DOS) on and after January 1, 2018, 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/*.

Changes to Pharmacy-Related Forms and Completion Instructions

Attachment 1 of this *Update* lists the prior authorization (PA) forms and completion instructions that have been revised or discontinued as a result of the January 2018 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, 2018. 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 PDL

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 PA for PDL 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 PA 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 their 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 PA for PDL 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 PDL

On November 8, 2017, 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, 2018. 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 8, 2017, meeting are effective January 1, 2018, and are included in Attachment 2.

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

New Drug Class

The ophthalmics, anti-inflammatory/immunomodulators drug class will be added to the PDL on January 1, 2018.

Pharmacy providers should begin working with prescribers to transition members using non-preferred drugs in the drug class or request PA for a non-preferred drug if it is medically appropriate for the member. Providers may refer to the Preferred Drug List Quick Reference on the Portal for the preferred and non-preferred drugs in the ophthalmics, anti-inflammatory/immunomodulators drug class.

Ophthalmics, Anti-Inflammatory/ Immunomodulators

Restasis® and Restasis® MultiDose™ will be preferred drugs in the ophthalmics, anti-inflammatory/immunomodulators drug class.

Xiidra® will be a non-preferred drug in the ophthalmics, anti-inflammatory/immunomodulators drug class.

Antipsychotics

ForwardHealth has revised the PA criteria for antipsychotic drugs for children to include children **8 years of age and younger**.

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

ForwardHealth has revised and renamed the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger form, F-00556 (01/2016). The form has been renamed the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 8 Years of Age and Younger form, F-00556 (01/2018).

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. PA requests submitted on and after January 1, 2018, must be submitted on the revised form or the PA request will be returned to the provider.

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

ForwardHealth has revised the clinical documentation required for antipsychotic drugs for children **8 years of age and younger**.

Clinical Documentation

If the PA request for antipsychotic drugs for children 8 years of age and younger is for a member who is being treated for autism or tics, the only documentation required is the diagnosis information described in the following list. Pharmacy providers are encouraged to submit all PA requests for autism and tics using the STAT-PA system. The following clinical documentation is required on PA requests for members who are being treated for a condition other than autism or tics and must be submitted on the Portal, by fax, or by mail:

- Information about the child's diagnoses — There are appropriate indications for the use of antipsychotic drugs in young children with certain diagnoses, including autism spectrum disorders, psychotic

disorders, and tic disorders. Antipsychotic drugs may also be helpful for severe symptoms of irritability, aggression, anger, or defiance that may accompany severe mood disorders, developmental disorders, or attention-deficit hyperactivity disorder (ADHD).

- Body mass index (BMI) measurements — Antipsychotic drugs can have profoundly adverse effects on weight, glucose, and lipids. Because of these well-documented side effects, the Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 8 years of Age and Younger form requires the submission of a BMI percentile measurement with each PA request. The BMI percentile measurement is required because it is the standard for stratifying individuals as obese or at-risk for obesity and, therefore, requiring closer monitoring and active intervention. Children who have a BMI percentile measurement greater than or equal to 85 percent are at risk for diabetes and the metabolic syndrome associated with many antipsychotic drugs. If the child's BMI percentile is 85 percent or greater, the PA request must include a triglyceride level and a fasting glucose or hemoglobin A1c drawn within the past six months for the PA request to be approved.
- Target symptoms — The prescriber is required to be very familiar with the criteria for disruptive mood dysregulation disorder and to clarify persistent versus episodic irritability/anxiety/anger/temper outbursts as well as to identify the presence, or absence, of comorbid conditions.
- Polypharmacy information — The Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 8 years of Age and Younger form requires documentation of the child's experience with any psychoactive drugs, concurrent drugs, as well as previous drug trials in the preceding 12 months.
- Specialty information — ForwardHealth is interested in tracking the prescriber's practice specialty information.
- Documentation for non-preferred antipsychotic drug requests — If the prescriber is requesting a non-preferred antipsychotic drug, clinical documentation must be provided to support the request and must include detailed reasons why preferred drugs were discontinued or not utilized.

For more information about antipsychotic drugs, providers may refer to the Antipsychotics topic (topic #18457) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

Cytokine and Cell Adhesion Molecule Antagonist Drugs

Kevzara®, Siliq™, and Tremfya® will become non-preferred drugs in the cytokine and cell adhesion molecule (CAM) antagonist drugs drug class.

Clinical PA is required for all cytokine and 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.

PA 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
- Giant cell arteritis
- Hidradenitis suppurativa
- Neonatal Onset Multisystem Inflammatory Disease (NOMID)
- Psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis (RA) and juvenile idiopathic arthritis (JIA)
- Ulcerative colitis
- Uveitis

PA 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.

Non-Preferred Oral Agents

The following will **not** be considered as criteria to support the need for a non-preferred oral cytokine and CAM antagonist drug 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 PA 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, F-11304 (01/2018)
- 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 (01/2018)
- Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Psoriasis, F-11306 (01/2018)
- 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 (01/2018)

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. PA requests submitted on and after January 1, 2018, must be submitted on the revised form or the PA request will be returned to the provider.

PA 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 Uveitis and Neonatal Onset Multisystem Inflammatory Disease Form

ForwardHealth has revised and renamed the 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). The form has been renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Uveitis, Giant Cell Arteritis, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) form, F-01952 (01/2018).

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. PA requests submitted on and after January 1, 2018, must be submitted on the revised form or the PA request will be returned to the provider.

PA 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, excluding the clinical conditions of hidradenitis suppurativa, NOMID, and uveitis. The clinical criteria for which PA requests are considered for cytokine and CAM antagonist drugs used to treat hidradenitis suppurativa, NOMID, and uveitis has not changed.

Clinical Criteria for Cytokine and CAM Antagonist Drugs for Ankylosing Spondylitis

Enbrel® and Humira® are preferred drugs used to treat ankylosing spondylitis.

Note: Enbrel Mini™ cartridge is a non-preferred drug.

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.
- The prescriber has indicated if the member has axial symptoms of ankylosing spondylitis.
- The prescriber has indicated if the member has attempted any of the following drugs for ankylosing spondylitis: leflunomide, methotrexate, non-steroidal anti-inflammatory drugs (NSAIDs), or sulfasalazine.
- The prescriber has indicated what other drugs 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 **all** 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.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

PA requests for drugs 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.

PA 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. PA 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).

