

Update June 2014

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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 2014 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, 2014, 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, 2014, 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 the Standard Plan, 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 *mmm.forwardhealth.wi.gov/*.

## Changes to Pharmacy-Related Forms and Completion Instructions

ForwardHealth no longer includes copies of revised forms and completion instructions as attachments to PDL *Updates*. Attachment 1 of this *Update* lists the prior authorization (PA) forms and completion instructions that are new or that have been revised, renamed, or discontinued as a result of the July 2014 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, 2014. Additional information regarding changes to clinical criteria or submission options is noted under the applicable drug classes in 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 Online Handbook for current policy and procedures and to the Forms page 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 Medicaid 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.

#### Clinical Criteria for Non-preferred Drugs

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

• The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with **at least one** of the preferred drugs from the same PDL drug class as the drug being requested.

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

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

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

- Alzheimer's agents drug class (excluding Namenda XR<sup>TM</sup> for members who are 44 years of age or younger).
- Anticonvulsants drug class.
- Antidepressants, other drug class.
- Antidepressants, SSRI drug class.
- Antiparkinson's agents drug class.
- Antipsychotics drug class.
- HIV-AIDS drug class (excluding Stribild<sup>TM</sup>).
- Pulmonary arterial hypertension drug class.

Alternate clinical criteria may be considered if a member does not meet the clinical criteria for non-preferred drugs listed above. 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 issued by ForwardHealth that recently expired for the nonpreferred 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 may not be used to circumvent PA policy. Use of manufacturer-provided samples does not provide claim history documentation regarding the dose of a medication that was taken or compliance with treatment so it 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 complete the appropriate PA form for the drug. Prescribers are required to send the PA form to the pharmacy where the prescription will be filled. Prescribers are required to include accurate and complete answers and clinical information about the member's medical history on the PA form. When completing the PA form, prescribers are required to provide a 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.

## 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 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.

Pharmacy providers are required to retain a completed, signed, and dated copy of the PA form and any supporting documentation received from the prescriber.

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

On May 14, 2014, the Medicaid PA Advisory Committee met to review new and existing therapeutic drug classes on the PDL.

Providers may refer to Attachment 2 of this *Update* 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, 2014. 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 their next scheduled class review by the Medicaid 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 14, 2014, meeting and effective July 1, 2014, are included in the table.

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

#### **Analgesics, Opioids Long-Acting**

Zohydro<sup>TM</sup> ER will remain a non-preferred drug for BadgerCare Plus, Medicaid, and SeniorCare members.

Prior authorization requests for Zohydro<sup>™</sup> ER must be completed and signed by prescribers. Prior authorization requests for Zohydro<sup>™</sup> ER 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), F-11049 (10/13), and the Prior Authorization Request Form (PA/RF), F-11018 (05/13).

Prior authorization requests for Zohydro<sup>TM</sup> ER may be submitted on the Portal, by fax, or by mail. Prior authorization requests for Zohydro<sup>TM</sup> ER may **not** be submitted via STAT-PA.

Prior authorization requests for Zohydro<sup>TM</sup> ER may be approved for up to a maximum of 183 days.

ForwardHealth has established clinical criteria for Zohydro<sup>TM</sup> ER.

## Clinical Criteria for Zohydro™ ER

Prior authorization requests for Zohydro<sup>TM</sup> ER must include documentation indicating that the prescriber has reviewed **all** of the preferred drugs in the analgesics, opioids long-acting drug class and determined that **none** of the preferred drugs are clinically appropriate for the member based on **at least one** of the following for each drug:

- The member has experienced an unsatisfactory therapeutic response with the preferred drug.
- The member has experienced a clinically significant adverse drug reaction with the preferred drug.

- There is a clinically significant drug interaction between another drug the member is taking and the preferred drug.
- The member has a medical condition(s) that prevents the use of the preferred drug.

The prescriber is required to identify each preferred drug in the analgesics, opioids long-acting drug class that has been reviewed and the specific reason each preferred drug would not be clinically appropriate for the member.

#### **Angiotensin Modulators, ACE Inhibitors**

Epaned<sup>TM</sup> will remain a non-preferred drug. Prior authorization is not required for members who are 12 years of age or younger. However, for members who are 13 years of age or older, PA is required for Epaned<sup>TM</sup>.

#### **Angiotensin Modulators, Combination**

Brand name Lotrel will no longer be a preferred drug and will require PA. ForwardHealth will no longer automatically apply the generic copayment or generic dispensing fee to claims for brand name Lotrel.

Generic amlodipine/benazepril will become a preferred drug.

#### **Antibiotics, Inhaled**

Tobramycin solution and TOBI® Podhaler<sup>TM</sup> will remain non-preferred drugs in the antibiotics, inhaled drug class. Cayston<sup>®</sup> continues to be a non-preferred drug.

Bethkis<sup>®</sup> will become a preferred drug in the antibiotics, inhaled drug class, and Tobi<sup>®</sup> inhalation solution continues to be a preferred drug.

Prior authorization requests for tobramycin solution, TOBI<sup>®</sup> Podhaler<sup>TM</sup>, and Cayston<sup>®</sup> must be completed and signed by the prescriber. Prior authorization requests for tobramycin solution, TOBI Podhaler<sup>TM</sup>, and Cayston<sup>®</sup> 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.

Prior authorization requests for tobramycin solution, TOBI<sup>®</sup> Podhaler<sup>TM</sup>, and Cayston<sup>®</sup> may be submitted on the Portal, by fax, or by mail; they may **not** be submitted via STAT-PA.

ForwardHealth has revised the clinical criteria for TOBI<sup>®</sup> Podhaler<sup>TM</sup> and the clinical criteria for Cayston<sup>®</sup>. The revised clinical criteria for TOBI<sup>®</sup> Podhaler<sup>TM</sup> will also apply to tobramycin solution.

## Clinical Criteria for Tobramycin Solution and TOBI<sup>®</sup> Podhaler™

Clinical criteria that must be documented for approval of a PA request for tobramycin solution or TOBI<sup>®</sup> Podhaler<sup>TM</sup> are **all** of the following:

- The member has a diagnosis of cystic fibrosis.
- The member is six years of age or older.
- The prescriber has confirmed that the member has a positive sputum culture for Pseudomonas aeruginosa. (Prescribers are required to include a copy of the sputum culture report with all PA requests.)
- The prescriber has confirmed that the member is not colonized with Burkholderia cepacia.
- The member's forced expiratory volume in 1 second (FEV1) is less than 90 percent predicted. (Prescribers are required to include the member's FEV1, FEV1 predicted, and FEV1 percent predicted, along with the dates taken.)
- The member is not receiving treatment with other inhaled antibiotics/anti-infective agents, including alternating treatment schedules. Providers should provide a history of all inhaled antibiotics/anti-infective agents within the most recent 90-day period.
- The prescriber has submitted detailed clinical justification for prescribing tobramycin solution or TOBI<sup>®</sup> Podhaler<sup>™</sup> instead of Bethkis<sup>®</sup> or Tobi<sup>®</sup> inhalation solution, including clinical information for why the member cannot use Bethkis<sup>®</sup> or Tobi<sup>®</sup> inhalation solution and why it is medically necessary

that the member receive tobramycin solution or TOBI<sup>®</sup> Podhaler<sup>™</sup> instead of Bethkis<sup>®</sup> or Tobi<sup>®</sup> inhalation solution.

