ForwardHealth
Wisconsin serving you

Update
April 2016

No. 2016-14

**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

# Changes to Pharmacy Policies for Hepatitis C Agents

This *ForwardHealth Update* provides information for prescribers and pharmacy providers about changes to pharmacy policies for hepatitis C agents effective for prior authorization requests received on and after April 15, 2016, unless otherwise noted. These interim changes will be in effect until more definitive decisions are made about coverage of hepatitis C agents during the next Preferred Drug List (PDL) review by the Medicaid Pharmacy Prior Authorization Advisory Committee in May 2016. Additional policy changes for hepatitis C agents, as well as other changes as a result of the May PDL review, will be communicated to providers in an *Update* this summer.

This *ForwardHealth Update* provides information for prescribers and pharmacy providers about changes to pharmacy policies for hepatitis C agents effective for prior authorization (PA) requests received on and after April 15, 2016, unless otherwise noted. These interim changes will be in effect until more definitive decisions are made about coverage of hepatitis C agents during the next Preferred Drug List (PDL) review by the Medicaid Pharmacy PA Advisory Committee in May 2016. Additional policy changes for hepatitis C agents, as well as other changes as a result of the May PDL review, will be communicated to providers in an *Update* this summer.

This *Update* provides comprehensive policy for hepatitis C agents, which includes policy already published in the ForwardHealth Online Handbook that is still current, as well as changes to policy. Information in this *Update* is intended to replace the content of the following topics in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook in their entirety:

- Hepatitis C Agents topic (topic #18297)
- Hepatitis C Agents, Viekira Pak™ topic (topic #16557)
- Hepatitis C Agents, Daklinza™ topic (topic #17697)
- Hepatitis C Agents, Harvoni® topic (topic #17977)
- Hepatitis C Agents, Olysio® topic (topic #17980)
- Hepatitis C Agents, Sovaldi™ topic (topic #18697)
- Hepatitis C Agents, Technivie™ topic (topic #18717)

This *Update* announces the following:

- Clinical information that must be documented for all hepatitis C agents has been revised.
- Clinical criteria for Viekira Pak™ have been revised.
- Clinical criteria for the use of Daklinza™ and Sovaldi™ as a combined treatment for hepatitis C virus (HCV) have been revised.
- Clinical criteria for Harvoni® have been revised.
- Clinical criteria for the use of Olysio® with pegylated interferon and ribavirin have been revised.
- Clinical criteria for the use of Olysio® and Sovaldi™ as a combined treatment for HCV have been revised.

- Clinical criteria for Sovaldi™ have been revised.
- Clinical criteria for Technivie™ have been revised.
- Clinical criteria for Zepatier™ have been established.

## Hepatitis C Agents

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

Viekira Pak™ is the preferred drug for members who have chronic HCV genotype 1 infection. Prior authorization requests for other hepatitis C agents for members who have chronic HCV genotype 1 infection will not be considered unless the member is clinically ineligible for treatment with Viekira Pak™ 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, 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 ForwardHealth Portal, or to the Additional Information section available on most PA request forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

Prior authorization requests for hepatitis C agents may be submitted on the Portal, by fax, or by mail. Prior authorization requests for hepatitis C agents may **not** be submitted using the Specialized Transmission Approval Technology-Prior Authorization system.

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

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

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

For initial PA requests for hepatitis C agents, prescribers should 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 magnetic resonance imaging (MRI) results
  - ✓ Liver biopsy results
  - ✓ Transient ultrasound elastography (Fibroscan) 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

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.

*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 calculations may include Aspartate Aminotransferase (AST) to Platelet Ratio Index (APRI), Fibrosis-4, and non-alcoholic fatty liver disease score. Some examples of blood assays may include FibroSURE™ and FIBROSpect®. ForwardHealth does accept liver biopsy to determine a Metavir score or to determine fibrosis staging. ForwardHealth does accept Fibroscan to determine a Metavir score of F3 or greater if the member's test results indicate a score of 9.5 kPa or greater in the absence of any ascites or clinically significant heart failure.

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

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

of the pharmacy provider-specific PA requirement. The provider should explain to the member that the drug therapy authorized must be dispensed by the pharmacy provider approved under the PA request.

Pharmacy providers should not submit PA requests for hepatitis C agents if they do not intend to also dispense the entire drug therapy approved under the PA to the member. If the member needs to discontinue receiving the drug from the approved pharmacy provider once the approved treatment has begun, the pharmacy provider must contact Provider Services. Provider Services will work with the pharmacy provider on the approved PA 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.

