ForwardHealth
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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

Revised Prior Authorization Forms and Changes to Pharmacy Policies for Hepatitis C Agents Effective August 1, 2016

This *ForwardHealth Update* announces revisions to the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (08/2016), and the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form, F-01248 (08/2016), to accommodate the revised hepatitis C agents clinical criteria that was published in the July 2016 *ForwardHealth Update* (2016-22), titled "July 2016 Preferred Drug List Review and Other Pharmacy Policy Changes." In addition, this *Update* provides information for prescribers and pharmacy providers about the following, effective for dates of service on and after August 1, 2016:

- Changes to pharmacy policies for hepatitis C agents
- The addition of Epclusa® as a non-preferred drug to the hepatitis C agents drug class of the Preferred Drug List

Revised Prior Authorization Forms

ForwardHealth has revised the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (08/2016), and the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form, F-01248 (08/2016), to accommodate the revised hepatitis C agents clinical criteria that was published in the July 2016 *ForwardHealth Update* (2016-22), titled "July 2016 Preferred Drug List Review and Other Pharmacy Policy Changes." As announced in *Update* 2016-22, the revised clinical criteria for hepatitis C agents are effective for prior authorization (PA) requests with a requested start date of July 1, 2016, or later. The revised Prior Authorization Drug Attachment for Hepatitis C Agents form and Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form must be used for PA requests received on and after August 1, 2016.

The previous versions of the forms will be removed from the Forms page of the ForwardHealth Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. Prior authorization requests for hepatitis C agents received on and after August 1, 2016, must be submitted on the appropriate revised form or they will be returned to the provider.

Providers may refer to the Forms page of the Portal for the revised completion instructions and forms. Approved PA requests on file with ForwardHealth dated prior to August 1, 2016, will be honored until they expire or until the approved days' supply is used up.

For more information about the clinical criteria for hepatitis C agents and PA request submission options, providers should refer to the Hepatitis C Agents topic (topic #18297) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the ForwardHealth Online Handbook.

Hepatitis C Agents

Effective for dates of service (DOS) on and after August 1, 2016, ForwardHealth has revised the clinical information that must be documented on initial PA requests for all hepatitis C agents.

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

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

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

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

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

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 Specialized Transmission Approval Technology-Prior Authorization system.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pharmacy Provider-Specific Prior Authorization Requests for Hepatitis C Agents

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

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

Renewal Prior Authorization Requests for Hepatitis C Agents

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

Epclusa®

Effective for DOS on and after August 1, 2016, Epclusa® will be a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection.

Epclusa® will be added to the PDL as a non-preferred drug in the hepatitis C agents drug class until the next class review by the Wisconsin Medicaid Pharmacy PA Advisory Committee. Until the next review has occurred, the following PA guidelines have been established for Epclusa®.

Prior Authorization Requests That Will Be Considered for Review

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

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

Note: For HCV genotype 1, the member must be clinically ineligible for treatment with Viekira Pak™ and Zepatier™ due

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

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

Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied

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

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™ and Zepatier™.
- The member has chronic HCV genotype 3 infection and does not have a medical or medication contraindication for treatment with Daklinza™.
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie™ and Zepatier™.
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has received a liver transplant.
- The member has HCV infection and cirrhosis with severe liver functional compromise (i.e., CTP class C). Currently, there is no evidence to support that HCV treatment of members with end-stage liver disease impacts morbidity or mortality. The severity of liver damage present in decompensated liver disease makes it unlikely that treating the underlying infection would lead to meaningful liver function improvement. The only definitive treatment for end-stage liver disease is a liver transplant.
- The member has cirrhosis and the member has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Harvoni®, Sovaldi®, or a sofosbuvir-containing product.
- The member is non-compliant with an approved HCV treatment regimen.

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

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

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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This *Update* was issued on 07/29/2016 and information contained in this *Update* was incorporated into the Online Handbook on 08/01/2016.