#### Clinical Criteria for Cayston®

Clinical criteria that must be documented for approval of a PA request for Cayston<sup>®</sup> are **all** of the following:

- The member has a diagnosis of cystic fibrosis.
- The member is six years of age or older.
- The prescriber has confirmed that the member has a positive sputum culture for Pseudomonas aeruginosa. (Prescribers are required to include a copy of the sputum culture report with all PA requests.)
- The prescriber has confirmed that the member is not colonized with Burkholderia cepacia.
- The member's FEV1 is less than 90 percent predicted. (Prescribers are required to include the member's FEV1, FEV1 predicted, and FEV1 percent predicted, along with the dates taken.)
- The member is not receiving treatment with other inhaled antibiotics/anti-infective agents, including alternating treatment schedules. Providers should provide a history of all inhaled antibiotics/anti-infective agents within the most recent 90-day period.
- At least **one** of the following is true:
  - The member has previously used Bethkis<sup>®</sup> or Tobi<sup>®</sup> inhalation solution and experienced a clinically significant adverse drug reaction or an unsatisfactory therapeutic response.
  - ✓ The member has a medical condition(s) that prevents the use of Bethkis<sup>®</sup> or Tobi<sup>®</sup> inhalation solution.
  - ✓ The member's sputum culture shows resistance to tobramycin.

Prescribers should indicate the specific details about the clinically significant adverse drug reaction(s), the unsatisfactory therapeutic response(s), or the medical condition(s) preventing the member from using Bethkis® or Tobi® inhalation solution.

The following indicate how PA requests for tobramycin solution, TOBI<sup>®</sup> Podhaler<sup>™</sup>, or Cayston<sup>®</sup> will be approved when clinical criteria have been met:

- Prior authorization requests will be approved for up to a maximum of a 28-day supply per dispensing.
- Prior authorization requests will be approved with an alternating 28-day treatment schedule of 28 days of tobramycin solution, TOBI<sup>®</sup> Podhaler<sup>™</sup>, or Cayston<sup>®</sup> treatment with 28 days of no inhaled antibiotics/anti-infective agents.
- Prior authorization requests may be approved for up to a maximum of 168 days.

#### Anticoagulants

The anticoagulants, oral drug class and the anticoagulants, injectable drug class will be combined into a single drug class, the anticoagulants drug class.

Eliquis<sup>®</sup> will become a preferred drug in the anticoagulants drug class.

## Prior Authorization/Preferred Drug List (PA/PDL) for Anticoagulants, Oral Form Being Discontinued

The Prior Authorization/Preferred Drug List (PA/PDL) for Anticoagulants, Oral form, F-00806 (07/13), will be discontinued and will no longer be accepted. 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.

Providers will be required to use the Prior Authorization/ Preferred Drug List (PA/PDL) Exemption Request form, F11075 (09/13), for all non-preferred anticoagulants. Prior authorization requests received on and after July 1, 2014, that are *not* submitted on the PA/PDL Exemption Request form will be returned.

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

#### Hepatitis C, Agents

Sovaldi<sup>™</sup> will remain a non-preferred drug that requires clinical PA.

Only PA requests for Sovaldi <sup>™</sup> for members whose hepatitis C liver disease has advanced to any of the following stages may be considered for review:

- Compensated cirrhosis.
- Metavir score of F3 or greater or evidence of bridging fibrosis.
- Hepatocellular carcinoma, if the member is on a liver transplant waiting list.
- Serious extra-hepatic manifestations of hepatitis C virus (HCV).

In addition, only HCV treatment prescribed by a gastroenterology or infectious disease provider practice for a member who is 18 years of age or older will be considered for review.

The decision to treat chronic hepatitis C is not always urgent and involves discussion with the member about the risks and benefits of treatment, the need for compliance with drug protocols, the side effects associated with prolonged use of a drug, and the rapidly changing breakthrough drug therapies that are currently in development for hepatitis C treatment. Prescribers should also carefully assess factors that may affect patient adherence, such as social supports, neurocognitive disorders, and active substance abuse.

In cases where the member does not meet the above review criteria, the provider and member may decide to proceed with treatment using preferred hepatitis C drugs.

## New Prior Authorization Drug Attachment Forms for Sovaldi™

ForwardHealth has created two new forms, the Prior Authorization Drug Attachment for Sovaldi<sup>™</sup>, F-01247 (07/14), and the Prior Authorization Drug Attachment for Sovaldi<sup>™</sup> Renewal, F-01248 (07/14); ForwardHealth has also established clinical information that must be documented on a PA request for Sovaldi<sup>™</sup>.

Prior authorization requests for Sovaldi<sup>TM</sup> must be completed and signed by prescribers. Initial PA requests for Sovaldi<sup>TM</sup> received on and after July 1, 2014, must be submitted on the Prior Authorization Drug Attachment for Sovaldi<sup>TM</sup> or they will be returned. Renewal PA requests for Sovaldi<sup>TM</sup> received on and after July 1, 2014, must be submitted on the Prior Authorization Drug Attachment for Sovaldi<sup>TM</sup> Renewal or they will be returned.

Prior authorization requests for Sovaldi<sup>™</sup> may be submitted on the Portal, by fax, or by mail. Prior authorization requests for Sovaldi<sup>™</sup> may **not** be submitted via STAT-PA.

# Initial Prior Authorization Requests for Sovaldi<sup>™</sup>

For initial PA requests for Sovaldi<sup>™</sup>, prescribers should complete the Prior Authorization Drug Attachment for Sovaldi<sup>™</sup> and submit the form to the pharmacy where the prescription will be filled. Pharmacy providers are required to submit to ForwardHealth the completed Prior Authorization Drug Attachment for Sovaldi<sup>™</sup> and a completed PA/RF.

If applicable, the clinical information that must be documented on an initial PA request for Sovaldi<sup>™</sup> are **all** of the following:

- Lab data, including the following:
  - ✓ Hepatitis C virus genotype.
  - ✓ Hepatitis C virus-ribonucleic acid (HCV-RNA) level.
  - ✓ Liver function tests.
  - ✓ Complete blood count.
  - ✓ Serum creatinine test.
  - ✓ Albumin test.
  - $\checkmark$  International normalized ratio.
  - Liver biopsy, scan, or ultrasound results (if performed).