Note: PA requests for Enbrel Mini™ should be submitted using Section VII (Clinical Information for Other Drug Requests) of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016). For more information about submitting PA requests for Enbrel Mini™, providers may refer to Clinical Information for Other Drug Requests in 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.

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 prescriber has indicated if the member has attempted any of the following drugs for Crohn's disease: 6-mercaptopurine (6MP), azathioprine, oral aminosalicylates (balsalazide, mesalamine, olsalazine, sulfasalazine), or methotrexate.
- The prescriber has indicated what other drugs 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 **all** 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.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

PA 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.

PA 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. PA 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 Giant Cell Arteritis

Actemra® is a non-preferred drug used to treat giant cell arteritis.

Clinical criteria for approval of a PA request for Actemra® used to treat giant cell arteritis are **both** of the following:

- The member has giant cell arteritis.
- 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 giant cell arteritis and outline the member's current treatment plan for giant cell arteritis.

PA requests for cytokine and CAM antagonist drugs used to treat giant cell arteritis must be submitted on the PA/PDL for Cytokine and CAM Antagonist Drugs for Uveitis, Giant Cell Arteritis, and NOMID form.

PA requests for Actemra® used to treat giant cell arteritis 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®, Humira®, and Otezla® are preferred drugs used to treat psoriasis.

Note: Enbrel Mini™ cartridge is a non-preferred drug.

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 (BSA) involved.
- The prescription is written by a dermatologist or through a dermatology consultation.
- The prescriber has indicated if the member has attempted any of the following drugs or therapies for psoriasis: cyclosporine, methotrexate, phototherapy, or acitretin.
- The prescriber has indicated what other drugs the member has attempted for psoriasis (e.g., topicals, glucocorticoids, or IV immunomodulators such as infliximab).

Cosentyx®, Siliq™, Stelara®, Taltz®, and Tremfya™ 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®, Siliq™, Stelara®, Taltz®, or Tremfya™ are **all** 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.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

PA 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.

PA 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. PA 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).

Note: PA requests for Enbrel Mini™ should be submitted using Section VII (Clinical Information for Other Drug Requests) of the PA/DGA form. For more information about submitting PA requests for Enbrel Mini™, providers may refer to Clinical Information for Other Drug Requests in the Prior Authorization/Drug Attachment topic (topic #15937).

Clinical Criteria for Cytokine and CAM Antagonist Drugs for Psoriatic Arthritis

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

Note: Enbrel Mini™ cartridge is a non-preferred drug.

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.
- The prescriber has indicated if the member has axial symptoms of psoriatic arthritis.
- The prescriber has indicated if the member has attempted any of the following drugs for psoriatic arthritis: azathioprine, hydroxychloroquine, leflunomide, or methotrexate.
- The prescriber has indicated what other drugs the member has attempted for psoriatic arthritis (e.g., NSAIDs, glucocorticoids, or IV immunomodulators such as infliximab).

Cimzia®, Cosentyx®, Orencia® subQ solution, Simponi®, Stelara®, and Taltz® 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®, Orencia® subQ solution, Simponi®, Stelara®, or Taltz® are **all** 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.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

PA 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.

PA 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. PA 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).

Note: PA requests for Enbrel Mini™ should be submitted using Section VII (Clinical Information for Other Drug Requests) of the PA/DGA form. For more information about submitting PA requests for Enbrel Mini™, providers may refer to Clinical Information for Other Drug Requests in the Prior Authorization/Drug Attachment topic (topic #15937).

Clinical Criteria for Cytokine and CAM Antagonist Drugs for RA and JIA

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

Note: Enbrel Mini™ cartridge is a non-preferred drug.

Clinical Criteria for RA

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 prescriber has indicated if the member has attempted any of the following drugs for RA: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine.
- The prescriber has indicated what other drugs the member has attempted for RA (e.g., NSAIDs, glucocorticoids, or IV immunomodulators such as infliximab).

Actemra® subQ solution, Cimzia®, Kevzara®, 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®, Kevzara®, Kineret®, Orencia® subQ solution, Simponi®, or Xeljanz®/Xeljanz® XR are **all** 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.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

Clinical Criteria for JIA

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 prescriber has indicated if the member has attempted any of the following drugs for JIA: azathioprine, leflunomide, methotrexate, or sulfasalazine.
- The prescriber has indicated what other drugs the member has attempted for JIA (e.g., NSAIDs, glucocorticoids, or IV immunomodulators such as infliximab).

Orencia® subQ solution is a non-preferred drug used to treat JIA.

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 Orencia® subQ solution are **all** 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.
  - ✓ 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.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

PA requests for drugs 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.

PA 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. PA 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).

Note: PA requests for Enbrel Mini™ should be submitted using Section VII (Clinical Information for Other Drug Requests) of the PA/DGA form. For more information about submitting PA requests for Enbrel Mini™, providers may refer to Clinical Information for Other Drug Requests in the Prior Authorization/Drug Attachment topic (topic #15937).

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 prescriber has indicated if the member has attempted any of the following drugs for ulcerative colitis: 6MP, azathioprine, or oral aminosalicylates (balsalazide, mesalamine, olsalazine, sulfasalazine).
- The prescriber has indicated what other drugs 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 **all** 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.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

PA 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.

PA requests for Humira® used to treat ulcerative colitis may be submitted using the STAT-PA system, on the Portal, by fax, or by mail. PA 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).

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.

Glucocorticoids, Oral

Emflaza® will become a non-preferred drug in the glucocorticoids, oral drug class.

Emflaza®

Clinical PA is required for Emflaza®.

Note: The superiority of Emflaza® over prednisone in the treatment of Duchenne muscular dystrophy (DMD) has not been established. There is also no quality evidence to support a clinically significant difference in the corticosteroid-induced side effect profiles of Emflaza® and prednisone. Studies evaluating the difference in weight gain between Emflaza® and prednisone are conflicting and the majority of studies are of poor quality. Prednisone is possibly associated with greater weight gain in the first 12 months of treatment; however, there appears to be no significant difference in weight gain with longer term use of prednisone compared with Emflaza®.

The following will **not** be considered as criteria to support the need for a non-preferred glucocorticoids, oral drug:

- Non-adherence to previous glucocorticoid therapies
- Member or prescriber preference

PA requests for Emflaza® must be completed and signed by the prescriber. PA requests for Emflaza® 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 Prior Authorization Request Form (PA/RF), F-11018 (05/13).

A copy of the member's medical records must be submitted with all PA requests for Emflaza®. Medical records should document the following:

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

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

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

ForwardHealth has established clinical criteria for Emflaza®.

