ForwardHealth
Wisconsin serving you

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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

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

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

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

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

## Changes to Pharmacy-Related Forms and Completion Instructions

Attachment 1 of this *Update* lists the prior authorization (PA) forms and completion instructions that are new or have been revised, renamed, or discontinued as a result of the July 2016 PDL review or as a result of other pharmacy policy changes. Providers should refer to the Forms page of the Portal for current copies of all PA forms and completion instructions. Unless otherwise noted, all forms listed in Attachment 1 are effective July 1, 2016. Additional information regarding changes to clinical criteria or submission options is noted in the applicable drug class section of this *Update*.

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

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

## A Brief Overview of the Preferred Drug List

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

therapeutically interchangeable alternative agents in the same drug class.

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

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

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

## A Prescriber's Responsibilities for Prior Authorization for Preferred Drug List Drugs

Prescribers are encouraged to write prescriptions for preferred drugs.

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

Prescribers are required to provide clinical information so that pharmacy providers can request and obtain PA. Prescribers are required to complete the Prior Authorization/Preferred Drug List (PA/PDL) Exemption Request form, F-11075 (09/13), for non-preferred drugs that do not require a drug- or drug class-specific PA form.

### *Clinical Criteria for Non-preferred Drugs*

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

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

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

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

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

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

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

non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.
- The member was recently discharged from an inpatient stay in which the member was stabilized on the non-preferred drug being requested.

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

### *Completing a Prior Authorization Form*

If a non-preferred drug or a preferred drug that requires clinical PA is medically necessary for a member, the prescriber is required to do the following:
- Complete the appropriate PA form for the drug.
- Send the PA form to the pharmacy where the prescription will be filled.
- Include accurate and complete answers and clinical information about the member's medical history on the PA form.
- Provide his or her handwritten signature and date on the form.

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

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

*Note:* If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet, F-01176 (12/11), which is available on the Forms page of the Portal, or to the Additional Information section available on most PA forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

## *A Pharmacy Provider's Responsibilities for Prior Authorization for Preferred Drug List Drugs*

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

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

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

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

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

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

On May 11, 2016, the Pharmacy PA Advisory Committee met to review new and existing therapeutic drug classes on the PDL.

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

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

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

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

## Acne Agents, Topical

Certain brand name drugs will be preferred over their generic equivalents. Brand name Retin-A® cream and gel will become preferred drugs (in addition to other preferred drugs) in the acne agents, topical drug class. ForwardHealth will automatically apply a generic copayment and dispensing fee to claims submitted for brand name Retin-A® cream and gel.

Generic tretinoin cream and tretinoin gel will become non-preferred drugs.

## Antibiotics, GI

Quantity limits will apply to Xifaxan® 200 mg tablets. Members will be limited to a maximum of nine tablets per 68 days.

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.

## Cytokine and Cell Adhesion Molecule Antagonist Drugs for Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, and Rheumatoid Arthritis

ForwardHealth has revised the list of non-preferred drugs used to treat ankylosing spondylitis and psoriatic arthritis to include Cosentyx®, the list of non-preferred drugs used to treat plaque psoriasis to include Taltz®, and the list of non-preferred drugs used to treat rheumatoid arthritis to include Xeljanz® XR.

The list of clinical conditions for which PA requests for cytokine and cell adhesion molecule (CAM) antagonist drugs will be approved has not changed.

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.

## Growth Hormone Drugs

ForwardHealth has revised the clinical criteria for growth hormone drugs.

For more information about growth hormone drugs, providers may refer to the Growth Hormone Drugs topic (topic #1988) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook. Prior authorization requests for growth hormone drugs must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Growth

Hormone Drugs form, F-11092 (10/14). Prior authorization requests for growth hormone drugs may be submitted using the STAT-PA system (for some conditions or indications), on the Portal, by fax, or by mail.

ForwardHealth does not cover growth hormone drugs for the following members and conditions:

- Members with idiopathic short stature, which is a growth failure or short stature not associated with growth hormone deficiency or disease state
- Pediatric members with growth failure or short stature with closed epiphyses
- Pediatric members who are currently being treated with growth hormone drugs and who have growth failure or short stature with a growth rate less than 2 cm/year or who do not demonstrate a significant increase in growth velocity
- Members who do not comply with their prescribed growth hormone therapy

Prior authorization requests submitted for these conditions will be returned as noncovered services. Members do not have appeal rights for noncovered services.

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

## Clinical Criteria for Adult Covered Indications for Growth Hormone Drugs

ForwardHealth covers growth hormone drugs for the following indications:

- Growth hormone deficiency confirmed with **at least two** appropriate growth hormone stimulation tests demonstrating a growth hormone peak response of less than the established reference value for the specific stimulation tests performed. Growth hormone stimulation testing should be conducted after an overnight fast, using a well-standardized protocol. Complete testing results must be included with the PA request, including the following:
  - ✓ The type of stimulation test and the dose of the stimulating agent
  - ✓ A copy of the medical notes taken during the entire testing procedure
  - ✓ The time and results from each blood sample taken
  - ✓ The provider interpretation of the testing results
- Hypothalamic-pituitary structural lesions and evidence of panhypopituitarism involving at least three pituitary hormone deficiencies, not including growth hormone

Providers must include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment, including, but not limited to, image results, lab testing, and medical office notes.

*Note:* All growth hormone prescriptions must be written by an endocrinologist or through an endocrinology consultation, except prescriptions written for Serostim® or Zorbtive®.