- Hepatitis C virus clinical data, including the following:
  - Current medical records for hepatitis C assessment and treatment.
  - History of liver transplant or on liver transplant wait list.
  - Clinical assessment of presence or absence of cirrhosis.
  - If cirrhotic, documentation of the following:
    - o Child-Turcotte-Pugh score.
    - Clinical evidence of the state of compensation.
    - Hepatocellular carcinoma status based on imaging study within the last six months.
  - ✓ Fibrosis stage or score.
- 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).
- Current medication list.
- Relevant medical history not related to hepatitis C, including the following:
  - ✓ Other liver disease.
  - ✓ Transplant history.
  - Hepatitis A, hepatitis B, or Human Immunodeficiency Virus (HIV) coinfection.
  - ✓ Autoimmune disease.
  - ✓ Information regarding birth control counseling the member has received. (*Note:* Two forms of birth control should be utilized when ribavirincontaining treatment regimen is prescribed. If the member is of child-bearing age, documentation of a negative pregnancy test must be submitted with the PA request).
  - Current and historical alcohol abuse or illicit drug use. (*Note:* Documentation of at least 6 months of abstinence from alcohol abuse or illicit drug use must be submitted with the PA request).
  - ✓ Other significant or uncontrolled diseases (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).

Prior authorization requests for an interferon-free treatment regimen of Sovaldi and ribavirin in HCV Genotype 1 may be considered for review in the following circumstances:

- The member has a platelet count less than 75,000/mm3.
- The member has a severe mental health conditions(s) that may be exacerbated by interferon or respond poorly to medical therapy (with risks of interferon use documented by mental health evaluation).
- The member has an autoimmune disease(s) that may be exacerbated by interferon-medicated immune modulation.
- The member was unable to complete a prior treatment course due to documented interferon-related adverse effects.

Prescribers are required to document this information on the Prior Authorization Drug Attachment for Sovaldi<sup>™</sup> and use Section V (Additional Information), if needed. The documentation may also be submitted as an attachment.

If the required information is not included on the Prior Authorization Drug Attachment for Sovaldi<sup>™</sup> and attachments, the PA request will be returned as incomplete.

Initial PA requests for Sovaldi<sup>™</sup> 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.

# Renewal Prior Authorization Requests for Sovaldi<sup>™</sup>

Renewal PA requests for Sovaldi<sup>™</sup> received on and after July 1, 2014, must be submitted on the Prior Authorization Drug Attachment for Sovaldi<sup>™</sup> Renewal or they will be returned. The member's HCV-RNA levels are required to be submitted with each renewal PA request for Sovaldi<sup>™</sup>. Prescribers should complete the Prior Authorization Drug Attachment for Sovaldi<sup>™</sup> Renewal and submit the form to the pharmacy where the prescription will be filled. Pharmacy providers are required to submit to ForwardHealth the completed Prior Authorization Drug Attachment for Sovaldi Renewal and a completed Prior Authorization Amendment Request, F-11042 (07/12). A PA/RF should *not* be submitted.

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

Prior authorization requests for Sovaldi<sup>™</sup> will be denied in the following circumstances:

- The member has autoimmune hepatitis or other conditions that are contraindications for interferon or ribavirin.
- The member has a significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).
- The member has decompensated cirrhosis.
- The member has acute hepatitis C.
- The member has received a liver transplant.
- The member is currently abusing drugs or alcohol.
- Non-compliance with approved hepatitis C treatment regimen (for renewals only).

#### Hepatitis C, Protease Inhibitors

Olysio will remain a non-preferred drug in the hepatitis C, protease inhibitors drug class. Incivek and Victrelis continue to be preferred drugs that require clinical PA.

## Prior Authorization Drug Attachment for Incivek and Victrelis Form Has Been Revised and Renamed

Prior authorization requests for Incivek, Olysio, and Victrelis must be completed and signed by prescribers. Prior authorization requests for Incivek, Olysio, and Victrelis should be submitted using the revised and renamed Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors, F-00583 (07/14). This form was previously named the Prior Authorization Drug Attachment for Incivek and Victrelis. The previous version of the form will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal. Prior authorization requests received on and after July 1, 2014, must be submitted on the revised form or they will be returned.

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

ForwardHealth has revised the clinical criteria for both preferred and non-preferred hepatitis C protease inhibitors.

## Clinical Criteria for Hepatitis C Protease Inhibitors

## Clinical Criteria for All Hepatitis C Protease Inhibitors

Clinical criteria that must be documented for approval of a PA request for a hepatitis C protease inhibitor are **all** of the following:

- The member has a diagnosis of chronic hepatitis C genotype 1.
- The member is 18 years of age or older.
- The member is not pregnant.
- The member has not had a liver transplant.
- The member has not received a prior course of therapy with a treatment regimen that includes the requested agent or any other HCV NS3/4A protease inhibitor.
- The member's treatment includes concurrent use of pegylated interferon and ribavirin.
- The member has compensated liver disease.
- The member is not taking any contraindicated drugs.

#### Additional Clinical Criterion for Victrelis

For PA requests for Victrelis, in addition to the clinical criteria previously listed in the Clinical Criteria for All Hepatitis C Protease Inhibitors section of this *Update*, the member's treatment must include a four-week lead-in period with pegylated interferon and ribavirin before starting Victrelis therapy.

#### Additional Clinical Criteria for Olysio

For PA requests for Olysio, in addition to the clinical criteria previously listed in the Clinical Criteria for All Hepatitis C Protease Inhibitors section of this *Update*, the member cannot be infected with HCV genotype 1a containing the Q80K polymorphism. Also, the prescriber is required to provide detailed clinical justification for prescribing Olysio instead of Incivek or Victrelis, including clinical information describing why the member cannot use Incivek or Victrelis and why it is medically necessary that the member receive Olysio instead of Incivek or Victrelis.

## Clinical Information That Must Be Documented for Hepatitis C Protease Inhibitors

Documentation Requirements for All Prior Authorization Requests for Hepatitis C Protease Inhibitors

All clinical criteria must be documented on PA requests for a hepatitis C protease inhibitor. In addition, if the member is coinfected with hepatitis B or HIV, prescribers are required to document the following on the PA request:

- The prescriber's medical specialty.
- The prescriber's experience with prescribing and managing HCV NS3/4 protease inhibitors in coinfected members.
- Why treatment with an HCV NS3/4 protease inhibitor is clinically appropriate for the member.

