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

Prior Authorization Required for Mavyret™ and Vosevi™

This *ForwardHealth Update* announces that effective October 9, 2017, the hepatitis C agents Mavyret™ and Vosevi™ require prior authorization (PA). Mavyret™ and Vosevi™ are non-preferred drugs that are scheduled to be reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee as part of the Preferred Drug List (PDL) review in November 2017 in the hepatitis C agents drug class. Until the November 2017 PDL review has occurred, PA criteria have been established for Mavyret™ and Vosevi™.

Hepatitis C Agents

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

Viekira Pak®/Viekira XR™ and Zepatier® are the preferred drugs for members who have chronic hepatitis C virus (HCV) genotype 1 infection. PA 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®/Viekira XR™ and Zepatier® due to a medical or medication contraindication.

Epclusa® is the preferred drug for members who have chronic HCV genotype 2 or 3 infection. PA requests for other hepatitis C agents for members who have chronic HCV genotype 2 or 3 infection will not be considered unless the member is clinically ineligible for treatment with Epclusa® due to a medical or medication contraindication.

Technivie™ and Zepatier® are the preferred drugs for members who have chronic HCV genotype 4 infection. PA 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.

PA requests for hepatitis C agents must be completed and signed by prescribers. PA requests for hepatitis C agents must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (07/2017).

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), 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.

PA requests for hepatitis C agents may be submitted on the Portal, by fax, or by mail (but **not** using the Specialized

Transmission Approval Technology-Prior Authorization system).

Note: When two or more hepatitis C agents are used as a **combined** treatment (e.g., Daklinza™ as a combined treatment with Sovaldi®), providers should not submit a separate PA request form for each drug. Hepatitis C agents that are used for a combined treatment must be submitted on **one** Prior Authorization Drug Attachment for Hepatitis C Agents form and one completed Prior Authorization Request Form, F-11018 (05/13).

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

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

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

- Lab data (within the last six months), including the following:
  - ✓ Albumin test
  - ✓ Complete blood count
  - ✓ Hepatitis B virus screening
  - ✓ HCV genotype
  - ✓ HCV-ribonucleic acid 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 results
  - ✓ Blood tests to assess liver fibrosis (i.e., FibroTest™/FibroSure®, FIBRO*Spect*®)
- HCV 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 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 any of the following:
    - o Ascites
    - o Esophageal varices
    - o Hepatic encephalopathy
    - o Jaundice
    - o 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)
- Current medical history and physical, including complete problem list and medication list
- Current and past psychosocial history including alcohol and IV drug use
- Planned HCV 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.

For members who have received a liver transplant, PA requests for all hepatitis C agents will be reviewed for the following: the member's HCV genotype, current liver disease status, past HCV treatment history, current medications,

other comorbidities, and requested HCV treatment regimen. ForwardHealth will consider the member's entire clinical record and the level of clinical evidence for the PA request determination decision, and if the requested HCV treatment regimen has low clinical evidence of effectiveness, the PA request will be denied.

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

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

Pharmacy Provider-Specific PA Requests for Hepatitis C Agents

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

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

Hepatitis C Agents, Mavyret™

Mavyret™ is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection.

Only PA requests for Mavyret™ for members with genotype 1, 2, 3, 4, 5, or 6 HCV liver infection will be considered for review. The member must meet **one** of the following clinical criteria sets:

- For HCV genotype 1 infection, the member must meet **both** of the following:
  - ✓ The member must be clinically ineligible for treatment with Viekira Pak®/Viekira XR™ and Zepatier® due to a medical or medication contraindication.
  - ✓ The member has **not** received prior treatment with **both** an HCV NS5A inhibitor **and** prior treatment with an HCV NS3/4A protease inhibitor (PI).
- For HCV genotype 2 or 3 infection, the member must meet **both** of the following:
  - ✓ The member must be clinically ineligible for treatment with Epclusa® due to a medical or medication contraindication.
  - ✓ The member has **not** received prior treatment with an HCV NS5A inhibitor **or** prior treatment with an HCV NS3/4A PI.
- For HCV genotype 4 infection, the member must meet **both** of the following:
  - ✓ The member must be clinically ineligible for treatment with Technivie™ and Zepatier® due to a medical or medication contraindication.
  - ✓ The member has **not** received prior treatment with an HCV NS5A inhibitor **or** prior treatment with an HCV NS3/4A PI.
- For HCV genotype 5 or 6 infection, the member has **not** received prior treatment with an HCV NS5A inhibitor **or** prior treatment with an HCV NS3/4A PI.