## Clinical Criteria for Pediatric Covered Indications for Growth Hormone Drugs

ForwardHealth covers growth hormone drugs for the following indications:

- Growth failure or short stature associated with one of the following congenital conditions:
  - ✓ Noonan syndrome
  - ✓ Prader-Willi syndrome
  - ✓ Short stature homeobox-containing gene (SHOX) deficiency
  - ✓ Turner syndrome
- Growth failure or short stature associated with chronic renal insufficiency in pre-transplant members. Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment.
- Growth failure or short stature associated with growth hormone deficiency confirmed with at least two appropriate growth hormone stimulation tests demonstrating a growth hormone peak response of less than 10 ng/mL. The member's height must be more

than two standard deviations below the mean for chronological age. Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment. The medical workup should include growth velocity, insulin-like growth factor-1 (IGF-1), insulin-like growth factor binding protein-3 (IGFBP-3), and bone age results. If these results are normal, best clinical practice would indicate growth hormone stimulation testing is not necessary since growth hormone deficiency can effectively be excluded without the need for growth hormone stimulation testing. If IGF-1/IGFBP-3 results are low, under-nutrition should be evaluated and addressed before proceeding with growth hormone stimulation testing. Growth hormone stimulation testing can be useful information, but it has not been shown to be by itself a definitive tool for diagnosing growth hormone deficiency by itself. ForwardHealth will consider the entire clinical record for the PA determination decision.

- Members born small for gestational age who are 2 years of age or older with a height that remains more than two standard deviations below the mean for chronological age. Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment.
- Hypothalamic-pituitary structural lesions and evidence of panhypopituitarism involving at least two pituitary hormone deficiencies, not including growth hormone. Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment.

Detailed documentation of the medical work-up and testing includes, at a minimum:

- Medical office notes
- Growth charts (including growth rate, growth percentiles, and Z-scores)
- Lab testing results

Additional required documentation to be submitted with the PA request, when applicable, includes the following:

- Bone age results
- Growth plate results
- Other image results
- Growth hormone stimulation results

Growth hormone stimulation testing should be conducted after an overnight fast, using a well-standardized protocol. Complete testing results must be included with the PA request, including the following:

- The type of stimulation test and the dose of stimulating agent
- A copy of the medical notes taken during the entire testing procedure
- The time and results from each blood sample taken
- The provider interpretation of the testing results

*Note:* All growth hormone prescriptions must be written by an endocrinologist or through an endocrinology consultation, except prescriptions written for Serostim® or Zorbtive®.

## Hepatitis C Agents

The following preferred and non-preferred statuses will apply to drugs in the hepatitis C agents drug class:

- Viekira Pak® will remain a preferred drug for members who have chronic hepatitis C virus (HCV) genotype 1 infection.
- Zepatier™ will become a preferred drug for members who have chronic HCV genotype 1 or 4 infection.
- Daklinza® (combined with Sovaldi® with or without ribavirin) will become a preferred drug for members who have chronic HCV genotype 3 infection.
- Technivie® will become a preferred drug for members who have chronic HCV genotype 4 infection.
- Harvoni®, Sovaldi®, and Olysio® will remain non-preferred drugs for members who have chronic HCV infection.

New hepatitis C agents not reviewed by the Pharmacy PA Advisory Committee at the May 11, 2016, meeting will be added to the PDL as non-preferred drugs until their next scheduled class review by the Pharmacy PA Advisory Committee. In addition, hepatitis C agents acquiring new indications for use will not be considered until criteria

addressing the new indication have been published in an *Update*.

*Note:* The Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (08/15), and the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form, F-01248 (12/14), are currently being revised to better address the new hepatitis C agents clinical criteria. The revised forms will be published in a future *Update*. In the meantime, providers should continue to use the current forms for PA requests. If additional information needs to be addressed, providers should submit this information using Section V (Additional Information) of the Prior Authorization Drug Attachment for Hepatitis C Agents form or the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form.

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

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

Daklinza® (combined with Sovaldi® with or without ribavirin) will be the preferred drug for members who have chronic HCV genotype 3 infection. Prior authorization requests for other hepatitis C agents for members who have chronic HCV genotype 3 infection will not be considered unless the member is clinically ineligible for treatment with Daklinza® (combined with Sovaldi® with or without ribavirin) due to a medical or medication contraindication.

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

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

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

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

*Note:* When two or more hepatitis C agents are used as **combined** treatment (e.g., Daklinza® as a combined treatment with Sovaldi®), providers should not submit separate PA request forms for each drug. For initial PA requests, the hepatitis C agents used for combined treatment must be submitted on **one** Prior Authorization Drug Attachment for Hepatitis C Agents form and one completed Prior Authorization Request Form (PA/RF), F-11018 (05/13). For renewal PA requests, the hepatitis C agents used for combined treatment must be submitted on one Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form. A PA/RF should not be submitted for hepatitis C agents renewal requests. Amendment PA requests for hepatitis C agents used for combined treatment must be submitted on **one** Prior Authorization Amendment Request form, F-11042 (07/12).

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

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

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

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

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

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

- Magnetic resonance elastography of 3.66 kPa or greater
- Shear wave elastography of 7.1 kPa or greater
- Fibroscan of 7.1 kPa or greater
- Liver biopsy

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

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

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

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

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

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

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

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

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

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

## Daklinza®

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

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

Only PA requests for the use of Daklinza® as a combined treatment with Sovaldi® with or without ribavirin for members with genotype 1 or 3 whose HCV liver disease has advanced to **any** of the following stages may be considered for review (for HCV genotype 1, the member must be clinically ineligible for treatment with Viekira Pak® and Zepatier™ due to a medical or medication contraindication):

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

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

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

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

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

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

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

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

## Technivie®

Technivie® will become a preferred drug that requires clinical PA for members who have chronic HCV genotype 4 infection.

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

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

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

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

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

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Technivie® or Viekira Pak®.

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

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

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

## Viekira Pak®

Viekira Pak® will remain a preferred drug that requires clinical PA for members who have HCV genotype 1 infection.

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

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

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

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

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

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

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

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

## Zepatier™

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

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

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

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

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

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

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

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

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

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

## Harvoni®

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

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

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

- Compensated cirrhosis (i.e., CTP class A)
- Moderate decompensated cirrhosis (i.e., CTP class B) for members who have chronic HCV genotype 1 infection only
- Metavir score of F2 or F3
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, B-cell non-Hodgkin's lymphoma, or porphyria cutanea tarda (laboratory-confirmed diagnosis)
- Liver transplant recipients with or without fibrosis or liver transplant recipients with compensated cirrhosis (i.e., CTP class A) for members who have chronic HCV genotype 1 or 4 infection only

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

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

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

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

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

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

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

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

## Olysio®

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- The member does not have a medical or medication contraindication for treatment with Viekira Pak® and Zepatier™.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis and the member has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.