Clinical Criteria for Emflaza®

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

- The member has a diagnosis of DMD.
- The member is 5 years of age or older.
- The prescription is written by or through consultation with a neurologist.
- The dose requested is consistent with the Food and Drug Administration (FDA)-recommended daily dosage based on the member's weight (approximately 0.9 mg/kg/day).
- At least **one** of the following is true:
  - ✓ The member has experienced a clinically significant glucocorticoid adverse drug reaction with an adequate trial of prednisone that has required a dose reduction or discontinuation of prednisone.
  - ✓ The member's BMI is considered obese and the member has experienced a rapid weight gain of at least 20 percent or greater over a six-month period while taking prednisone.

Renewal PA requests for members who have DMD must meet the clinical criteria for initial PA requests for Emflaza® and have documentation to support that the member has experienced an improvement or resolution of the initial glucocorticoid adverse effects experienced with prednisone. The member must also continue to take a dose consistent with the FDA-recommended daily dosage based on the member's weight (approximately 0.9 mg/kg/day).

If clinical criteria for Emflaza® are met, initial PA requests may be approved for up to 92 days. Renewal PA requests for Emflaza® may be approved for up to 183 days.

Note: All renewal PA requests require the member to be adherent with the prescribed treatment regimen. A copy of the current medical records must be included with the PA request.

Gout Agents

Colchicine capsule will become a preferred drug in the gout agents drug class.

Duzallo® and Zurampic®

PA requests for Duzallo® and Zurampic® must be completed and signed by the prescriber. PA requests for Duzallo® and Zurampic® 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.

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

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

ForwardHealth has established clinical criteria for Duzallo® and Zurampic®.

Clinical Criteria for Duzallo®

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

- The member has symptomatic hyperuricemia associated with gout.
- The member's current estimated creatinine clearance rate (eCLcr) (measured within the past six months) has been provided.
- The member's current serum uric acid level (measured within the past six months) has been provided.
- **At least one** of the following is true:
  - ✓ The member has taken a minimum of 300 mg of allopurinol daily (eCLcr above 60 mL/min.) for at least three consecutive months and has not achieved target serum uric acid levels.
  - ✓ The member has taken a minimum of 200 mg of allopurinol daily (eCLcr 45–60 mL/min.) for at

least three consecutive months and has not achieved target serum uric acid levels.

- The member does **not** have any of the following contraindications to Duzallo®:
  - ✓ eCLcr below 45 mL/min.
  - ✓ Kidney transplant recipient
  - ✓ Dialysis treatment
  - ✓ Tumor lysis syndrome (TLS)
  - ✓ Lesch-Nyhan syndrome (LNS)

PA requests for Duzallo® may be approved for up to a maximum of 365 days.

Clinical Criteria for Zurampic®

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

- The member has symptomatic hyperuricemia associated with gout.
- The member's current eCLcr (measured within the past six months) has been provided.
- The member's current serum uric acid level (measured within the past six months) has been provided.
- The member has been treated with the maximum tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least three consecutive months and has not achieved target serum uric acid levels.
- The member will continue to take a xanthine oxidase inhibitor (allopurinol or febuxostat) along with Zurampic®.
- The member does **not** have any of the following contraindications to Zurampic®:
  - ✓ eCLcr below 45 mL/min.
  - ✓ Kidney transplant recipient
  - ✓ Dialysis treatment
  - ✓ TLS
  - ✓ LNS

PA requests for Zurampic® may be approved for up to a maximum of 365 days.

Hepatitis C Agents

Revised Prior Authorization Drug Attachment for Hepatitis C Agents Form

ForwardHealth has revised the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (01/2018). 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. PA requests submitted on and after January 1, 2018, must be submitted on the revised form or the PA request will be returned to the provider.

PA 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.

PA requests for hepatitis C agents must be completed and signed by prescribers. PA requests for hepatitis C agents must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents form.

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

PA 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. 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.

Approved PA requests for hepatitis C agents will be authorized for the full treatment course approved by ForwardHealth for the member.

Pharmacy Provider-Specific PA Requests for Hepatitis C Agents

PA 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 pharmacy 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 request 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.

Clinical Information That Must Be Documented on All PA Requests for Hepatitis C Agents

For 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 PA requests for hepatitis C agents are **all** of the following:

- Hepatitis C virus (HCV) assessment and treatment plan
- Current history and physical, including complete problem and medication list
- Current and past psychosocial history, including alcohol and IV drug use
- Lab tests (performed within the last six months):
  - ✓ Albumin
  - ✓ Complete blood count
  - ✓ International normalized ratio
  - ✓ Liver function panel
  - ✓ Serum creatinine
  - ✓ HCV-ribonucleic acid (HCV-RNA) level
- HCV genotype and subtype
- HCV clinical data and medication treatment history, including the following:
  - ✓ Likely source of the HCV infection and date diagnosed
  - ✓ Liver biopsy, imaging studies, or blood assay tests to determine hepatic fibrosis
  - ✓ History of liver transplant
  - ✓ History of previous hepatitis C drug therapy to include medication name(s), dates taken, and treatment results (e.g., null response, partial response, or relapse)
- If the member has cirrhosis, documentation of the following clinical assessments:
  - ✓ Child-Turcotte-Pugh (CTP) class and score
  - ✓ Hepatocellular carcinoma status based on an imaging study performed within the last six months
  - ✓ Presence or treatment of any of the following:
    - Ascites
    - Hepatic encephalopathy
    - Portal hypertension
    - Hepatocellular cancer
  - ✓ Liver transplant workup, if performed, and waitlist status

The PA request will be considered incomplete and will be returned to the provider or may be denied if the required documentation is not submitted with the PA request.

ForwardHealth has revised the clinical criteria for hepatitis C agents.

Clinical Criteria for Hepatitis C Agents

PA requests for a preferred drug appropriate for the member's HCV genotype will be considered for review.

The following are preferred drugs for the following HCV genotypes:

- **Genotype 1:** Epclusa®, Harvoni®, Mavyret™, Viekira Pak®/Viekira XR™, or Zepatier®
- **Genotype 2:** Epclusa®, Mavyret™
- **Genotype 3:** Epclusa®, Mavyret™
- **Genotype 4:** Epclusa®, Harvoni®, Mavyret™, or Zepatier®
- **Genotype 5:** Epclusa®, Harvoni®, Mavyret™
- **Genotype 6:** Epclusa®, Harvoni®, Mavyret™

Daklinza™, **Olysio®**, **Sovaldi®**, **Technivie™**, and **Vosevi®** are non-preferred drugs used to treat HCV infection.