## Additional Documentation Requirements for Initial Prior Authorization Requests for Hepatitis C Protease Inhibitors

In addition to the information previously listed in the Documentation Requirements for All Prior Authorization Requests for Hepatitis C Protease Inhibitors section of this *Update*, the following must also be documented for initial PA requests:

- The initial HCV-RNA level before therapy began.
- The date the initial HCV-RNA level was obtained.

## Additional Documentation Requirements for Renewal Prior Authorization Requests for Incivek and Olysio

In addition to the information previously listed in the Documentation Requirements for All Prior Authorization Requests for Hepatitis C Protease Inhibitors section of this *Update*, the following must also be documented for renewal PA requests for Incivek or Olysio:

- The HCV-RNA level at treatment week four.
- The date the HCV-RNA level was obtained.

## Additional Documentation Requirements for Renewal Prior Authorization Requests for Victrelis

In addition to the information previously listed in the Documentation Requirements for All Prior Authorization Requests for Hepatitis C Protease Inhibitors section of this *Update*, for renewal PA requests for Victrelis, the HCV-RNA level and the date the level was obtained must also be documented at the following appropriate intervals indicated in the Victrelis Response Guided Therapy guidelines:

- Treatment week eight (i.e., at four weeks taking Victrelis) (for members who are naïve to treatment with pegylated interferon and ribavirin prior to current treatment with Victrelis).
- Treatment week 12 (i.e., at eight weeks taking Victrelis).
- Treatment week 24 (i.e., at 20 weeks taking Victrelis).

## Submitting Prior Authorization Requests for Hepatitis C Protease Inhibitors

Prior authorization requests for hepatitis C protease inhibitors must be completed and signed by prescribers. Prescribers should complete the Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors form for initial and renewal PA requests.

Pharmacy providers may submit PA requests for hepatitis C protease inhibitors on the Portal, by fax, or by mail. Prior authorization requests for hepatitis C protease inhibitors may **not** be submitted via STAT-PA.

## Initial Prior Authorization Requests for Hepatitis C Protease Inhibitors

For initial PA requests for hepatitis C protease inhibitors, prescribers should complete Sections I, II, III, IIIA, and VI of the Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors form and submit the form to the pharmacy where the prescription will be filled. Pharmacy providers are required to submit to ForwardHealth the completed Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors form and a completed PA/RF.

## Renewal Prior Authorization Requests for Hepatitis C Protease Inhibitors

For renewal PA requests for hepatitis C protease inhibitors, prescribers are required to complete Sections I, II, IV or V, and VI of the Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors form and submit the form to the pharmacy where the prescription will be filled. Pharmacy providers are required to submit to ForwardHealth the completed Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors form and a completed Prior Authorization Amendment Request. A PA/RF should **not** be submitted.

## Prior Authorization Approval Periods for Hepatitis C Protease Inhibitors

### Approval Periods for Incivek

Initial PA requests for Incivek may be approved for up to a maximum of eight weeks. Prior authorization requests may be renewed for up to an additional four weeks if the member's HCV-RNA is 1,000 IU/ml or less at treatment week four.

Treatment with Incivek may be approved for up to a maximum treatment period of 12 weeks. Treatment with Incivek should be discontinued at treatment week four if the member's HCV-RNA is greater than 1,000 IU/ml.

If treatment with pegylated interferon or ribavirin is discontinued for any reason, treatment with Incivek must be discontinued.

#### Approval Periods for Victrelis

Initial PA requests for Victrelis may be approved for up to a maximum of 12 weeks. Prior authorization requests may be renewed for up to an additional 12 weeks if the member's HCV-RNA is less than 100 IU/ml at treatment week 12 (i.e., at eight weeks taking Victrelis). A final renewal request may be approved for up to an additional 20 weeks if the member's HCV-RNA is undetectable at treatment week 24 (i.e., at 20 weeks taking Victrelis).

Treatment with Victrelis may be approved for up to a maximum treatment period of 44 weeks. The maximum approval period for PA requests for Victrelis is based on the Victrelis Response-Guided Therapy guidelines. If the member's HCV-RNA is greater than or equal to 100 IU/ml at treatment week 12 or if the member's HCV-RNA is detectable at treatment week 24, treatment with Victrelis should be discontinued.

If treatment with pegylated interferon or ribavirin is discontinued for any reason, treatment with Victrelis must be discontinued.

#### Approval Periods for Olysio

For Olysio, initial PA requests may be approved for up to a maximum of eight weeks. Prior authorization requests may be renewed for up to an additional four weeks if the member's HCV-RNA is less than 25 IU/ml at treatment week 4.

Treatment with Olysio may be approved for up to a maximum treatment period of 12 weeks. Treatment with Olysio should be discontinued at treatment week four if the member's HCV-RNA is 25 IU/ml or greater.

If treatment with pegylated interferon or ribavirin is discontinued for any reason, treatment with Olysio must be discontinued.

#### **HIV-AIDS**

## New Prior Authorization Drug Attachment for Stribild™ Form

ForwardHealth has created a new form, the Prior Authorization Drug Attachment for Stribild<sup>™</sup>, F-01249 (07/14), and revised the clinical criteria for coverage of Stribild<sup>™</sup>. Prior authorization requests for Stribild<sup>™</sup> received on and after July 1, 2014, must be submitted on the Prior Authorization Drug Attachment for Stribild<sup>™</sup> or they will be returned.

Prior authorization requests for Stribild<sup>™</sup> may be submitted on the Portal, by fax, or by mail. Prior authorization requests for Stribild<sup>™</sup> may **not** be submitted via STAT-PA.

Prior authorization requests for other non-preferred drugs in the HIV-AIDS drug class must be submitted on the PA/PDL Exemption Request form.

## Clinical Criteria for Members Currently Taking Stribild™ Who Have Had a Previous Stribild™ Prior Authorization Request Approved

Clinical criteria for approval of a PA request for Stribild<sup>™</sup> for members currently taking Stribild<sup>™</sup> who have had a previous PA request for Stribild<sup>™</sup> approved by ForwardHealth are **all** of the following:

- The member's estimated creatinine clearance (CrCl) is 50 ml/min or greater.
- The member is not receiving any contraindicated drugs, including:
  - Drugs that are highly dependent on CYP3A for clearance and are associated with serious adverse events.\*
  - ✓ Drugs that strongly induce CYP3A and may lead to loss of efficacy of Stribild<sup>™</sup> and possible resistance.\*
  - ✓ Other antiretroviral therapy (ART) medications for treatment of an HIV-1 infection.
- The member has been adherent with Stribild<sup>™</sup> treatment.

• The member is having a successful virologic response, evidenced by HIV-1 RNA assay.

\* Examples of these drugs include alfuzosin, cisapride, dihydroergotamine, ergotamine, lovastatin, methylergonovine, midazolam, pimozide, rifampin, sildenafil, simvastatin, St. John's wart, and triazolam.