- The member has taken a prior course of therapy with Harvoni®, Olysio®, Sovaldi®, a sofosbuvir-containing product, or any other HCV protease inhibitor.
- The member is non-compliant with an approved HCV treatment regimen.

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

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

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

## Sovaldi®

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

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

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

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

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

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

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

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

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak® and Zepatier™.
- The member has chronic HCV genotype 3 infection and does not have a medical or medication contraindication for treatment with Daklinza®.
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie® and Zepatier™.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).

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

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

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

## Hypoglycemics, Incretin Mimetics/Enhancers

Symlin® will become a preferred drug and will no longer be diagnosis restricted.

## *Prior Authorization/Preferred Drug List for Symlin® Form Being Discontinued*

Effective for PA requests submitted on and after July 1, 2016, the Prior Authorization/Preferred Drug List (PA/PDL) for Symlin® form, F-00080 (10/11), will no longer be accepted. This form is being discontinued. It will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal.

## Hypoglycemics, Insulins

Due to the addition of multiple drugs to the hypoglycemics, insulins PDL drug class, the hypoglycemics, insulins drug class will be split to include a subclass for long-acting insulin on the Preferred Drug List Quick Reference. ForwardHealth will monitor the subclass separately.

The subclass will be named hypoglycemics, insulin — long-acting.

## Hypoglycemics, Insulin — Long-Acting

Lantus® and Levemir® will be preferred drugs in the hypoglycemics, insulin — long-acting drug class.

Toujeo® and Tresiba® will be non-preferred drugs in the hypoglycemics, insulin — long-acting drug class.

Prior authorization requests for non-preferred hypoglycemics, insulin — long-acting must be completed and signed by the prescriber. Prior authorization requests for non-preferred hypoglycemics, insulin — long-acting must be submitted using the Prior Authorization/Preferred Drug List (PA/PDL) for Hypoglycemics, Insulin — Long-Acting form, F-01749 (07/2016), and the PA/RF.

Prior authorization requests for non-preferred hypoglycemics, insulin — long-acting drugs may be submitted on the Portal, by fax, or by mail. Prior authorization requests for non-preferred hypoglycemics, insulin — long-acting drugs may **not** be submitted using the STAT-PA system.

Approved PA requests on file with ForwardHealth dated prior to July 1, 2016, will be honored until they expire or until the approved days' supply is used up.

ForwardHealth has established clinical criteria for non-preferred hypoglycemics, insulin — long-acting drugs.

### *Clinical Criteria for Non-preferred Hypoglycemics, Insulin — Long-Acting Drugs*

Clinical criteria that must be documented for approval of a PA request for a non-preferred hypoglycemics, insulin — long-acting drug are **all** of the following:

- The member has diabetes.
- The member is unable to use Lantus® due to **one** of the following:
  - ✓ The member has used Lantus® for at least three consecutive months and was unable to obtain adequate fasting glucose control.

- ✓ The member has used Lantus® for at least three consecutive months and experienced continued episodes of hypoglycemia.

- The member is unable to use Levemir® due to **one** of the following:
  - ✓ The member has used Levemir® for at least three consecutive months and was unable to obtain adequate fasting glucose control.
  - ✓ The member has used Levemir® for at least three consecutive months and experienced continued episodes of hypoglycemia.
- The member's insulin regimen was adjusted to optimize glycemic control or reduce hypoglycemia and the member was compliant with the insulin treatment regimen and blood glucose monitoring schedule. (Insulin regimen adjustment options should include basal dose escalation, splitting the daily basal dose, adjusting the basal dosing time, and the addition or dose escalation of meal-time insulin.)

*Note:* Members who are using greater than or equal to 80 units per day of Lantus® or Levemir® are not required to attempt both products.

In addition to meeting the above clinical criteria, the following must be documented:

- The member's current insulin treatment regimen
- The member's previous insulin treatment regimen(s)
- The member's proposed insulin treatment regimen to include the non-preferred long-acting insulin (initial request only)
- The glycemic treatment goals the prescriber has established for the member, such as hemoglobin A1c (HbA1c) and fasting blood glucose (FBG)

The following will not be considered as criteria to support the need for a non-preferred hypoglycemics, insulin — long-acting drug:

- Non-adherence to previous insulin treatment
- Member or prescriber preference for the use of a non-preferred long-acting insulin
- Member or prescriber preference for a smaller injection volume

If clinical criteria for a non-preferred hypoglycemics, insulin — long-acting drug are met, initial PA requests may be approved for up to a maximum of 183 days. Medical records must be submitted to support the need for a non-preferred long-acting insulin.

Renewal PA requests may be approved for up to a maximum of 365 days. A copy of the member's diabetes management medical records must be submitted demonstrating an improvement in the member's glycemic control. Examples include a decrease in HbA1c, improved FBG, and decreased hypoglycemia.

## Lipotropics, Other

Due to the addition of multiple drugs to the lipotropics, other PDL drug class, the lipotropics, other drug class will be split to include a subclass for apolipoprotien B (apo-B) inhibitors on the Preferred Drug List Quick Reference. ForwardHealth will monitor the subclass separately.

The subclass will be named lipotropics, apo-B inhibitors.

### *Lipotropics, Apo-B Inhibitors*

ForwardHealth has revised the clinical criteria for the lipotropics, apo-B inhibitors Juxtapid® and Kynamro®.

Diagnosis restrictions will no longer apply to Juxtapid® and Kynamro®.

Clinical PA is required for Juxtapid® and Kynamro®.

Prior authorization requests for Juxtapid® and Kynamro® must be completed and signed by the prescriber. Prior authorization requests for Juxtapid® and Kynamro® should be submitted using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016), and the PA/RF.

Clinical documentation supporting the use of Juxtapid® or Kynamro® must also be submitted with the PA request.