PA requests for a non-preferred drug will not be considered unless the member is clinically ineligible for the preferred hepatitis C agents due to a medical or medication contraindication.

Clinical PA criteria are **all** of the following:

- The member does not have acute HCV infection.
- The member is 18 years of age or older **or** 12 years of age or older for Harvoni® and Sovaldi® requests.
- The member does not have a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- For PA requests for Daklinza™, Mavyret™, Olysio®, Sovaldi®, Viekira Pak®/Viekira XR™, Vosevi®, or Zepatier®, the member does not have cirrhosis with moderate liver functional compromise (i.e., CTP class B).
- The member does not have 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 does not have HCV reinfection after prior treatment.
- If the member has cirrhosis or an alcohol use disorder, they have abstained from alcohol for at least six months prior to and during HCV treatment.
- The member does not have a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care, including, but not limited to, the following: medications, lab testing, and medical visits. (*Note:* Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.)

In addition to meeting all of the above clinical criteria and HCV treatment program requirements, **Zepatier®** requests for members with HCV genotype 1a infection must be tested for the presence of NS5A resistance-associated polymorphisms.

For members who have received a liver transplant, ForwardHealth will consider the requested HCV treatment regimen based on the member's entire medical record. The level of clinical evidence for the requested HCV treatment regimen will be considered, and if low clinical evidence of effectiveness is established, the PA request will be denied.

For members who have received prior HCV treatment, ForwardHealth will consider the requested HCV treatment regimen based on the member's entire medical record in addition to the HCV treatment history and response (e.g.,

null response, partial response, or relapse). The level of clinical evidence for the requested HCV treatment regimen will be considered, and the PA request will be denied if low clinical evidence of effectiveness is established.

PA request approval for a member's HCV treatment regimen will be based on the drug's FDA-recommended dosage and administration information.

Note: Only eight weeks of Harvoni® treatment will be approved for treatment-naïve members who have HCV genotype 1 infection without cirrhosis, have an HCV-RNA level less than 6 million IU/mL, are non-Black, and are HIV uninfected.

Immunomodulators, Atopic Dermatitis

Protopic® will become a preferred drug (in addition to the preferred drug Elidel®) in the immunomodulators, atopic dermatitis drug class.

Protopic® 0.1% for members younger than 16 years of age will no longer require PA.

Dupixent® and Eucrisa® will become non-preferred drugs in the immunomodulators, atopic dermatitis drug class.

Tacrolimis will remain a non-preferred drug and will be classified as a brand before generic (BBG) drug requiring PA.

For more information and clinical criteria for BBG PA requests, providers may refer to the following topics in the Brand Medically Necessary Drugs and Brand Before Generic Drugs chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook:

- An Introduction to Brand Medically Necessary Drugs and Brand Before Generic Drugs (topic #20078)
- Brand Before Generic Drugs (topic #20077)

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

The following will **not** be considered as criteria to support the need for a non-preferred immunomodulators, atopic dermatitis agent:

- Non-adherence to previous topical therapies
- Member or prescriber preference
- The use of samples to start a member on a medication

Dupixent® and Eucrisa®

PA requests for Dupixent® and Eucrisa® must be completed and signed by the prescriber. PA requests for Dupixent® and Eucrisa® 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. Clinical documentation supporting the use of Dupixent® and Eucrisa® must be submitted with the PA request.

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

ForwardHealth has established clinical criteria for Dupixent® and Eucrisa®.

Clinical Criteria for Dupixent®

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

- The member is 18 years of age or older.
- The member has moderate to severe atopic dermatitis. Documentation must include the approximate BSA involved and the area(s) affected.
- The prescription is written by or through consultation with a dermatologist, an allergist, or immunologist.
- Other causes of exacerbating factors that may contribute to the member's atopic dermatitis, such as member non-compliance with therapy, environmental factors, dietary factors, and other similar dermatologic conditions, have been ruled out.
- At least **one** of the following is true:
  - ✓ The member has a recent history (within six months of the clinical visit when Dupixent® treatment was first prescribed) of use of at least a medium potency topical corticosteroid for at least

two months and experienced an unsatisfactory therapeutic response.
    - ✓ The member has used at least a medium potency corticosteroid and experienced a clinically significant adverse drug reaction.
- At least **one** of the following is true:
    - ✓ The member has a recent history (within six months of the clinical visit when Dupixent® treatment was first prescribed) of topical calcineurin inhibitor use for at least two months and experienced an unsatisfactory therapeutic response.
    - ✓ The member used a topical calcineurin inhibitor and experienced a clinically significant adverse drug reaction.
- The member will not use Dupixent® in combination with other biologics (e.g., Xolair® [omalizumab], Remicade® [infliximab], Enbrel® [etanercept]).
- The member does not have a parasitic infection.

A copy of the member's medical records must be submitted with all PA requests for Dupixent®. Medical records should document the following:

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

If clinical criteria for Dupixent® are met, initial PA requests for Dupixent® may be approved for up to a maximum of 183 days. Renewal PA requests for Dupixent® may be approved for up to 365 days.

Renewal PA requests for members who have moderate to severe atopic dermatitis (eczema) must meet the clinical criteria for initial PA requests for Dupixent®. Renewal requests must include copies of the current medical records demonstrating the member has had a significant reduction in the area(s) affected and/or severity of atopic dermatitis and the member is not using Dupixent® in combination with other biologics (e.g., Xolair® [omalizumab], Remicade® [infliximab], Enbrel® [etanercept]).

Note: All renewal PA requests require the member to be adherent to the prescribed treatment regimen.

Clinical Criteria for Eucrisa®

Clinical criteria for approval of a PA request for Eucrisa® for members 2–17 years of age are **all** of the following:

- The member has mild to moderate atopic dermatitis. Documentation must include the approximate BSA involved and the area(s) affected.
- At least **one** of the following is true:
    - ✓ The member used a topical steroid for a minimum of two months and experienced an unsatisfactory therapeutic response.
    - ✓ The member used a topical steroid and experienced a clinically significant adverse drug reaction.
- At least **one** of the following is true:
    - ✓ The member used Elidel® or Protopic® for a minimum of two months and experienced an unsatisfactory therapeutic response.
    - ✓ The member used Elidel® or Protopic® and experienced a clinically significant adverse drug reaction.

