

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

Pharmacy Policy Changes Effective October 15, 2015

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 October 15, 2015, unless otherwise noted.

With the rapid development and approval by the Food and Drug Administration of several new drugs, ForwardHealth plans to address the most current information available for recently approved drugs. This *ForwardHealth Update* announces the following:

- Clinical criteria for the use of Orkambi™ in the treatment of cystic fibrosis.
- Revised policy for hepatitis C agents and clinical criteria for two new drugs, Daklinza™ and Technivie™.
- Clinical criteria for the new drug class, lipotropics, Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) inhibitors, which will include two new drugs, Praluent® and Repatha™.

Orkambi™

Orkambi™ requires clinical prior authorization (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 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 Orkambi™ may be submitted on the ForwardHealth Portal, by fax, or by mail. Prior authorization requests for Orkambi™ may **not** be submitted using the Specialized Transmission Approval Technology-Prior Authorization (STAT-PA) system.

Clinical Criteria for Initial Prior Authorization Requests for Orkambi™

Clinical criteria that must be documented for approval of an initial PA request for Orkambi™ are **all** of the following:

- The member has cystic fibrosis.
- The member is 12 years of age or older.
- The prescriber has confirmed that the member is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
- The member's baseline forced expiratory volume in 1 second (FEV1) is between 40 and 90 percent predicted.
- The member's baseline aspartate aminotransferase (AST) is less than three times the upper limit of normal (ULN).
- The member's baseline alanine aminotransferase (ALT) is less than three times the ULN.
- The member's baseline bilirubin is less than two times the ULN.
- The member's current body mass index (BMI) has been provided.

- The prescriber has evaluated the member's liver function and adjusted the daily dose of Orkambi™ appropriately.

Initial PA requests must include the following:

- A copy of gene test results.
- A copy of the lab results (AST, ALT, and bilirubin) completed within the last 90 days.
- The member's FEV1, FEV1 predicted, and FEV1 percent predicted, along with the dates taken.
- Medical records demonstrating the member meets the initial clinical PA criteria for treatment with Orkambi™.

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

Clinical Criteria for Renewal Prior Authorization Requests for Orkambi™

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

- The member has shown improvement compared to the member's baseline, as evidenced by **at least one** of the following:
 - ✓ Stable or improved FEV1 percent predicted.
 - ✓ Improvement of 1.0 or greater in BMI, **and** FEV1 percent predicted remains 40 percent or greater.
- The member's liver function tests have not exceeded either of the following levels:
 - ✓ ALT or AST is five times the ULN.
 - ✓ ALT or AST is three times the ULN, **and** bilirubin is two times the ULN.
- The prescriber has evaluated the member's liver function and adjusted the daily dose of Orkambi™ appropriately.

Renewal PA requests must include the following:

- A copy of the lab results (AST, ALT, and bilirubin) completed within the last 90 days.
- Medical records demonstrating that the member meets renewal PA clinical criteria for treatment with Orkambi™.

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

Hepatitis C Agents

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

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, F-01247 (08/15). Renewal PA requests for hepatitis C agents must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form, F-01248 (12/14).

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet form, 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.

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 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 PA/RF. 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 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 hepatitis C virus (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 should complete 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 is **all** of the following:

- Lab data (within the last six months), including the following:
 - ✓ Albumin test.
 - ✓ Complete blood count (CBC).
 - ✓ Hepatitis C virus genotype.
 - ✓ Hepatitis C virus-ribonucleic acid (HCV-RNA) level.
 - ✓ International normalized ratio (INR).
 - ✓ Liver function tests (LFTs).
 - ✓ Serum creatinine test.
- Tests (if performed), including the following:
 - ✓ Liver computed tomography (CT) scan, ultrasound, or MRI results.
 - ✓ Liver biopsy results.

- Hepatitis C virus clinical data, including the following:
 - ✓ Likely source of the HCV infection.
 - ✓ Current medical records for hepatitis C assessment and treatment.
 - ✓ 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 (HCC) 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.

Note: Fibroscan results may be provided as one component of cirrhosis assessment.

- 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 hepatitis C treatment regimen.

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.

Note: ForwardHealth does not accept fibrosis staging as determined by calculators or blood assays to differentiate between F2 and F3 or greater Metavir scores. Some examples of fibrosis staging calculators may include AST to Platelet Ratio Index (APRI), Fibrosis-4 (FIB-4), and Non-alcoholic Fatty Liver Disease (NAFLD). Some examples of blood assays may include FibroSURE™ and FIBROSpect®. ForwardHealth does accept liver biopsy results to determine a Metavir score or to determine fibrosis staging.

Pharmacy Provider-Specific Prior Authorization Requests for Hepatitis C Agents

For PA requests approved on and after October 15, 2015, hepatitis C agents included in the hepatitis C agents drug class on the Preferred Drug List (PDL) will be 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 drugs 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 at 800-947-9627. Provider Services will work with the pharmacy provider on the approved PA 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. A PA/RF should **not** be submitted.

Prior Authorization Required for Daklinza™ and Technivie™

Daklinza™ and Technivie™, which are hepatitis C agents, require PA until further notice.

Daklinza™ and Technivie™ are non-preferred drugs and are scheduled to be reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee as part of the PDL review in the summer of 2016 in the hepatitis C agents drug class. Until the next PDL review of this drug class has occurred, the following PA criteria have been established for Daklinza™ and Technivie™.