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

### *Clinical Criteria for Juxtapid® and Kynamro®*

Clinical criteria that must be documented for approval of an initial PA request for Juxtapid® or Kynamro® are **both** of the following:

- The member has homozygous familial hypercholesterolemia (HoFH).
- The member has taken the highest available dose or maximally tolerated dose of a high potency statin (atorvastatin or Crestor®) combined with Repatha™ and Zetia® for at least three continuous months with failure to reach a low-density lipoprotein (LDL) level of 100 mg/dL or less, or the member has had a clinically significant adverse drug reaction, clinically significant drug interaction, or medical condition preventing the member from using these drugs.

*Note:* The member's inability to use one or more of the previously described drug therapies does not preclude the requirement for the member to use all of the above drug therapies for which the member does not have a clinically significant adverse drug reaction, clinically significant drug interaction, or medical condition preventing the member from using a specific drug.

The following medical records must be included with the initial PA request to demonstrate the member meets these criteria:

- Medical records demonstrating that the member has HoFH
- 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

If the member is not able to use the highest available dose or maximally tolerated dose of a high potency statin due to prior treatment history with significant skeletal muscle-related symptoms (e.g., pain, weakness) during statin treatment, documentation must demonstrate that a causal relationship has been established between statin use and skeletal muscle-related symptoms. Documentation must demonstrate **all** of the following:

- Skeletal muscle-related symptoms resolved after discontinuation of statin.
- Skeletal muscle-related symptoms occurred when rechallenged at a lower dose of the same statin.
- Skeletal muscle-related symptoms occurred after switching to an alternative statin.
- Non-statin causes of significant skeletal muscle-related symptoms were ruled out.

If clinical criteria for Juxtapid® or Kynamro® are met, initial PA requests will be approved for up to a maximum of 120 days. For renewal requests, if the member's LDL level decreased by at least 25 percent from baseline or decreased to 100 mg/dL or less, PA requests may be approved for an additional 183 days of treatment.

*Note:* All renewal PA requests require the member to be adherent with the prescribed treatment regimen. A copy of a current lipid panel report (within the past 30 days) must be included with the PA request.

## ***Lipotropics, PCSK9 Inhibitors***

ForwardHealth has revised the clinical criteria for lipotropics, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors.

Clinical PA is required for all lipotropics, PCSK9 inhibitors.

Prior authorization requests for lipotropics, PCSK9 inhibitors must be completed and signed by the prescriber. Prior authorization 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 and the PA/RF. Clinical documentation supporting the use of a

lipotropics, PCSK9 inhibitor must also be submitted with the PA request.

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

### *Clinical Criteria for Lipotropics, PCSK9 Inhibitors*

Clinical criteria that must be documented for approval of an initial PA request for lipotropics, PCSK9 inhibitors are **both** of the following:

- The member has **one** of the following medical conditions:
  - ✓ Heterozygous familial hypercholesterolemia (HeFH) if 18 years of age or older
  - ✓ Homozygous familial hypercholesterolemia if 13 years of age or older (Repatha™ only)
  - ✓ Clinical atherosclerotic cardiovascular disease as evidenced by **one** of the following:
    - History of myocardial infarction (heart attack)
    - History of stroke or transient ischemic attack
    - History of coronary revascularization (angioplasty/percutaneous coronary intervention)
- The member has taken the highest available dose or maximally tolerated dose of a high potency statin (atorvastatin or Crestor®) combined with Zetia® for **at least three** continuous months with failure to reach an LDL level of 100 mg/dL or less, or the member has had a clinically significant adverse drug reaction, clinically significant drug interaction, or medical condition preventing the member from using these drugs.

*Note:* The member's inability to use one of the previously described drug therapies does not preclude the requirement for the member to use the other drug therapy for which the member does not have a clinically significant adverse drug reaction, clinically significant drug interaction, or medical condition preventing the member from using a specific drug.

The following medical records must be included with the initial PA request to demonstrate the member meets these criteria:

- Medical records demonstrating that the member has HeFH, HoFH, 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

If the member is not able to use the highest available dose or maximally tolerated dose of a high potency statin due to prior treatment history with significant skeletal muscle-related symptoms (e.g., pain, weakness) during statin treatment, documentation must demonstrate that a causal relationship has been established between statin use and skeletal muscle-related symptoms. Documentation must demonstrate **all** of the following:

- Skeletal muscle-related symptoms resolved after discontinuation of statin.
- Skeletal muscle-related symptoms occurred when rechallenged at a lower dose of the same statin.
- Skeletal muscle-related symptoms occurred after switching to an alternative statin.
- Non-statin causes of significant skeletal muscle-related symptoms were ruled out.

If clinical criteria for a lipotropics, PCSK9 inhibitor are met, initial PA requests will be approved for up to a maximum of 120 days. For renewal requests, if the member's LDL level decreased by at least 25 percent from baseline or decreased to 100 mg/dL or less, PA requests may be approved for an additional 183 days of treatment.

*Note:* All renewal PA requests require the member to be adherent with the prescribed treatment regimen. A copy of a

current lipid panel report (within the past 30 days) must be included with the PA request.

## Multiple Sclerosis Agents, Immunomodulators

ForwardHealth has established clinical criteria for Glatopa™.

### *Revised Prior Authorization/Preferred Drug List for Multiple Sclerosis Agents, Immunomodulators*

ForwardHealth has revised the Prior Authorization/ Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators form, F-00805 (07/2016). The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. Prior authorization requests submitted on and after July 1, 2016, must be submitted on the revised form or the PA request will be returned to the provider.

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

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

For more information about MS agents, immunomodulator drugs, providers may refer to the Multiple Sclerosis Agents, Immunomodulators topic (topic #10997) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

#### *Clinical Criteria for Glatopa™*

The prescriber must submit detailed clinical justification for prescribing Glatopa™ instead of the preferred agents, Copaxone® 20 mg and Copaxone® 40 mg. This clinical information must document why the member cannot use Copaxone® 20 mg and Copaxone® 40 mg, including why it is medically necessary that the member receive Glatopa™ instead of Copaxone® 20 mg and Copaxone® 40 mg.