Clinical criteria for approval of a PA request for Eucrisa® for members 18 years of age and older are **all** of the following:

- The member has mild to moderate atopic dermatitis. Documentation must include approximate BSA involved and the area(s) affected.
- At least **one** of the following is true:
    - ✓ The member used a medium to high potency topical steroid for at least two months and experienced an unsatisfactory therapeutic response.
    - ✓ The member used a medium to high potency topical steroid and experienced a clinically significant adverse drug reaction.
- At least **one** of the following is true:
    - ✓ The member used Elidel® or Protopic® for at least two months and experienced an unsatisfactory therapeutic response.
    - ✓ The member used Elidel® or Protopic® and experienced a clinically significant adverse drug reaction.

A copy of the member's medical records must be submitted with all PA requests for Eucrisa®. Medical records should document the following:

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

If clinical criteria for Eucrisa® are met, initial PA requests for Eucrisa® may be approved for up to a maximum of 183 days. Renewal PA requests for Eucrisa® may be approved for up to 365 days.

Renewal PA requests for members who have mild to moderate atopic dermatitis must meet the clinical criteria for initial PA requests for Eucrisa®. Renewal PA requests must include copies of the current medical records demonstrating the member has had a significant reduction in the area(s) affected and/or severity of atopic dermatitis.

Note: All renewal PA requests require the member to be adherent to the prescribed treatment regimen.

Lipotropics, PCSK9 Inhibitors

Clinical PA is required for all lipotropics, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors.

PA requests for lipotropics, PCSK9 inhibitors must be completed and signed by the prescriber. PA requests for lipotropics, PCSK9 inhibitors 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. Clinical documentation supporting the use of a lipotropics, PCSK9 inhibitor must also be submitted with the PA request.

PA requests for lipotropics, PCSK9 inhibitors may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

ForwardHealth will require the submission of certain medical records with initial PA requests for lipotropics, PCSK9 inhibitors in addition to existing clinical criteria for this drug class.

Medical records that document the following must be submitted with an initial PA request for lipotropics, PCSK9 inhibitors:

- Medical records demonstrating that the member has heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia, or clinical atherosclerotic cardiovascular disease
- Current lipid panel lab report
- Documentation of the member's current and previous lipid-lowering drug therapies, including the following:
  - ✓ Drug name and dosage
  - ✓ Dates taken
  - ✓ Lipid panel report prior to and during drug therapy (including dates taken)
  - ✓ Reasons for discontinuation if drug therapy was discontinued

Clinical criteria for lipotropics, PCSK9 inhibitors will remain unchanged. For more information and clinical criteria for lipotropics, PCSK9 inhibitors, providers may refer to the Lipotropics, PCSK9 Inhibitors topic (topic #18737) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

Non-Steroidal Anti-Inflammatory Drugs

Revised and Renamed Prior Authorization/Preferred Drug List for Non-Steroidal Anti-Inflammatory Drugs, Including Cyclo-Oxygenase Inhibitors

ForwardHealth has revised and renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Including Cyclo-Oxygenase Inhibitors form, F-11077 (12/12). The form has been renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) form, F-11077 (01/2018).

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. PA requests submitted on and after January 1, 2018, must be submitted on the revised form or the PA request will be returned to the provider.

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

PA requests for non-preferred NSAIDs must be completed and signed by the prescriber and submitted using the PA/PDL for NSAIDs form.

PA requests for non-preferred NSAIDs may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

ForwardHealth has revised the clinical criteria for NSAIDs.

Clinical Criterion for NSAIDs

The clinical criterion for approval of a PA request for a non-preferred NSAID requires that the member has experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction with **at least two** preferred NSAIDs. (The two preferred NSAIDs cannot be ibuprofen or naproxen.)

If the clinical criterion for a non-preferred NSAID is met, PA requests may be approved for up to 365 days.

Opioid Dependency Agents

The opioid dependency agents drug class contains the following subclasses:

- Opioid dependency agents — buprenorphine
- Opioid dependency agents — methadone
- Opioid dependency agents — rescue agent
- Opioid dependency and alcohol abuse/dependency agents

Opioid Dependency Agents — Buprenorphine

Revised Prior Authorization/Preferred Drug List for Opioid Dependency Agents — Buprenorphine Form

ForwardHealth has revised the Prior Authorization/ Preferred Drug List (PA/PDL) for Opioid Dependency Agents – Buprenorphine form, F-00081 (01/2018). 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. PA requests submitted on and after January 1, 2018, must be submitted on the revised form or the PA request will be returned to the provider.

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

Drugs in the opioid dependency agents — buprenorphine drug class **are** 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.

PA requests for drugs in the opioid dependency agents — buprenorphine drug class must be submitted on the PA/PDL for Opioid Dependency Agents — Buprenorphine form.

Submitting PA Requests for Opioid Dependency Agents — Buprenorphine

PA requests for buprenorphine tablets, Suboxone® film, and Zubsolv® for BadgerCare Plus, Medicaid, and SeniorCare members may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

PA requests for non-preferred buprenorphine-naloxone drugs may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

PA requests for preferred Suboxone® film and Zubsolv® submitted by a narcotic treatment service provider (provider type 52) as the billing provider may be approved for up to a maximum of 365 days. PA requests for preferred Suboxone® film and Zubsolv® submitted by other allowable provider types as the billing provider may be approved for up to a maximum of 183 days.

As a reminder, the following drugs in the opioid dependency agents — buprenorphine drug class are available through an expedited emergency supply request, which may be granted for up to a 14-day supply:

- Buprenorphine tablets (pregnant women only)
- Suboxone® film
- Zubsolv®

For more information about expedited emergency supply drugs, providers may refer to the Emergency Medication Dispensing topic (topic #1399) in the Covered Services and Requirements chapter of the Covered and Noncovered Services section of the Pharmacy service area of the Online Handbook.

ForwardHealth has revised the clinical criteria for opioid dependency agents — buprenorphine. ForwardHealth has **removed** the following clinical criteria from the opioid dependency agents — buprenorphine drug class:

- The prescriber has indicated if the member is taking any benzodiazepines.
- For members who are taking benzodiazepines, the prescriber of buprenorphine-containing transmucosal products for opioid dependence has indicated if they are also the prescriber of the benzodiazepine(s).

For more information about drugs in the opioid dependency agents — buprenorphine drug class, providers may refer to the Opioid Dependency Agents topic (topic #8917) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

Stimulants

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.