Prior authorization requests for Stribild<sup>™</sup> for members currently taking Stribild<sup>™</sup> who have had a previous PA request approved by ForwardHealth may be approved for up to a maximum of one year.

## Clinical Criteria for Members Currently Taking Stribild™ Who Have Not Had a Previous Stribild™ Prior Authorization Request Approved

Clinical criteria for approval of a PA request for Stribild<sup>™</sup> for members currently taking Stribild<sup>™</sup> who have **not** had a previous PA request for Stribild<sup>™</sup> approved are **all** of the following:

- Prior to the member's current treatment with Stribild<sup>™</sup>, the member did not use any ART medications. The member was ART naïve prior to Stribild<sup>™</sup>.
- The member's estimated CrCl is 50 ml/min or greater.
- The member is not receiving any contraindicated drugs, including:
  - ✓ Drugs that are highly dependent on CYP3A for clearance and are associated with serious adverse events.\*
  - ✓ Drugs that strongly induce CYP3A and may lead to loss of efficacy of Stribild<sup>™</sup> and possible resistance.\*
  - ✓ Other ART medications for treatment of HIV-1 infection.
- The member has been adherent with Stribild<sup>™</sup> treatment.
- The member is having a successful virologic response, evidenced by HIV-1 RNA assay.

\* Examples of these drugs include alfuzosin, cisapride, dihydroergotamine, ergotamine, lovastatin,

methylergonovine, midazolam, pimozide, rifampin, sildenafil, simvastatin, St. John's wart, and triazolam.

Prior authorization requests for Stribild<sup>™</sup> for members currently taking Stribild<sup>™</sup> who have not had a previous PA request approved by ForwardHealth may be approved for up to a maximum of 183 days.

*Note:* Starting a member on a medication by using manufacturer-provided samples may not be used to circumvent PA policy.

## Clinical Criteria for Members Not Currently Taking Stribild™

Clinical criteria for approval of a PA request for Stribild<sup>TM</sup> for members who are not currently taking Stribild<sup>TM</sup> are **all** of the following:

- The member has never had ART in the past. The member is ART naïve.
- The member's estimated CrCl is 70 ml/min or greater.
- The member is not receiving any contraindicated drugs, including:
  - Drugs that are highly dependent on CYP3A for clearance and are associated with serious adverse events.\*
  - ✓ Drugs that strongly induce CYP3A and may lead to loss of efficacy of Stribild<sup>™</sup> and possible resistance.\*
  - ✓ Other ART medications for treatment of HIV-1 infection.

\* Examples of these drugs include alfuzosin, cisapride, dihydroergotamine, ergotamine, lovastatin, methylergonovine, midazolam, pimozide, rifampin, sildenafil, simvastatin, St. John's wart, and triazolam.

Prior authorization requests for Stribild<sup>™</sup> for members who are not currently taking Stribild<sup>™</sup> may be approved for up to a maximum of 183 days.

#### **Lipotropics, Other**

The lipotropics, statins drug class and the lipotropics, other drug class will be combined into a single drug class, the lipotropics, other drug class.

All PA requests for non-preferred lipotropics, other drugs must be submitted on the PA/PDL Exemption Request form or they will be returned. Prior authorization requests for Juxtapid<sup>®</sup>, Kynamro<sup>®</sup>, and Liptruzet<sup>™</sup> should no longer be submitted on the PA/DGA, and PA requests for Zetia and Vytorin should no longer be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Zetia or Vytorin form, F-00279 (10/11).

Pharmacy providers may submit PA requests for lipotropics, other drugs using the STAT-PA system, on the Portal, by fax, or by mail.

Juxtapid<sup>®</sup> and Kynamro<sup>®</sup> will be diagnosis-restricted drugs. Providers may refer to the Diagnosis Restricted Drugs data table for the most current list of diagnosis-restricted drugs and allowable diagnosis codes.

## Prior Authorization/Preferred Drug List (PA/PDL) For Zetia or Vytorin Form Being Discontinued

The PA/PDL for Zetia or Vytorin form will be discontinued and will no longer be accepted. 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.

Providers will be required to use the PA/PDL Exemption Request form for all non-preferred lipotropics, other drugs. Prior authorization requests received on and after July 1, 2014, that are *not* submitted on the PA/PDL Exemption Request form will be returned.

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

#### Multiple Sclerosis Agents, Immunomodulators

## Revised Prior Authorization/Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators Form

ForwardHealth has revised the Prior Authorization/ Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators form, F-00805 (07/14). 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 on the Pharmacy Resources page of the Portal. Prior authorization requests received on and after July 1, 2014, must be submitted on the revised form or they will be returned.

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

Pharmacy providers may submit PA requests for nonpreferred immunomodulators on the Portal, by fax, or by mail. Prior authorization requests for non-preferred immunomodulators may **no longer** be submitted using the STAT-PA system.

If clinical criteria for non-preferred immunomodulators for treatment of MS 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 one year.

ForwardHealth has established clinical criteria for coverage of Copaxone<sup>®</sup> 40 mg and clinical criteria for coverage of oral agents, including Aubagio, Gilenya, and Tecfidera, in the multiple sclerosis agents, immunomodulators drug class.

#### Clinical Criteria for Copaxone® 40 mg

## Clinical Criteria for Members Currently Being Treated with Copaxone<sup>®</sup> 40 mg

Clinical criteria for approval of a PA request for Copaxone<sup>®</sup> 40 mg for members currently being treated with Copaxone<sup>®</sup> 40 mg are **all** of the following:

- The member and prescriber are following established monitoring guidelines outlined in the Food and Drug Administration (FDA)-approved patient labeling.
- The member has been adherent with Copaxone<sup>®</sup> 40 mg treatment.
- The member's MS is stable and well-controlled, not having disease-progressing symptoms.

*Note:* Starting a member on a medication by using manufacturer-provided samples may not be used to circumvent PA policy.

## *Clinical Criteria for Members Not Currently Being Treated with Copaxone*<sup>®</sup> 40 mg

Clinical criteria for approval of a PA request for Copaxone<sup>®</sup> 40 mg for members **not** currently being treated with Copaxone<sup>®</sup> 40 mg are **all** of the following:

- The member and prescriber will follow established monitoring guidelines outlined in the FDA-approved patient labeling.
- The member is currently taking or has previously taken Copaxone<sup>®</sup> 20 mg.
- While taking Copaxone<sup>®</sup> 20 mg, the member's MS was stable and well-controlled, not having diseaseprogressing symptoms.
- While taking Copaxone<sup>®</sup> 20 mg, the member experienced significant injection site reactions that could not be managed with conventional techniques (e.g., injection site rotation, icing, or analgesics).