## Opioid Dependency Agents

Due to the addition of multiple drugs to the opioid dependency agents PDL drug class, the opioid dependency agents drug class will be split into multiple subclasses on the Preferred Drug List Quick Reference. ForwardHealth will monitor the subclasses individually.

The subclasses will be:

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

Pharmacy providers should refer to the Preferred Drug List Quick Reference for a complete list of covered opioid dependency agents and their individual subclasses. Prescribers are encouraged to write prescriptions for preferred opioid dependency agents.

### *Opioid Dependency Agents — Buprenorphine*

#### *Revised and Renamed Prior Authorization/Preferred Drug List for Opioid Dependency Agents*

ForwardHealth has revised and renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents form, F-00081 (07/14). The form has been renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents — Buprenorphine form, F-00081 (07/2016). The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. Prior authorization requests submitted on and after July 1, 2016, must be submitted on the revised form or the PA request will be returned to the provider.

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

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.

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

Prior authorization 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 Prior Authorization Requests for Opioid Dependency Agents — Buprenorphine*

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

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

Prior authorization requests for preferred Suboxone® film 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. Prior authorization requests for preferred Suboxone® film submitted by other allowable provider types as the billing provider may be approved for up to a maximum of 183 days.

ForwardHealth has revised the clinical criteria for opioid dependency agents — buprenorphine.

### *Clinical Criteria for Suboxone® Film*

Suboxone® film is a preferred drug that requires clinical PA.

Clinical criteria for approval of a PA request for Suboxone® film are **all** of the following:

- The member has a diagnosis of opioid type dependence.
- The member is 16 years of age or older.
- The drug is being prescribed by a physician who has obtained a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver allowing him or her to prescribe buprenorphine-based agents for opioid dependency treatment.
- The prescriber has indicated that he or she has read the educational brochure titled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers, which is provided through the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) Risk Evaluation and Mitigation Strategy (REMS) program.
- The prescriber has communicated the key messages to the member about the risks of accidental overdose, misuse, and abuse while taking products covered under the BTOD REMS program.
- The member is not taking other opioids, tramadol, or carisoprodol.
- The prescriber has indicated whether the member has been receiving BTOD treatment for more than two years.
- For members who have been receiving BTOD treatment for more than two years, the prescriber has indicated whether the member is being maintained on a daily dose of 12 mg or less of a BTOD.
- The prescriber has indicated if the member is taking any benzodiazepines.
- For members who are taking benzodiazepines, the prescriber of BTOD has indicated if he or she is also the prescriber of the benzodiazepine(s).
- The prescriber has indicated that he or she has read the attestation statement on the PA form and that he or she agrees to follow guidelines set forth by the United States

Department of Health and Human Services Federation of State Medical Boards — Model Policy Guidelines for Opioid Addiction Treatment.

### *Clinical Criteria for Buprenorphine Tablets*

Buprenorphine tablets are a non-preferred drug in the opioid dependency agents — buprenorphine drug class.

Clinical criteria for approval of a PA request for buprenorphine tablets are **all** of the following:

- The member has a diagnosis of opioid type dependence.
- The member is 16 years of age or older.
- The drug is being prescribed by a physician who has obtained a DATA 2000 waiver allowing him or her to prescribe buprenorphine-based agents for opioid dependency treatment.
- The prescriber has indicated that he or she has read the educational brochure titled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers, which is provided through the BTOD REMS program.
- The prescriber has communicated the key messages to the member about the risks of accidental overdose, misuse, and abuse while taking products covered under the BTOD REMS program.
- The member is not taking other opioids, tramadol, or carisoprodol.
- The prescriber has indicated whether the member has been receiving BTOD treatment for more than two years.
- For members who have been receiving BTOD treatment for more than two years, the prescriber has indicated whether the member is being maintained on a daily dose of 12 mg or less of a BTOD.
- The prescriber has indicated if the member is taking any benzodiazepines.
- For members who are taking benzodiazepines, the prescriber of BTOD has indicated if he or she is also the prescriber of the benzodiazepine(s).
- The prescriber has indicated that he or she has read the attestation statement on the PA form and that he or she agrees to follow guidelines set forth by the United States Department of Health and Human Services Federation of State Medical Boards — Model Policy Guidelines for Opioid Addiction Treatment.
- The member is pregnant and the prescriber has indicated the member's expected delivery date.
- The prescriber discussed with the member that methadone maintenance is the standard of care for opioid addiction treatment in pregnant women.
- The prescriber informed the member about the limited safety data for the support of buprenorphine use in pregnant women.

### *Clinical Criteria for Non-preferred Buprenorphine-Naloxone Drugs*

Clinical criteria for approval of a PA request for non-preferred buprenorphine-naloxone drugs are **all** of the following:

- The member has a diagnosis of opioid type dependence.
- The member is 16 years of age or older.
- The drug is being prescribed by a physician who has obtained a DATA 2000 waiver allowing him or her to prescribe buprenorphine-based agents for opioid dependency treatment.
- The prescriber has indicated that he or she has read the educational brochure titled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers, which is provided through the BTOD REMS program.
- The prescriber has communicated the key messages to the member about the risks of accidental overdose, misuse, and abuse while taking products covered under the BTOD REMS program.
- The member is not taking other opioids, tramadol, or carisoprodol.
- The prescriber has indicated whether the member has been receiving BTOD treatment for more than two years.
- For members who have been receiving BTOD treatment for more than two years, the prescriber has indicated whether the member is being maintained on a daily dose of 12 mg or less of a BTOD.
- The prescriber has indicated if the member is taking any benzodiazepines.

- For members who are taking benzodiazepines, the prescriber of BTOD has indicated if he or she is also the prescriber of the benzodiazepine(s).
- The prescriber has indicated that he or she has read the attestation statement on the PA form and that he or she agrees to follow guidelines set forth by the United States Department of Health and Human Services Federation of State Medical Boards— Model Policy Guidelines for Opioid Addiction Treatment.
- The prescriber has submitted detailed clinical justification for prescribing a non-preferred buprenorphine-naloxone drug instead of Suboxone® film, including clinical information explaining why the member cannot use Suboxone® film and explaining why it is medically necessary that the member receive a non-preferred buprenorphine-naloxone drug instead of Suboxone® film.