PA requests for non-preferred stimulants must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Non-Preferred Stimulants form, F-01672 (01/2017).

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 will be required.

Certain brand name drugs will be preferred over their generic equivalents. Effective January 1, 2018, brand name Concerta® will become a preferred drug (in addition to other preferred drugs) in the stimulants drug class. ForwardHealth will automatically apply a generic copayment to claims submitted for Concerta®.

For the month of January 2018, Wisconsin Medicaid, BadgerCare Plus, and SeniorCare will allow a transition period and generic methylphenidate ER (generic of Concerta®) will remain a preferred drug. Effective February 1, 2018, generic methylphenidate ER (generic of Concerta®) will become a non-preferred drug requiring PA.

New Stimulant Quantity Limits

Effective for DOS on and after March 1, 2018, quantity limits will apply to all preferred and non-preferred stimulants, with the exception of liquids. Quantity limits will not apply to liquid dosage forms of stimulants. When a claim is submitted with a quantity that exceeds the limit, the claim will be denied.

All stimulants (with the exception of liquid dosage forms) will have a cumulative quantity limit of 136 units per month

across the stimulants drug class. Members will be limited to a combined total of 136 stimulant units (tablets/capsules/patches) per month.

In order to prepare for this upcoming quantity limit, a transition period will be allowed so that pharmacy providers can work with prescribers to consolidate, adjust, or change members' stimulant medication(s) and dosage(s) as appropriate.

ForwardHealth will allow a **one-time** stimulant quantity limit override to be requested during the transition period from March 1, 2018, through March 31, 2018. To request an override of the new quantity limit, providers may call the Drug Authorization and Policy Override (DAPO) Center at 800-947-9627. Hours of operation are from 8:00 a.m. to 5:30 p.m., Monday through Friday. After business hours and on weekends, providers may leave a voicemail message for DAPO Center staff to return the next business day.

Notes:

- Prior to March 1, 2018, providers should not contact the DAPO Center to request this one-time stimulant quantity limit override.
- Pharmacy providers are reminded that they may dispense up to the allowed quantity limit without contacting the DAPO Center.

Effective April 1, 2018, if the member does not meet the policy for a stimulant quantity limit override through the DAPO Center, and the claim submitted exceeds the allowed stimulant quantity limit, the claim will be denied and the service will be a noncovered service. Members do not have appeal rights for noncovered services.

Quantity Limits Policy

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

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.

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

Prior to requesting a quantity limit policy override, the pharmacy provider should contact the prescriber to determine whether or not it is medically appropriate for a member to exceed the quantity limit. If it is medically appropriate for a member to exceed a quantity limit, pharmacy providers may request a quantity limit policy override by calling the DAPO Center.

Note: Pharmacy providers may dispense up to the allowed quantity limit without contacting the DAPO Center.

Pharmacy providers may request a quantity limit policy override for members enrolled in BadgerCare Plus, Medicaid, and SeniorCare.

Examples of when a quantity limit override request for a **non-stimulant drug** may be approved through the DAPO Center include, but are not limited to, the following:

- If the member has an appropriate medical need (e.g., the member's medications were lost or stolen, the member has requested a vacation supply)
- If the member has been taking too much of a medication because he or she misunderstood the directions for administration by the prescriber
- If the prescriber changed the directions for administration of the drug and did not inform the pharmacy provider

Effective April 1, 2018, a quantity limit override request for a **stimulant drug** will be limited to a one-month override and will only be approved for the following situations:

- Lost or stolen medication
- Vacation supply
- Medication and/or dosage change by the prescriber

Pharmacy providers may dispense up to a 96-hour supply of a drug to a member when the DAPO Center is closed and a policy override to exceed a quantity limit must be obtained. If the DAPO Center grants a policy override to exceed a quantity limit, the policy override will be retroactive and the pharmacy provider may submit a claim for the drug using the Point-of-Sale system or on paper. If the claim for a 96-hour supply is submitted on paper, the pharmacy provider will be required to complete and submit a Pharmacy Special Handling Request form, F-13074 (04/14).

If the DAPO Center denies the policy override, ForwardHealth will reimburse the provider for the 96-hour supply. A claim must be submitted on paper with the Pharmacy Special Handling Request.

Service Limitations

If an override of the service limitation, such as a quantity limit override, is requested and the request does not meet service limitation override criteria, the override will be denied and the service will be noncovered. Members do not have appeal rights for noncovered drugs or services.

ForwardHealth has revised the grandfathering policy for stimulants.

Grandfathering for Stimulants

BadgerCare Plus, Medicaid, and SeniorCare members who were grandfathered on certain amphetamine formulations for DOS on and after January 1, 2016, and remained eligible for grandfathering throughout 2017, will no longer be grandfathered for DOS on and after January 1, 2018, 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 2017.
- For members with other primary insurance on file with ForwardHealth, they have no claim activity for grandfathered amphetamine formulations for DOS in all of 2017.

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 (NCPDP) 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.

Note: The grandfathering of a member overrides the PDL PA policy only. Other policies, such as member enrollment eligibility, diagnosis restriction, quantity limit, and noncovered services policies continue to apply.

As a reminder, the following clinical criteria and PA request submission requirements apply to non-preferred stimulants.

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 dexmethylphenidate stimulant for at least 60 consecutive days with a minimum of

one dosage adjustment and experienced an unsatisfactory therapeutic response.

- ✓ The member took a dexmethylphenidate stimulant and experienced a clinically significant adverse drug reaction.

Submitting PA Requests for Non-Preferred Stimulants

PA 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.

PA requests for non-preferred stimulants (except for generic amphetamine salt combo ER, generic Concerta® ER, or methamphetamine requests) may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

Methamphetamine

PA requests for methamphetamine 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.

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

ForwardHealth has established clinical criteria for methamphetamine.

Clinical Criteria for Methamphetamine

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

- The member is 6–17 years of age.
- The member has had neuropsychological/psychological assessment that supports a diagnosis of ADHD.
- The prescriber has provided documented and objective evidence (supplied by third-party, unrelated adult observers) of functioning deficits secondary to ADHD in at least **two** of the following domains of functioning:
  - ✓ Home
  - ✓ Work
  - ✓ School
  - ✓ Community
- 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.
- At least **one** of the following is true:
  - ✓ The member took a dexmethylphenidate stimulant for at least 60 consecutive days with a minimum of one dosage adjustment and experienced an unsatisfactory therapeutic response.
  - ✓ The member took a dexmethylphenidate stimulant and experienced a clinically significant adverse drug reaction.