## Viekira Pak™

Viekira Pak™ is a preferred drug that requires clinical PA.

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

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

- Compensated cirrhosis (i.e., CTP class A)
- Evidence of bridging fibrosis (e.g., Metavir score of F3 or greater)
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, or porphyria cutanea tarda (laboratory-confirmed diagnosis)
- Liver transplant recipients with or without fibrosis or liver transplant recipients with compensated cirrhosis (i.e., CTP class A)

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

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

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease (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).
- The member has cirrhosis and the member is not abstinent from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Technivie™ or Viekira Pak™.
- The member is non-compliant with approved HCV treatment regimen.

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, 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.

## Daklinza™

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

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

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

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

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

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

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

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

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, the member must also be an active participant in a recovery program.

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

## Harvoni®

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

Only PA requests for Harvoni® for members with genotype 1, 4, 5, or 6 whose HCV liver disease has advanced to any of the following stages may be considered for review (for HCV genotype 1, the member must be clinically ineligible for treatment with Viekira Pak™ due to a medical or medication contraindication):

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

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

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

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

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

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

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, the member must also be an active participant in a recovery program.

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

## Olysio®

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

Only PA requests for the use of Olysio® with pegylated interferon and ribavirin for members with genotype 1 or 4 whose HCV liver disease has advanced to any of the following stages may be considered for review (for HCV genotype 1, the member must be clinically ineligible for treatment with Viekira Pak™ due to a medical or medication contraindication):

- 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, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

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

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

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

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™.
- The member has acute HCV.
- 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).
- The member has cirrhosis and the member is not abstinent from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with a treatment regimen that includes Olysio® or any other HCV protease inhibitor.
- The member is non-compliant with approved HCV treatment regimen.

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, the member must also be an active participant in a recovery program.

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

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

Only PA requests for the use of Olysio® and Sovaldi™ as a combined treatment for members with genotype 1 whose HCV liver disease has advanced to any of the following stages and who are clinically ineligible for treatment with Viekira Pak™ due to a medical or medication contraindication 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, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

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

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

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

- The member does not have a medical or medication contraindication for treatment with Viekira Pak™.
- The member has acute HCV.
- 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).
- The member has cirrhosis and the member is not abstinent from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Harvoni®, Olysio®, Sovaldi™, a sofosbuvir-containing product, or any other HCV protease inhibitor.
- The member is non-compliant with approved HCV treatment regimen.

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, the member must also be an active participant in a recovery program.

*Notes:*

- Use of Olysio® and Sovaldi™ as a combined treatment will only be considered for members who have contraindications to the use of Daklinza™, Harvoni®, interferon, ribavirin, Viekira Pak™, and Zepatier™. Providers are required to clearly document why the member is unable to take Daklinza™, Harvoni®, interferon, ribavirin, Viekira Pak™, or Zepatier™.
- The member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

## Sovaldi™

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

Only PA requests for Sovaldi™ for members with genotype 1, 2, 3, or 4 whose HCV liver disease has advanced to any of the following stages may be considered for review (for HCV genotype 1, the member must be clinically ineligible for treatment with Viekira Pak™ due to a medical or medication contraindication):

- 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, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

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

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

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

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™.

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

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, the member must also be an active participant in a recovery program.

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

## Technivie™

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

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

- Evidence of bridging fibrosis (e.g., Metavir score of F3 or greater)
- Serious extra-hepatic manifestations of HCV, such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

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

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

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease, thyroid disease).
- The member has cirrhosis.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Technivie™ or Viekira Pak™.
- The member is non-compliant with approved HCV treatment regimen.

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, the member must also be an active participant in a recovery program.

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

## Zepatier™

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

Only PA requests for Zepatier™ for members with genotype 1 or 4 whose HCV liver disease has advanced to any of the following stages may be considered for review (for HCV genotype 1, the member must be clinically ineligible for treatment with Viekira Pak™ due to a medical or medication contraindication):

- 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, such as leukocytoclastic vasculitis, membranoproliferative

glomerulonephritis, symptomatic cryoglobulinemia, or porphyria cutanea tarda (laboratory-confirmed diagnosis)

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

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

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

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak™.
- The member has acute HCV.
- 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).
- The member has cirrhosis and the member is not abstinent from alcohol for at least six months prior to and during HCV treatment.
- The member has received a liver transplant.
- The member has taken a prior course of therapy with Zepatier™.
- The member is non-compliant with approved HCV treatment regimen.

In addition, members with a history of abusing drugs or alcohol 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 abusing drugs or alcohol, 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/*.

P-1250