### Opioid Dependency Agents — Methadone

Methadone dispersible tablets and methadone oral concentrate will become preferred drugs in the opioid dependency agents — methadone drug class; PA will not be required.

Drugs in the opioid dependency agents — methadone drug class **will be** diagnosis restricted. Providers may refer to the Diagnosis Restricted Drugs data table on the Pharmacy Resources page of the Providers area of the Portal for the most current list of allowable diagnosis codes.

### Opioid Dependency Agents — Rescue Agent

Naloxone syringe, naloxone vial, and Narcan® nasal spray will become preferred drugs in the opioid dependency agents — rescue agent drug class; PA will not be required.

Evzio® will become a non-preferred drug in the opioid dependency agents — rescue agent drug class.

Prior authorization is required for non-preferred drugs in the opioid dependency agents — rescue agent drug class. Drugs in the opioid dependency agents — rescue agent drug class **are not** diagnosis restricted.

#### *Submitting Prior Authorization Requests for Opioid Dependency Agents — Rescue Agent*

Prior authorization requests for non-preferred drugs in the opioid dependency agents — rescue agent drug class must be completed and signed by the prescriber and must be submitted using the PA/PDL Exemption Request form. Prior authorization requests for non-preferred opioid dependency agents — rescue agent drugs may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

### Opioid Dependency and Alcohol Abuse/Dependency Agents

Vivitrol® injection and naltrexone tablets will become preferred drugs in the opioid dependency and alcohol abuse/dependency agents drug class; PA will not be required.

As a reminder, the following policy for obtaining provider-administered drugs will continue to apply to Vivitrol® injection.

#### *Obtaining Provider-Administered Drugs*

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

Drugs in the opioid dependency and alcohol abuse/ dependency agents 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.

## Proton Pump Inhibitors

Certain brand name drugs will be preferred over their generic equivalents. Brand name Nexium® will become a preferred

drug (in addition to other preferred drugs) in the proton pump inhibitors drug class. ForwardHealth will automatically apply a generic copayment and dispensing fee to claims submitted for Nexium®.

Generic esomeprazole will remain a non-preferred drug.

## Pharmacy Policy Changes

### *Kalydeco®*

ForwardHealth has revised the clinical criteria for Kalydeco®.

Kalydeco® requires clinical PA.

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

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

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

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

- The member has cystic fibrosis.
- The member is 2 years of age or older.
- The member has a gene mutation consistent with the Food and Drug Administration (FDA)-approved indications for use of Kalydeco® and does not have a homozygous F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

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

With all PA requests, the prescriber must include progress notes and pulmonary function testing related to the member's current cystic fibrosis treatment plan.

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

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

### *Orkambi®*

ForwardHealth has revised the clinical criteria for Orkambi®.

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

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

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

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

- The member has cystic fibrosis.
- The member is 12 years of age or older.
- The member has a homozygous F508del mutation in the CFTR gene.

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

With all PA requests, the prescriber must include progress notes and pulmonary function testing related to the member's current cystic fibrosis treatment plan.

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

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

## Revised Prior Authorization/Drug Attachment

ForwardHealth has revised the PA/DGA form (dated 07/2016). The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. Prior authorization requests submitted on and after July 1, 2016, must be submitted on the revised form or the PA request will be returned to the provider.

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

When completing the PA/DGA form, prescribers should complete the most appropriate section as it pertains to the drug being requested. The specific sections are as follows:

- HealthCheck "Other Services" drug requests
- Diagnosis-restricted drug requests
- Drugs with specific PA criteria addressed in the Online Handbook
- Other drug requests

Prescribers are required to fill out the appropriate section(s), then provide a handwritten signature and date on the PA/DGA form. Once completed, the prescriber should send the PA/DGA form to the pharmacy. The pharmacy should complete a PA/RF and submit it to ForwardHealth with the PA/DGA form from the prescriber.

### *Clinical Information for HealthCheck "Other Services" Drug Requests*

If the prescriber writes a prescription for a drug that is not covered under the member's ForwardHealth benefit plan, the prescriber is required to document the clinical rationale to support the medical necessity of the drug being requested through a HealthCheck "Other Services" PA request. Documentation of previous treatments and detailed reasons why other covered drug treatments were discontinued or not used are required. Medical records and peer-reviewed medical literature should be provided as necessary to support the PA request. This information should be documented in Section IV (Clinical Information for HealthCheck "Other Services" Drug Requests) of the PA/DGA.

When completing the PA/DGA form, prescribers should provide the diagnosis code and description, complete Section IV, and use Section VIII (Additional Information), if needed. Prescribers are reminded to provide a handwritten signature and date on the form before submitting it to the pharmacy provider where the prescription will be filled. The pharmacy provider is required to complete a PA/RF before submitting the forms and supporting documentation to ForwardHealth. Prescribers should not submit PA/DGA forms to ForwardHealth.

*Note:* All HealthCheck "Other Services" drug PA requests must also include the date of the member's most recent HealthCheck screen, along with the name of the HealthCheck screener (who is required to be Medicaid-enrolled). HealthCheck "Other Services" is limited to members under 21 years of age.

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

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

When completing the PA/DGA, prescribers should provide the diagnosis code and description, complete Section V, and use Section VIII (Additional Information), if needed. Prescribers are reminded to provide a handwritten signature and date on the form before submitting it to the pharmacy provider where the prescription will be filled. The pharmacy provider is required to complete a PA/RF before submitting

the forms and supporting documentation to ForwardHealth. Prescribers should not submit PA/DGA forms to ForwardHealth.

### *Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook*

If a prescriber writes a prescription for one of the following drugs, a PA request must be submitted on the PA/DGA form:

- Amphetamine salt combo ER
- Ampyra®
- Aripiprazole
- Cayston®
- Crinone®
- Hetlioz®
- Imatinib
- Jublia® and Kerydin®
- Kalydeco®
- Lipotropics, apo-B inhibitors
- Lipotropics, PCSK9 inhibitors
- Memantine (members 44 years of age and younger)
- Misoprostol
- Namenda XR® (members 44 years of age and younger)
- Orkambi®
- Paliperidone
- Rosuvastatin
- TOBI® inhalation solution
- TOBI® Podhaler™
- Tobramycin solution
- Vyvanse® (for the treatment of binge eating disorder)

This information should be documented using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form.