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Mavyret™ will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and **one or more** of the following is true:
  - ✓ The member does not have a medical or medication contraindication for treatment with Viekira Pak®/Viekira XR™ and Zepatier®.
  - ✓ The member has received prior treatment with **both** an HCV NS5A inhibitor and prior treatment with an HCV NS3/4A PI.
- The member has chronic HCV genotype 2 or 3 infection and **one or more** of the following is true:
  - ✓ The member does not have a medical or medication contraindication for treatment with Epclusa®.
  - ✓ The member has received prior treatment with an HCV NS5A inhibitor.
  - ✓ The member has received prior treatment with an HCV NS3/4A PI.
- The member has chronic HCV genotype 4 infection and **one or more** of the following is true:
  - ✓ The member does not have a medical or medication contraindication for treatment with Technivie™ and Zepatier®.
  - ✓ The member has received prior treatment with an HCV NS5A inhibitor.
  - ✓ The member has received prior treatment with an HCV NS3/4A PI.
- The member has chronic HCV genotype 5 or 6 infection and **one or more** of the following is true:
  - ✓ The member has received prior treatment with an HCV NS5A inhibitor.
  - ✓ The member has received prior treatment with an HCV NS3/4A PI.
- 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, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, 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.

Hepatitis C Agents, Vosevi™

Vosevi™ is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection.

Only PA requests for Vosevi™ for members with genotype 1, 2, 3, 4, 5, or 6 HCV liver infection will be considered for review. The member must meet **one** of the following clinical criteria sets:

- For HCV genotype 1a infection, the member must meet **both** of the following:
  - ✓ The member must be clinically ineligible for treatment with Viekira Pak®/Viekira XR™ and Zepatier® due to a medical or medication contraindication.
  - ✓ The member has received prior treatment with an HCV NS5A inhibitor **or** a sofosbuvir-containing regimen **without** an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- For HCV genotype 1b infection, the member must meet **both** of the following:
  - ✓ The member must be clinically ineligible for treatment with Viekira Pak®/Viekira XR™ and

Zepatier® due to a medical or medication contraindication.
    - ✓ The member has received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- For HCV genotype 2 infection, the member must meet **both** of the following:
    - ✓ The member must be clinically ineligible for treatment with Epclusa® due to a medical or medication contraindication.
    - ✓ The member has received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- For HCV genotype 3 infection, the member must meet **both** of the following:
    - ✓ The member must be clinically ineligible for treatment with Epclusa® due to a medical or medication contraindication.
    - ✓ The member has received prior treatment with an HCV NS5A inhibitor **or** a sofosbuvir-containing regimen **without** an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- For HCV genotype 4 infection, the member must meet **both** of the following:
    - ✓ The member must be clinically ineligible for treatment with Technivie™ and Zepatier® due to a medical or medication contraindication.
    - ✓ The member has received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- For HCV genotype 5 or 6 infection, the member has received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.

Vosevi™ treatment regimens will only be approved for a maximum of 12 weeks of treatment.

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Vosevi™ will be denied in the following circumstances:

- The member has chronic HCV genotype 1a infection and **one or more** of the following is true:
    - ✓ The member does not have a medical or medication contraindication for treatment with Viekira Pak®/Viekira XR™ and Zepatier®.
    - ✓ The member has **not** received prior treatment with an HCV NS5A inhibitor **or** the member has **not** received prior treatment with an HCV sofosbuvir-containing regimen **without** an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- The member has chronic HCV genotype 1b infection and **one or more** of the following is true:
    - ✓ The member does not have a medical or medication contraindication for treatment with Viekira Pak®/Viekira XR™ and Zepatier®.
    - ✓ The member has **not** received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- The member has chronic HCV genotype 2 infection and **one or more** of the following is true:
    - ✓ The member does not have a medical or medication contraindication for treatment with Epclusa®.
    - ✓ The member has **not** received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- The member has chronic HCV genotype 3 infection and **one or more** of the following is true:
    - ✓ The member does not have a medical or medication contraindication for treatment with Epclusa®.
    - ✓ The member has **not** received prior treatment with an HCV NS5A inhibitor **or** the member has **not** received prior treatment with an HCV sofosbuvir-containing regimen **without** an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.

- The member has chronic HCV genotype 4 infection and **one or more** of the following is true:
  - ✓ The member does not have a medical or medication contraindication for treatment with Technivie™ and Zepatier®.
  - ✓ The member has **not** received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- The member has chronic HCV genotype 5 or 6 infection and has **not** received prior treatment with an HCV NS5A inhibitor and had no response, a partial response, or has relapsed.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member has taken a prior course of therapy with Vosevi™.
- The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, 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 Medicaid Services, the Wisconsin Department of Health Services (DHS). The Wisconsin AIDS Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, DHS.

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

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This *Update* was issued on 10/06/2017 and information contained in this *Update* was incorporated into the Online Handbook on 10/09/2017.