Prior authorization requests for Copaxone<sup>®</sup> 40 mg must include detailed documentation regarding why the member is unable to take Copaxone<sup>®</sup> 20 mg. Medical records should be provided, as necessary, to support the need for Copaxone<sup>®</sup> 40 mg. Non-adherence to previous MS treatment will not be considered as a criterion prohibiting the use of the preferred agent, Copaxone<sup>®</sup> 20 mg. In addition, member or prescriber preference for Copaxone<sup>®</sup> 40 mg will not be considered as a criterion prohibiting the use of the preferred agent, Copaxone<sup>®</sup> 20 mg.

## Clinical Criteria for Oral Agents, Including Aubagio, Gilenya, and Tecfidera

## *Clinical Criteria for Members Currently Being Treated with an Oral Agent*

Clinical criteria for approval of a PA request for an oral agent, including Aubagio, Gilenya, or Tecfidera, for members currently being treated with an oral agent are **all** of the following:

- The member and prescriber are following established monitoring guidelines outlined in the FDA-approved patient labeling.
- The member has been adherent with the oral agent treatment regimen.
- The member's MS is stable and well-controlled, not having disease-progressing symptoms.

*Note:* Starting a member on a medication by using manufacturer-provided samples may not be used to circumvent PA policy.

## *Clinical Criteria for Members Not Currently Being Treated with an Oral Agent*

Clinical criteria for approval of a PA request for an oral agent, including Aubagio, Gilenya, or Tecfidera, for members **not** currently being treated with an oral agent are **at least one** of the following:

- The member has experienced an unsatisfactory therapeutic response to Copaxone<sup>®</sup> as evidenced by increasing relapses and/or disability.
- The member has experienced an unsatisfactory therapeutic response to an MS interferon (e.g., Avonex<sup>®</sup>, Betaseron<sup>®</sup>, Extavia, or Rebif) as evidenced by increasing relapses and/or disability.

- The member is unable to take Copaxone<sup>®</sup> and the member is unable to take an MS interferon due to **one** of the following for each drug:
  - The member experienced a clinically significant adverse drug reaction.
  - ✓ There is a clinically significant drug interaction with another drug the member is taking.
  - ✓ The member has a medical condition(s) that prevents use of the drug.

Prior authorization requests must include detailed documentation regarding why the member is unable to take the preferred agents, including both Copaxone<sup>®</sup> and an MS interferon. Medical records should be provided, as necessary, to support the need for a non-preferred oral agent. The following will **not** be considered as criteria for use of a non-preferred oral agent:

- Non-adherence to previous MS treatment.
- The member's fear of needles.
- Member or prescriber preference for the use of an oral agent.

#### **Multiple Sclerosis Agents, Other**

ForwardHealth has revised the clinical criteria that must be documented for approval of a PA request for Ampyra<sup>®</sup>.

#### Clinical Criteria for Ampyra®

Clinical criteria that must be documented for approval of a PA request for Ampyra<sup>®</sup> are **all** of the following:

- The member has been diagnosed with MS. The documentation must include the type of MS with which the member has been diagnosed.
- The member has been diagnosed with an MS-related walking impairment.
- The member is able to walk, as documented with the following information:
  - $\checkmark$  Distance the member is able to walk.
  - $\checkmark$  Length of time the member is able to walk.
  - ✓ Assistive devices the member uses.
  - How the member's walking ability is being measured.

✓ The date the member's walking ability was last measured (must be within the past three months for initial PA requests, or within the past six months for members with a previous Ampyra<sup>®</sup> PA request approved by ForwardHealth).

Initial PA requests for Ampyra<sup>®</sup> may be approved for up to a maximum of 183 days.

## Additional Documentation Requirement for Ampyra® for Members Who Have Had a Previous Ampyra® Prior Authorization Request Approved

Additional clinical information that must be documented on a PA request for Ampyra<sup>®</sup> for members who have had a previous Ampyra<sup>®</sup> PA request approved by ForwardHealth is documentation of how the member's ability to walk has improved while on Ampyra<sup>®</sup>.

Prior authorization requests for Ampyra<sup>®</sup> for members currently taking Ampyra<sup>®</sup> who have had a previous Ampyra<sup>®</sup> PA request approved by ForwardHealth may be approved for up to a maximum of one year.

#### **Opioid Dependency Agents**

Zubsolv<sup>®</sup> and buprenorphine-naloxone tablets will remain non-preferred drugs. Suboxone<sup>®</sup> film continues to be a preferred drug that requires clinical PA.

Buprenorphine tablets will become a non-preferred drug. Prior authorization requests for buprenorphine tablets will only be considered for members who are pregnant and meet **all** of the clinical criteria listed in the Clinical Criteria for Buprenorphine Tablets section of this *Update*.

As a reminder, Suboxone<sup>®</sup> film, Zubsolv<sup>®</sup>, buprenorphinenaloxone tablets, and buprenorphine tablets are diagnosisrestricted drugs. Providers may refer to the Diagnosis Restricted Drugs data table on the Pharmacy Resources page of the Portal for the most current list of allowable diagnosis codes.

## Revised Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents Form

ForwardHealth has revised the Prior

Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents form, F-00081 (07/14). The previous version of this form will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal. Prior authorization requests received on and after July 1, 2014, must be submitted on the revised form or they will be returned.

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

# Submitting Prior Authorization Requests for Opioid Dependency Agents

Prior authorization requests for Suboxone<sup>®</sup> film and buprenorphine tablets may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

Prior authorization requests for buprenorphine-naloxone tablets (including Zubsolv<sup>®</sup>) may be submitted on the Portal, by fax, or by mail. Prior authorization requests for buprenorphine-naloxone tablets (including Zubsolv<sup>®</sup>) may **not** be submitted via STAT-PA.

Prior authorization requests for opioid dependency agents may be approved for up to a maximum of 183 days.

ForwardHealth has revised the clinical criteria for coverage of Suboxone<sup>®</sup> film, buprenorphine tablets, and buprenorphine-naloxone tablets (including Zubsolv<sup>®</sup>).

## Clinical Criteria for Suboxone® Film

Clinical criteria for approval of a PA request for Suboxone<sup>®</sup> 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 (DATA 2000) waiver allowing him or her to prescribe buprenorphine-based agents for opioid dependency treatment.
- The member is not taking other opioids, tramadol, or carisoprodol.
- The prescribing physician has indicated that he or she has read the attestation statement on the form and that he or she agrees to follow guidelines set forth by the U.S. Department of Health and Human Services (HHS) Federation of State Medical Boards — Model Policy Guidelines for Opioid Addiction Treatment.
- The prescriber has indicated whether the member has been receiving buprenorphine-based opioid dependency treatment for more than two years.
- For members who have been receiving buprenorphinebased opioid dependency treatment for more than two years, the prescriber has indicated whether the member is being maintained on a single daily dose of 16 mg or less of the buprenorphine-based treatment.