When completing the PA/DGA form, prescribers should provide the diagnosis code and description, complete Section VI, and use Section VIII (Additional Information), if needed. Prescribers are reminded to provide a handwritten signature and date on the form before submitting it to the pharmacy provider where the prescription will be filled. The pharmacy provider is required to complete a PA/RF before submitting the forms and supporting documentation to ForwardHealth. Prescribers should not submit PA/DGA forms to ForwardHealth.

### *Clinical Information for Other Drug Requests*

If the prescriber writes a prescription for a drug that requires the use of the PA/DGA form and has not been previously referenced in the above PA/DGA sections, the prescriber is required to document the clinical rationale to support the medical necessity of the drug being requested. Documentation of previous treatments and detailed reasons why other covered drug treatments were discontinued or not used are required. In addition, if the drug requested is a non-preferred PDL drug, prescribers are required to specifically address why other preferred PDL drugs cannot be used. Medical records and peer-reviewed medical literature should be provided as necessary to support the PA request. This information should be documented in Section VII (Clinical Information for Other Drug Requests) of the PA/DGA.

If the pharmacy submitting the PA request is an out-of-state pharmacy providing a non-emergency service and the drug being requested does not have specific PA criteria established, additional documentation is required to be submitted. Prior authorization documentation must demonstrate that the member has a medical condition for which the requested drug has FDA approval (medical records must be provided to verify the member's medical condition). Additionally, the drug must be prescribed in a dose and manner consistent with the FDA-approved product labeling.

When completing the PA/DGA form, prescribers should provide the diagnosis code and description, complete Section VII, and use Section VIII (Additional Information), if needed. Prescribers are reminded to provide a handwritten signature and date on the form before submitting it to the pharmacy provider where the prescription will be filled. The pharmacy provider is required to complete a PA/RF before submitting the forms and supporting documentation to ForwardHealth. Prescribers should not submit PA/DGA forms to ForwardHealth.

Prescribers and pharmacy providers are required to retain a completed copy of the PA form(s). For more information about record retention, providers may refer to the Record Retention topic (topic #204) in the Documentation chapter of the Provider Enrollment and Ongoing Responsibilities section of the Online Handbook.

*Note:* For assistance in identifying PDL drugs that require completion of Sections VI and VII of the PA/DGA form, providers may refer to the Preferred Drug List Quick Reference on the Pharmacy Resources page of the Providers area of the Portal.

### Quantity Limit Updates

Effective for DOS on and after July 1, 2016, several new quantity limits will be implemented. In particular, new quantity limits have been established for several inhalation products.

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.

As a result of the addition of several new quantity limits, the Quantity Limit Drugs and Diabetic Supplies data table on the Pharmacy Resources page of the Providers area of the Portal has also been revised to a more user-friendly format. Providers are encouraged to review the data table on the Pharmacy 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, the pharmacy provider may request a quantity limit policy override by calling 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.

*Note:* Pharmacy providers are reminded that they may dispense up to the allowed quantity limit without contacting the DAPO Center.

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

### Stimulants and Related Agents

ForwardHealth has revised the list of non-preferred amphetamine formulations for which PA is not required for members 6 years of age or younger. The list now includes amphetamine salt combo, Dexedrine® tablets, dextroamphetamine solution, dextroamphetamine tablets, and Evekeo™.

Procentra® and Zenzedi® continue to be included in the list of non-preferred amphetamine formulations for which PA is not required for members 6 years of age or younger.

*Note:* Prior authorization is required for members who are 7 years of age or older.

The list of clinical conditions for which PA requests for non-preferred amphetamine formulations will be approved has not changed.

For more information about stimulants and related agents, providers may refer to the Stimulants and Related Agents topic (topic #16357) and the Grandfathering for Stimulants and Related Agents topic (topic #10662) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

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

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

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

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

The following table includes the most current list of drugs for which this policy applies. Drugs shown in bold letters are drugs that have been added to this list. This list is available on the Preferred Drug List Quick Reference 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® cream | 01/01/2012 |
| | **Retin-A®** | 07/01/2016 |
| Anticonvulsants | Tegretol® suspension | 01/01/2016 |
| | Tegretol® tablet | 01/01/2016 |
| Anticonvulsants (Continued) | 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, Fibric Acids | TriCor® | 07/01/2015 |
| Migraine Agents, Injectable | Imitrex® Injection | 07/01/2012 |
| Migraine Agents, Other | Imitrex® Nasal Spray | 07/01/2012 |
| Ophthalmics, Antibiotic-Steroid Combinations | TobraDex® suspension | 01/01/2012 |
| Opthalmics, Gluacoma — Other | Alphagan® P 0.15% | 01/01/2012 |
| Proton Pump Inhibitors | **Nexium®** | 07/01/2016 |
| Stimulants and Related Agents | Adderall XR® | 01/01/2012 |

## Expedited Emergency Supply

As a result of changes made during the July 2016 PDL review, the Expedited Emergency Supply Request Drugs data table on the Pharmacy Resources page of the Providers area of the Portal has been updated. The Emergency Medication Dispensing topic (topic #1399) of the Covered Services and Requirements chapter of the Covered and Noncovered Services section of the Pharmacy service area of the Online Handbook includes more information about dispensing an emergency supply of medication.

## For More Information

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

## Information Regarding Managed Care Organizations

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

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

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

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

P-1250

This Update was issued on 06/17/2016 and information contained in this Update was incorporated into the Online Handbook on 07/01/2016.