PA requests must include medical records to support the above criteria have been met, including documentation of all past and current treatments that have been attempted (both pharmacologic and non-pharmacologic).

If clinical criteria for methamphetamine are met, PA requests will be approved for up to a maximum of 183 days.

Stimulants – Related Agents

Revised Prior Authorization Drug Attachment for Modafinil and Nuvigil® Form

ForwardHealth has revised the Prior Authorization Drug Attachment for Modafinil and Nuvigil® form, F-00079 (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. PA requests submitted on and after January 1, 2018, must be submitted on the revised form or the PA request will be returned to the provider.

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

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

PA requests for modafinil and Nuvigil® must be completed and signed by the prescriber. PA requests for modafinil and Nuvigil® should be submitted using the PA/RF and the appropriate sections of the Prior Authorization Drug Attachment for Modafinil and Nuvigil® form.

PA requests for modafinil and Nuvigil® may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

Conditions for Which PA Requests for Use of Modafinil Will Be Considered for Review

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

- Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)
- Narcolepsy with cataplexy
- Narcolepsy without cataplexy
- Shift work sleep disorder
- ADHD

Clinical Criteria for Modafinil for Members with OSAHS

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.
- The member had an overnight polysomnogram (PSG) sleep study that confirms the member has OSAHS. (*Note:* The member's apnea-hypopnea index [AHI] must be documented.)
- The member is not taking any other stimulants or related agents.
- The member has tried continuous positive airway pressure (CPAP).

Note: If requested by ForwardHealth, the provider is required to submit the test results and provider interpretation for the PSG.

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

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.
- The member has had an overnight PSG sleep study followed by a multiple sleep latency test (MSLT) that confirm the member has narcolepsy.
- The overnight PSG test results include the following:
  - ✓ The member's total sleep time was at least 360 minutes.
  - ✓ The member experienced minimal sleep interruptions (e.g., respiratory events, periodic leg movements).
  - ✓ The provider interpretation indicates that an adequate night's sleep was achieved.
- The MSLT results include the following:
  - ✓ The MSLT was conducted the morning after the overnight PSG.
  - ✓ The average sleep latency for all naps was 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 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.

Note: If requested by ForwardHealth, the provider is required to submit the test results and provider interpretation for the PSG and MSLT, along with medical record documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy.

If clinical criteria for modafinil for members with narcolepsy with or without cataplexy are met, PA requests 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 has shift work sleep disorder.
- The member is a night shift worker. (*Note:* The member's current employer and weekly work schedule must be documented.)
- The member is not 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 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 a maximum of 365 days.

Clinical Criteria for Modafinil for Members with ADHD

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

- The member is at least 16 years of age.
- The member is not 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 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 atomoxetine.

If clinical criteria for modafinil for members with ADHD are met, initial PA requests 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 has experienced a partial response to a modafinil dose of 200 mg per day.

Members must have an existing approved PA request for modafinil in order to request a dose limit override. To request a modafinil dose limit override, providers may call the DAPO Center at 800-947-9627. Hours of operation are from 8:00 a.m. to 5:30 p.m., Monday through Friday. After business hours and on weekends, providers may leave a voicemail message for DAPO Center staff to return the next business day.

Conditions for Which PA Requests for Use of Nuvigil® Will Be Considered for Review

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

- OSAHS
- Narcolepsy with cataplexy
- Narcolepsy without cataplexy

- Shift work sleep disorder

Clinical Criteria for Nuvigil® for Members with OSAHS

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.
- The member had an overnight PSG sleep study that confirms the member has OSAHS. (*Note:* The member's AHI must be documented.)
- The member is not taking any other stimulants or related agents.
- The member has tried CPAP.

Note: If requested by ForwardHealth, the provider is required to submit the test results and provider interpretation for the PSG.

If clinical criteria for Nuvigil® for members with OSAHS are met, PA requests may be approved for up to a maximum of 365 days.

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.
- The member has had an overnight PSG sleep study followed by a MSLT that confirm the member has narcolepsy.
- The overnight PSG test results include the following:
  - ✓ The member's total sleep time was at least 360 minutes.
  - ✓ The member experienced minimal sleep interruptions (e.g., respiratory events, periodic leg movements).
  - ✓ The provider interpretation indicates that an adequate night's sleep was achieved.
- The MSLT results include the following:
  - ✓ The MSLT was conducted the morning after the overnight PSG.
  - ✓ The average sleep latency for all naps was 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 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.

Note: If requested by ForwardHealth, the provider is required to submit the test results and provider interpretation for the PSG and MSLT, along with medical record documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy.

If clinical criteria for Nuvigil® for members with narcolepsy with or without cataplexy are met, PA requests 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 has shift work sleep disorder.
- The member is a night shift worker. (*Note:* The member's current employer and weekly work schedule must be documented.)
- The member is not 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 taking any other stimulants or related agents.

If clinical criteria for Nuvigil® for members with shift work sleep disorder are met, initial PA requests 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 Policy Changes

Copayment for Brand Name Drugs Preferred Over Generic Drugs

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

This does not include brand name drugs that were preferred over generic equivalents because the generic equivalents are new to the marketplace and not yet cost-effective when compared to brand pricing.

For drugs determined to be included in this policy, ForwardHealth will automatically apply the generic copayment when a specific brand name drug is preferred over a generic equivalent. Providers do not need to indicate an NCPDP Dispense as Written/Product Selection code on claims to ensure the generic copayment deduction.

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

Drug Class	Drug Name	Effective Date
Acne Agents, Topical	Differin® 0.1% cream	01/01/2012
	Differin® 0.3% gel pump	02/01/2017
	Retin-A®	07/01/2016
Anticonvulsants	Tegretol® suspension	01/01/2016
	Tegretol® tablet	01/01/2016
	Tegretol® XR 100 mg	04/06/2016
	Tegretol® XR 200 mg	01/01/2012
	Tegretol® XR 400 mg	01/01/2012
Antihypertensives, Sympatholytics	Catapres-TTS®	01/01/2014
Glucocorticoids, Inhaled	Pulmicort Respules®	01/01/2016
Immunomodulators, Topical	Aldara®	01/01/2014
Lipotropics, Other	Zetia®	07/01/2017
Ophthalmics, Antibiotic-Steroid Combinations	TobraDex® suspension	01/01/2012
Ophthalmics, Glaucoma — Other	Alphagan® P 0.15%	01/01/2012
Proton Pump Inhibitors	Nexium®	07/01/2016
Stimulants	Adderall XR®	01/01/2012
	Concerta®	**01/01/2018**

Expedited Emergency Supply

As a result of changes made during the January 2018 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) 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 Medicaid Services, the 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, DHS.