## Clinical Criteria for Buprenorphine Tablets

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

- The member is pregnant and the prescribing physician has indicated the member's expected delivery date.
- 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 member is not taking other opioids, tramadol, or carisoprodol.
- The prescribing physician has indicated that he or she has read the attestation statement on the form and that he or she agrees to follow guidelines set forth by the U.S. HHS Federation of State Medical Boards —

Model Policy Guidelines for Opioid Addiction Treatment.

- The prescriber has indicated whether the member has been receiving buprenorphine-based opioid dependency treatment for more than two years.
- For members who have been receiving buprenorphinebased opioid dependency treatment for more than two years, the prescriber has indicated whether the member is being maintained on a single daily dose of 16 mg or less of the buprenorphine-based treatment.
- The prescribing physician discussed with the member that methadone maintenance is the standard of care for opioid addiction treatment in pregnant women.
- The prescribing physician 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 nonpreferred 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 member is not taking other opioids, tramadol, or carisoprodol.
- The prescribing physician has indicated that he or she has read the attestation statement on the form and that he or she agrees to follow guidelines set forth by the U.S. HHS Federation of State Medical Boards — Model Policy Guidelines for Opioid Addiction Treatment.
- The prescriber has indicated whether the member has been receiving buprenorphine-based opioid dependency treatment for more than two years.
- For members who have been receiving buprenorphinebased opioid dependency treatment for more than two

years, the prescriber has indicated whether or not the member is being maintained on a single daily dose of 16 mg or less of the buprenorphine-based treatment.

The prescriber has submitted detailed clinical justification for prescribing a non-preferred buprenorphine-naloxone drug instead of Suboxone<sup>®</sup> film, including clinical information why the member cannot use Suboxone<sup>®</sup> film and why it is medically necessary that the member receive a non-preferred buprenorphine-naloxone drug instead of Suboxone<sup>®</sup> film.

#### **Proton Pump Inhibitors**

Aciphex<sup>®</sup> tablets will become a non-preferred drug. Aciphex<sup>®</sup> Sprinkle<sup>™</sup> and federal legend drug esomeprazole will remain non-preferred drugs (in addition to other nonpreferred drugs) in the proton pump inhibitors drug class.

Rabeprazole will become a preferred drug in the proton pump inhibitors drug class. As a reminder, Nexium Suspension, omeprazole RX, pantoprazole, Prilosec suspension, and Protonix suspension are also preferred drugs in the proton pump inhibitors drug class.

ForwardHealth covers only the prescription form of esomeprazole; over-the-counter esomeprazole is not covered.

## **Other Pharmacy Policy Changes**

#### Namenda

Namenda is being discontinued by the manufacturer and will no longer be available. Pharmacy providers are encouraged to work with prescribers to begin switching members to a preferred drug or to obtain PA for a nonpreferred drug in the Alzheimer's agents drug class. As a reminder, preferred drugs in the Alzheimer's agents drug class are donepezil 5 mg, donepezil 10 mg, donepezil 5 mg orally disintegrating tablet (ODT), donepezil 10 mg ODT, Exelon<sup>®</sup>, and Exelon<sup>®</sup> patch.

#### Namenda XR™

Namenda XR<sup>™</sup> continues to be a non-preferred drug. Prior authorization requests for Namenda XR<sup>™</sup> must be completed and signed by prescribers. As a reminder, PA requests for members who are 45 years of age or older must be submitted on the PA/PDL Exemption Request form.

Prior authorization requests for Namenda XR<sup>™</sup> for members who are 44 years of age or younger 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. Clinical documentation supporting an Alzheimer's disease or dementia indication for members 44 years of age or younger must be submitted with the PA request.

Effective for DOS on and after July 1, 2014, BadgerCare Plus and Medicaid members who are 44 years of age or younger, were taking Namenda (as identified from claims history) prior to February 15, 2013, and are still actively taking Namenda will be transitioned to Namenda XR<sup>™</sup>. For these members, PA is not required for Namenda XR<sup>™</sup> until further notice.

#### Special Enrollment Circumstances

As a reminder, some state prison inmates may qualify for Wisconsin Medicaid or BadgerCare Plus during impatient hospital stays; however, these qualified inmates are not eligible for outpatient hospital services, including covered outpatient drug services, under Wisconsin Medicaid and BadgerCare Plus.

To qualify for Wisconsin Medicaid or BadgerCare Plus, state prison inmates must meet all applicable eligibility criteria. The Department of Corrections coordinates and reimburses inpatient hospital services for inmates who do not qualify for Wisconsin Medicaid or BadgerCare Plus.

These inmates are eligible for Wisconsin Medicaid or BadgerCare Plus only for the duration of their inpatient hospital stay. Eligibility begins on the date of their inpatient admission and ends on the date of their discharge. For more information about inmate eligibility, providers may refer to the Persons Detained by Legal Process topic (topic #278) and the State Prison Inmates May Qualify for Wisconsin Medicaid or BadgerCare Plus During Inpatient Hospital Stays topic (topic #16657) in the Special Enrollment Circumstances chapter of the Member Information section of the Pharmacy service area of the Online Handbook.

### **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 Web site at *www.forwardhealth.wi.gov/*.

P-1250

This Update was issued on 06/20/2014 and information contained in this Update was incorporated into the Online Handbook on 07/01/2014.

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

The table below lists the pharmacy prior authorization (PA) forms and completion instructions that are new or that have been revised, renamed, or discontinued as a result of the July 2014 PDL 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, 2014. The old versions of these forms and completion instructions will be moved to the Pharmacy-Related Forms and Completion Instructions archive page that is linked under the Archives section on the Pharmacy Resources page of the Portal. Additional information regarding changes to clinical criteria or submission options is noted under the applicable drug classes in this *ForwardHealth Update*.