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

| Form Name | Form Number | Revised, Renamed, Discontinued, or New | Effective Date |
|---|---|---|---|
| Prior Authorization/Drug Attachment (PA/DGA) | F-11049 | Revised | 07/01/2016 |
| Completion Instructions | F-11049A | Revised | 07/01/2016 |
| Prior Authorization/Preferred Drug List (PA/PDL) for Hypoglycemics, Insulin — Long-Acting | F-01749 | New | 07/01/2016 |
| Completion Instructions | F-01749A | New | 07/01/2016 |
| Prior Authorization/Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators | F-00805 | Revised | 07/01/2016 |
| Completion Instructions | F-00805A | Revised | 07/01/2016 |
| Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents | F-00081 | Revised and Renamed: Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents — Buprenorphine | 07/01/2016 |
| Completion Instructions | F-00081A | Revised and Renamed | 07/01/2016 |
| Prior Authorization/Preferred Drug List (PA/PDL) for Symlin | F-00080 | Discontinued | 07/01/2016 |
| Completion Instructions | F-00080A | Discontinued | 07/01/2016 |

# ATTACHMENT 2
# Changes to the Preferred or Non-preferred Status of Drugs on the Preferred Drug List

The following table lists drugs that have had a change in their preferred or non-preferred status as a result of the July 2016 Preferred Drug List review. The updated statuses are effective July 1, 2016. Drugs that have not been previously reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee are marked with an asterisk (*). The complete Preferred Drug List Quick Reference 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 July 1, 2016 |
|---|---|---|
| Acne Agents, Topical | adapalene gel pump* | Non-preferred |
| | Avar® foam* | Non-preferred |
| | BenzePrO™ cleanser* | Non-preferred |
| | clindamycin phosphate lotion | Non-preferred |
| | Duac®* | Non-preferred |
| | Epiduo® Forte gel w/pump* | Non-preferred |
| | erythromycin gel | Non-preferred |
| | Ovace® Plus foam* | Non-preferred |
| | Retin-A® cream | Preferred |
| | Retin-A® gel* | Preferred |
| | tretinoin cream | Non-preferred |
| | tretinoin gel | Non-preferred |
| Analgesics, Opioids Long-Acting | Belbuca™* | Non-preferred |
| | Hysingla™ ER | Preferred |
| | methadone tablet | Non-preferred |
| | methadone solution | Non-preferred |
| Androgenic Agents | Natesto™* | Non-preferred |
| | testosterone gel packet* | Non-preferred |
| | testosterone gel pump* | Non-preferred |
| Angiotensin Modulators, ARBs and DRIs | Entresto™* | Non-preferred |
| Angiotensin Modulators, Combination | amlodipine/valsartan* | Non-preferred |
| | Tarka® | Non-preferred |
| | Prestalia®* | Non-preferred |
| Antibiotics, Beta-Lactam | cefixime suspension* | Non-preferred |
| | Suprax® chewable tablets | Preferred |
| Antibiotics, Macrolides/Ketolides | erythromycin base capsule DR | Preferred |
| | erythromycin base tablet | Non-preferred |
| Antibiotics, Tetrayclines | doxycycline hyclate capsule* | Non-preferred |
| Anticoagulants | Fragmin® syringe | Non-preferred |

| Drug Class | Drug Name | Status Effective July 1, 2016 |
|---|---|---|
| Antiemetics/Antivertigo | metoclopramide ODT* | Non-preferred |
| | Varubi™* | Non-preferred |
| Antifungals, Oral | Cresemba®* | Non-preferred |
| | Sporanox® solution | Preferred |
| Antifungals, Topical | naftifine cream* | Non-preferred |
| Bladder Relaxant Preparations | Enablex® | Preferred |
| Bone Resorption Suppression | risedronate* | Non-preferred |
| Calcium Channel Blocking Agents | Cardizem® LA | Non-preferred |
| GI Motility, Chronic | alosetron* | Non-preferred |
| | Lotronex® | Preferred |
| | Viberzi™* | Preferred |
| Growth Hormone | Zomacton™ vial* | Non-preferred |
| H. Pylori | Pylera® | Preferred |
| Hepatitis C Agents | Daklinza®* | Preferred |
| | Technivie®* | Preferred |
| | Zepatier™* | Preferred |
| Hypoglycemics, Insulin | Tresiba® FlexTouch®* | Non-preferred |
| Hypoglycemics, Meglitinides | repaglinide | Preferred |
| Hypoglycemics, Other | metformin ER (Glumetza®)* | Non-preferred |
| | Riomet® | Non-preferred |
| Hypoglycemics, SGLT2 | Invokamet™ | Preferred |
| | Synjardy®* | Non-preferred |
| Hypoglycemics, Sulfonylureas | glipizide/metformin | Non-preferred |
| Hypoglycemics, Symlin | Symlin® pen | Preferred |
| Hypoglycemics, Thiazolidinediones | pioglitazone/glimepiride* | Non-preferred |
| Lipotropics, Fibric Acids | fenofibrate tablet* | Non-preferred |
| | Fenoglide®* | Non-preferred |
| Lipotropics, Other | fluvastatin* | Non-preferred |
| | fluvastatin ER* | Non-preferred |
| | Zetia® | Preferred |
| Lipotropics, PCSK9 Inhibitors | Repatha™ SureClick®* | Non-preferred |
| | Repatha™ syringe* | Non-preferred |
| Migraine Agents, Other | almotriptan* | Non-preferred |
| | Zecuity®* | Non-preferred |
| Multiple Sclerosis Agents, Immunomodulators | glatiramer 20 mg/mL* | Non-preferred |

| Drug Class | Drug Name | Status Effective July 1, 2016 |
|---|---|---|
| Opioid Dependency Agents | Evzio®* | Non-preferred |
| | naloxone syringe* | Preferred |
| | naloxone vial* | Preferred |
| | naltrexone* | Preferred |
| | Narcan® spray* | Preferred |
| | Vivitrol®* | Preferred |
| Phosphate Binders | Fosrenol® powder pack* | Non-preferred |
| Platelet Aggregation Inhibitors | Durlaza®* | Non-preferred |
| | aspirin/dipyridamole* | Non-preferred |
| Proton Pump Inhibitors | Nexium® | Preferred |
| Pulmonary Arterial Hypertension | Uptravi®* | Non-preferred |
| | Uptravi® tablet dose pack* | Non-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*.