Hepatitis C Agents, Daklinza™

Prior Authorization Requests for Use of Daklinza™ as a Combined Treatment with Sovaldi™ That Will Be Considered for Review

Only PA requests for the use of Daklinza™ and Sovaldi™ as a combined treatment for members whose hepatitis C liver disease has advanced to **any** of the following stages may be considered for review:

- Compensated cirrhosis (i.e., CTP class A)
- Evidence of bridging fibrosis (e.g., Metavir score of F3 or greater)
- Serious extra-hepatic manifestations of HCV

In addition, only PA requests for members who have chronic hepatitis C genotype 3 infection will be considered for review.

Conditions or Circumstances for Use of Daklinza™ as a Combined Treatment with Sovaldi™ for Which Prior Authorization Requests Will Be Denied

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

- The member has acute hepatitis C.
- The member has a significant or uncontrolled concurrent disease (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease, thyroid disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C). (*Note:* If the member is currently on a liver transplant wait list with an elevated Model for End-Stage Liver Disease [MELD] score, individual circumstances will be considered for review.)
- The member has received a liver transplant.
- The member is currently abusing drugs or alcohol.
 - ✓ Members with compensated cirrhosis must be abstinent from alcohol for the six months prior to and during HCV treatment.
 - ✓ Members must no longer be abusing drugs for at least six months prior to HCV treatment.
 - ✓ Active participation in a recovery program is required for members with a recent history of alcohol or drug abuse.
- The member has taken a prior course of therapy with Daklinza™ or Sovaldi™.
- Non-compliance with approved hepatitis C treatment regimen.

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

Hepatitis C, Agents, Technivie™

Prior Authorization Requests That Will Be Considered for Review

Only PA requests for Technivie™ for members whose hepatitis C liver disease has advanced to **any** of the following stages may be considered for review:

- Evidence of bridging fibrosis (e.g., Metavir score of F3 or greater)
- Serious extra-hepatic manifestations of HCV

In addition, only PA requests for members who have chronic hepatitis C genotype 4 infection will be considered for review.

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 hepatitis C.
- The member has a significant or uncontrolled concurrent disease (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease, thyroid disease).
- The member has cirrhosis.
- The member has received a liver transplant.
- The member is currently abusing drugs or alcohol.
 - ✓ Members must no longer be abusing drugs for at least six months prior to HCV treatment.
 - ✓ Active participation in a recovery program is required for members with a recent history of alcohol or drug abuse.
- The member has taken a prior course of therapy with Technivie™ or Viekira Pak™.
- The member has demonstrated non-compliance with approved hepatitis C treatment regimen.

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

Prior Authorization Required for Lipotropics, PCSK9 Inhibitors Praluent® and Repatha™

Praluent® and Repatha™, lipotropics PCSK9 inhibitors, require PA until further notice.

Praluent® and Repatha™ are non-preferred drugs that are scheduled to be reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee as part of the PDL review in summer 2016 in the lipotropics, other drug class. Until the next PDL review of this drug class has occurred, the following PA criteria have been established for lipotropics, PCSK9 inhibitors, which include the new drugs Praluent® and Repatha™.

Lipotropics, 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 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

Only PA requests for lipotropics, PCSK9 inhibitors for members with **one** of the following medical conditions will be considered for review:

- Heterozygous familial hypercholesterolemia (HeFH) for members who are 18 years of age or older

- Homozygous familial hypercholesterolemia (HoFH) for members who are 13 years of age or older (Repatha™ only)
- Clinical atherosclerotic cardiovascular disease (ASCVD) as evidenced by one of the following:
 - ✓ History of myocardial infarction (heart attack)
 - ✓ History of stroke

Clinical Information That Must Be Documented on All Initial Prior Authorization Requests for Lipotropics, PCSK9 Inhibitors

The clinical information that must be submitted with all initial PA requests for PCSK9 inhibitors is **all** of the following:

- Medical records demonstrating that the member meets one of the medical conditions required for consideration of PA review with a lipotropics, PCSK9 inhibitor
- 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
 - ✓ Low-density lipoprotein (LDL) prior to and during drug therapy (including dates taken)
 - ✓ Reasons for discontinuation if drug therapy was discontinued

Clinical Criteria for Approval of an Initial Prior Authorization Request for a Lipotropics, PCSK9 Inhibitor

One of the following clinical criteria is required for approval of an initial PA request for a lipotropics, PCSK9 inhibitor:

- 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 of 100mg/dL or less.
- The member is not able to use the highest available dose or maximally tolerated dose of atorvastatin or Crestor® due to prior treatment history with significant skeletal muscle-related symptoms (e.g., pain, weakness).

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.
- The member has been diagnosed with statin-induced rhabdomyolysis. The diagnosis must be supported by acute neuromuscular illness or dark urine **and** an acute elevation in creatine kinase (usually greater than 5,000 IU/L or five times the upper limit of normal).
- The member has a medical contraindication to treatment with a high potency statin. Prescribers are required to specifically address the reasons for the medical contraindication. Medical records should be provided as necessary to support the contraindication.

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

For initial and renewal PA requests for lipotropics, PCSK9 inhibitors, the member must continue to take a maximally tolerated dose of a statin combined with Zetia® in conjunction with the lipotropics, PCSK9 inhibitor unless the member has one of the following:

- A statin-induced rhabdomyolysis.
- Significant statin-induced skeletal muscle-related symptoms.
- A medical contraindication to treatment with a high potency statin.

Note: All renewal PA requests require the member to be adherent with the lipotropics, PCSK9 inhibitor treatment regimen. A copy of the lab results (within the past 30 days) must be included with the PA request.

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.

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

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

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

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