Form Name	Form Number	Revised, Renamed, Discontinued, or New	Effective Date
Prior Authorization Drug Attachment for Incivek and Victrelis	F-00583	Revised and Renamed: Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors	07/01/14
Completion Instructions	F-00583A	Revised and Renamed: Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors Completion Instructions	07/01/14
Prior Authorization Drug Attachment for Sovaldi	F-01247	New	07/01/14
Completion Instructions	F-01247A	New	07/01/14
Prior Authorization Drug Attachment for Sovaldi Renewal	F-01248	New	07/01/14
Completion Instructions	F-01248A	New	07/01/14
Prior Authorization Drug Attachment for Stribild	F-01249	New	07/01/14
Completion Instructions	F-01249A	New	07/01/14
Prior Authorization/Preferred Drug List (PA/PDL) for Anticoagulants, Oral	F-00806	Discontinued	07/01/14
Completion Instructions	F-00806A	Discontinued	07/01/14
Prior Authorization/Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators	F-00805	Revised	07/01/14
Completion Instructions	F-00805A	Revised	07/01/14

Form Name	Form Number	Revised, Renamed, Discontinued, or New	Effective Date
Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents	F-00081	Revised	07/01/14
Completion Instructions	F-00081A	Revised	07/01/14
Prior Authorization/Preferred Drug List (PA/PDL) for Zetia or Vytorin	F-00279	Discontinued	07/01/14
Completion Instructions	F-00279A	Discontinued	07/01/14

## 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 2014 PDL review. The updated statuses are effective July 1, 2014. Drugs that have not been previously reviewed by the Medicaid 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, 2014
Acne Agents, Topical	cleocin t solution	Non-preferred
	Epiduo®	Preferred
	Fabior™*	Non-preferred
	Retin-A micro <sup>®</sup>	Non-preferred
	tretinoin microspheres gel*	Non-preferred
	tretinoin microspheres gel pump*	Non-preferred
Analgesics, Opioids Long-Acting	Kadian®	Preferred
	morphine ER capsules*	Non-preferred
	Zohydro™ ER*	Non-preferred
Analgesics, Opioids Short-Acting	dihydrocodeine/asa/caffeine*	Non-preferred
Angiotensin Modulators, ARBs and DRIs	candesartan tablets*	Non-preferred
	candesartan HCTZ*	Non-preferred
	telmisartan tablets*	Non-preferred
	telmisartan/HCTZ*	Non-preferred
Angiotensin Modulators, ACE Inhibitors	benazepril/HCTZ	Non-preferred
	captropril/HCTZ	Non-preferred
	Epaned™*	Non-preferred
	fosinopril	Preferred
Angiotensin Modulators, Combination	amlodipine/benazepril	Preferred
	Lotrel®	Non-preferred
	telmisartan/amlodipine*	Non-preferred
Antibiotics, Beta-Lactam	ceftibuten capsule*	Non-preferred
	ceftibuten suspension*	Non-preferred
	Suprax <sup>®</sup> capsules*	Preferred
Antibiotics, Inhaled	Bethkis <sup>®</sup> *	Preferred
	Tobi <sup>®</sup> Podhaler™*	Non-preferred
	tobramycin ampule*	Non-preferred
Antibiotics, Tetracyclines	doxycycline monohydrate suspension*	Non-preferred
Antibiotics, Topical	gentamicin cream	Non-preferred
	gentamicin ointment	Non-preferred

Drug Class	Drug Name	Status Effective July 1, 2014
Anticoagulants	Eliquis®	Preferred
Antiemetics/Antivertigo	Diclegis <sup>®</sup> *	Non-preferred
Antifungals, Oral	clotrimazole	Preferred
	griseofulvin	Preferred
	Noxafil <sup>®</sup> suspension*	Non-preferred
	voriconazole suspension*	Non-preferred
Antifungals, Topical	Luzu®*	Non-preferred
Antiparasitics, Topical	Natroba™	Preferred
	Sklice®	Preferred
Antivirals, Influenza	amantadine capsules	Preferred
Antivirals, Topical	acyclovir ointment*	Preferred
	Denavir®	Non-preferred
	Zovirax <sup>®</sup> cream	Preferred
	Zovirax <sup>®</sup> ointment	Non-preferred
Beta Blockers	bisoprolol	Preferred
	bisoprolol/HCTZ	Preferred
Bladder Relaxant Preparations	oxybutynin ER	Preferred
	tolterodine ER*	Non-preferred
Bone Resorption Suppression	alendronate solution*	Non-preferred
BPH Agents, Andrenergic	doxazosin	Non-preferred
Calcium Channel Blocking Agents	Nymalize <sup>®</sup> solution*	Non-preferred
Fluoroquinolones	moxifloxacin*	Non-preferred
H. Pylori	lansoprazole/amoxicillin/clarithrmycin*	Non-preferred
Hepatitis B Agents	lamivudine HBV tablet*	Non-preferred
Hepatitis C, Agents	Sovaldi <sup>®</sup> *	Non-preferred
Hepatitis C, Nucleoside Analogues	ribavirin dose pack*	Non-preferred
Hepatitis C, Protease Inhibitors	Olysio™*	Non-preferred
HIV-AIDS	abacavir/lamivudine/zidovudine*	Non-preferred
	Tivicay®*	Non-preferred
Hypoglycemics, Meglitinides	repaglinide*	Non-preferred
Hypoglycemics, Other	Farxiga™*	Non-preferred
	Invokana <sup>®</sup> *	Non-preferred
	metformin ER 1000 mg	Non-preferred
Hypoglycemics, Sulfonylureas	tolazamide	Non-preferred
	tolbutamide	Non-preferred
Irritable Bowel Syndrome	Lotronex®*	Non-preferred
Lipotropics, Bile Acid Sequestrants	colestipol tablets	Preferred
Lipotropics, Fibric Acids	fenofibrate 48 mg, 145 mg tablets*	Non-preferred
	fenofibric acid capsule*	Non-preferred
	fenofibric acid tablet	Non-preferred

Drug Class	Drug Name	Status Effective July 1, 2014
Lipotropics, Niacin	niacin ER*	Non-preferred
Lipotropics, Other	Juxtapid <sup>®</sup> *	Non-preferred
	Kynamaro®*	Non-preferred
	Lescol®	Non-preferred
	Lescol® XL	Non-preferred
	Liptruzet <sup>™</sup> *	Non-preferred
	Simcor <sup>®</sup>	Non-preferred
Migraine Agents, Other	naratriptan	Non-preferred
	rizatriptan ODT	Preferred
	zolmitriptan tablets*	Non-preferred
	zolmitriptan ODT*	Non-preferred
Multiple Sclerosis Agents,	Copaxone <sup>®</sup> 40 mg syringe*	Non-preferred
Immunomodulators	Extavia® kit	Preferred
	Extavia® vial	Preferred
	Tecfidera®*	Non-preferred
Opioid Dependency Agents	buprenorphine HCL	Non-preferred
	buprenorphine-naloxone tab*	Non-preferred
	Zubsolv <sup>®</sup> *	Non-preferred
Pulmonary Arterial Hypertension	Adempas <sup>®</sup> *	Non-preferred
	Opsumit <sup>®</sup> *	Non-preferred
Phosphate Binders	calcium acetate 667 mg capsule	Non-preferred
	Eliphos™	Preferred
	Fosrenol®	Non-preferred
	Phoslyra®	Preferred
	Velphoro®*	Non-preferred
Proton Pump Inhibitors	Aciphex®	Non-preferred
	Aciphex <sup>®</sup> Sprinkle™ DR caps*	Non-preferred
	esomeprazole strontium DR*	Non-preferred
	rabeprazole	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*.