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

P-1250

This *Update* was issued on 12/15/2017 and information contained in this *Update* was incorporated into the Online Handbook on 01/02/2018.

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 2018 Preferred Drug List review or as a result of other pharmacy policy changes. Providers should refer to the Forms page of the ForwardHealth Portal at *www.forwardhealth.wi.gov/* for current copies of these forms and completion instructions. Unless otherwise noted, all form changes listed are effective January 1, 2018. 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 or Revised and Renamed	Effective Date
Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 7 Years of Age and Younger	F-00556	Revised and Renamed: Prior Authorization Drug Attachment for Antipsychotic Drugs for Children 8 Years of Age and Younger	01/01/2018
Instructions	F-00556A	Revised and Renamed	01/01/2018
Prior Authorization Drug Attachment for Hepatitis C Agents	F-01247	Revised	01/01/2018
Instructions	F-01247A	Revised	01/01/2018
Prior Authorization Drug Attachment for Modafinil and Nuvigil®	F-00079	Revised	01/01/2018
Instructions	F-00079A	Revised	01/01/2018
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Ankylosing Spondylitis	F-11304	Revised	01/01/2018
Instructions	F-11304A	Revised	01/01/2018
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	Revised	01/01/2018
Instructions	F-01950A	Revised	01/01/2018

Form Name	Form Number	Revised or Revised and Renamed	Effective Date
Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Psoriasis	F-11306	Revised	01/01/2018
Instructions	F-11306A	Revised	01/01/2018
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	Revised	01/01/2018
Instructions	F-01951A	Revised	01/01/2018
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	Revised and Renamed: Prior Authorization/Preferred Drug List (PA/PDL) for Cytokine and Cell Adhesion Molecule (CAM) Antagonist Drugs for Uveitis, Giant Cell Arteritis, and Neonatal Onset Multisystem Inflammatory Disease (NOMID)	01/01/2018
Instructions	F-01952A	Revised and Renamed	01/01/2018
Prior Authorization/Preferred Drug List (PA/PDL) for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Including Cyclo-Oxygenase Inhibitors	F-11077	Revised and Renamed: Prior Authorization/Preferred Drug List (PA/PDL) for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	01/01/2018
Instructions	F-11077A	Revised and Renamed	01/01/2018
Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents — Buprenorphine	F-00081	Revised	01/01/2018
Instructions	F-00081A	Revised	01/01/2018

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 2018 Preferred Drug List review. The updated statuses are effective January 1, 2018. 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/*.

Drug Class	Drug Name	Status Effective January 1, 2018**
Alzheimer's Agents	Namzaric® dose pack*	Non-Preferred
Antidepressants, Other	desvenlafaxine ER*	Non-Preferred
Antihistamines, Minimally Sedating	fexofenadine OTC*	Non-Preferred
Antiparkinson's Agents	rasagiline*	Non-Preferred
	Xadago®*	Non-Preferred
Antipsoriatics, Oral	methoxsalen rapid*	Non-Preferred
	Oxsoralen-Ultra®	Non-Preferred
Antipsychotics	Aristada®	Preferred
COPD Agents	Bevespi Aerosphere®	Preferred
Cytokine and CAM Antagonists	Kevzara®*	Non-Preferred
	Siliq™*	Non-Preferred
	Tremfya™*	Non-Preferred
Epinephrine, Self-Injected	epinephrine 0.15 mg (Adrenaclick®)	Non-Preferred
	epinephrine 0.3MG (Adrenaclick®)	Non-Preferred
Glucocorticoids, Inhaled	AirDuo RespiClick®*	Non-Preferred
	ArmonAir™ RespiClick®*	Non-Preferred
	Flovent® HFA	Preferred
	fluticasone/salmeterol*	Non-Preferred
Glucocorticoids, Oral	Emflaza® suspension*	Non-Preferred
	Emflaza® tablet*	Non-Preferred
	prednisolone sodium phosphate solution (Millipred®)*	Non-Preferred
	prednisolone sodium phosphate solution (Veripred®)*	Non-Preferred
Gout Agents	colchicine capsule	Preferred

Drug Class	Drug Name	Status Effective January 1, 2018**
Hepatitis C Agents	Harvoni®	Preferred
	Mavyret™*	Preferred
	Technivie™	Non-Preferred
	Vosevi®*	Non-Preferred
Immunomodulators, Atopic Dermatitis	Dupixent®*	Non-Preferred
	Eucrisa®	Non-Preferred
	Protopic®	Preferred
Intranasal Rhinitis Agents	azelastine	Preferred
Leukotriene Modifiers	zileuton ER*	Non-Preferred
NSAIDs	celecoxib	Preferred
	Naprosyn® suspension	Non-Preferred
	naproxen suspension	Non-Preferred
Ophthalmics, Antibacterial	moxifloxacin (Vigamox®)*	Non-Preferred
Ophthalmics for Allergic Conjunctivitis	olopatadine (Patanol®)	Preferred
	olopatadine drops (Pataday)*	Non-Preferred
	Pataday®	Non-Preferred
Ophthalmics, Anti-Inflammatories	FML®	Non-Preferred
Ophthalmics, Anti-Inflammatory/ Immunomodulators	Restasis®*	Preferred
	Restasis® MultiDose™*	Preferred
	Xiidra®*	Non-Preferred
Otic Antibiotics	ciprofloxacin	Non-Preferred
	ofloxacin	Preferred
Sedative Hypnotics	eszopiclone	Preferred
Steroids, Topical Low	MiCort™ HC*	Non-Preferred
Steroids, Topical Medium	flurandrenolide ointment*	Non-Preferred
Steroids, Topical Very High	clobetasol propionate foam	Preferred
Stimulants	Aptensio XR®	Preferred
	Concerta®*	Preferred
	Cotempla XR-ODT™*	Non-Preferred
	Methylin® solution	Preferred
	methylphenidate ER (Concerta®)	Non-Preferred**
	Mydayis® ER*	Non-Preferred
Stimulants – Related Agents	atomoxetine*	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*.

** Generic methylphenidate ER (generic of Concerta®) will remain a preferred drug in the stimulants drug class for the month of January 2018 to allow a transition period. Effective February 1, 2018, methylphenidate ER will become a non-preferred drug requiring PA.