ForwardHealth
Wisconsin serving you

Update
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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

Changes to Pharmacy Policies for Hepatitis C Agents Effective April 1, 2015

This *ForwardHealth Update* provides information for prescribers and pharmacy providers about changes to pharmacy policies for hepatitis C agents effective for dates of service on and after April 1, 2015, unless otherwise noted.

This *ForwardHealth Update* provides information for prescribers and pharmacy providers about changes to pharmacy policies for hepatitis C agents effective for dates of service on and after April 1, 2015, unless otherwise noted. This *Update* announces the following:

- Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors form, F-00583 (dated 07/14), has been discontinued.
- Incivek® has been discontinued.
- Victrelis® has been discontinued.
- Clinical criteria for Viekira Pak™ have been established.
- Clinical criteria for 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 hepatitis C have been established.

Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors Has Been Discontinued

The Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors form will be discontinued and will no longer be accepted. It will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal.

Providers will be required to use the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (12/14), for all initial PA requests for hepatitis C protease inhibitors, and the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form, F-01248 (12/14), for all renewal PA requests for hepatitis C protease inhibitors. Providers may refer to the Forms page of the Portal for copies of the forms and completion instructions. Prior authorization (PA) requests received on and after April 1, 2015, that are *not* submitted on the appropriate forms will be returned.

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

Incivek® Discontinued by Manufacturer

On August 11, 2014, Vertex announced the voluntary market withdrawal of Incivek®, a hepatitis C drug. Vertex has discontinued the sales and distribution of Incivek®. The decision to withdraw Incivek® was based upon the availability of alternative treatments for hepatitis C and the diminishing market demand for Incivek®.

Vertex intends to supply enough of the drug for current users to finish their treatment but is asking providers not to start anyone on the drug going forward. For those currently under treatment with an approved PA, ForwardHealth will continue to allow providers who are able to fill these prescriptions to submit claims for reimbursement. For members unable to obtain the drug needed to complete treatment, Vertex will address available drug supply needs to complete the treatment regimen. For questions or product support information, providers may contact Vertex at (877) 824-4281.

Prior authorization requests for Incivek® that have already been approved will be honored until they expire or until the approved days' supply is finished. For further assistance with allowing a member to complete his or her prescribed treatment course, providers may contact Provider Services at (800) 947-9627.

Victrelis® Discontinued by Manufacturer

On January 20, 2015, Merck announced the voluntary market withdrawal of Victrelis®, a hepatitis C drug. Merck will discontinue the sales and distribution of Victrelis® in the United States by December 2015. The decision to withdraw Victrelis® was based upon the availability of alternative treatments for hepatitis C and the diminishing market demand for Victrelis®.

Merck intends to supply Victrelis® to wholesalers through December 2015 on an as-needed basis from existing inventories but is asking providers not to start anyone on the drug going forward. For those currently under treatment with an approved PA, ForwardHealth will continue to allow providers who are able to fill these prescriptions to submit claims for reimbursement. For questions or product support information, providers may contact Merck at (800) 444-2080.

Prior authorization requests for Victrelis® that have already been approved will be honored until they expire or until the approved days' supply is finished. For further assistance with allowing a member to complete his or her prescribed treatment course, providers may contact Provider Services at (800) 947-9627.

Metavir Score

At this time, 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 to determine a Metavir score or to determine fibrosis staging.

Viekira Pak™

Viekira Pak™, a hepatitis C agent, requires PA until further notice.

Viekira Pak™ is a non-preferred drug that is scheduled to be reviewed by the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee as part of the Preferred Drug List (PDL) review in summer 2015 in the hepatitis C agents drug class. Until the summer PDL review has occurred, PA criteria have been established for Viekira Pak™.

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

Prior authorization requests for Viekira Pak™ may be submitted on the ForwardHealth Portal, by fax, or by mail. Prior authorization requests for Viekira Pak™ may *not* be submitted via Specialized Transmission Approval Technology-Prior Authorization (STAT-PA).

Prior Authorization Requests That Will Be Considered for Review

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

- Compensated cirrhosis.
- Metavir score of F3 or greater or evidence of bridging fibrosis.
- Serious extra-hepatic manifestations of hepatitis C virus (HCV).
- Liver transplant recipients with normal hepatic function and mild fibrosis (Metavir score less than or equal to F2).

In addition, only HCV treatment prescribed by a gastroenterologist or infectious disease provider practice for a member who has chronic hepatitis C genotype 1 infection and is 18 years of age or older will be considered for review.

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 autoimmune hepatitis or other conditions that are contraindications for ribavirin.
- The member has a significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).
- The member has decompensated cirrhosis.
- The member has acute hepatitis C.
- The member is currently abusing drugs or alcohol.
- The member has taken or is currently taking Sovaldi™, Harvoni®, Olysio™, Incivek®, or Victrelis®.
- Non-compliance with approved hepatitis C treatment regimen (for renewals only).

Note: The member's complete medication profiles will be evaluated to determine if any significant drug interactions are present and may result in denial of the PA request.

Clinical Information That Must Be Documented on Initial Prior Authorization Requests

For initial PA requests for Viekira Pak™, 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 Prior Authorization Request Form (PA/RF), F-11018 (05/13), to ForwardHealth.

If applicable, the clinical information that must be documented on an initial PA request for Viekira Pak™ are *all* of the following:

- Lab data, including the following:
  - ✓ Hepatitis C virus genotype.
  - ✓ Hepatitis C virus-ribonucleic acid (HCV-RNA) level.
  - ✓ Liver function tests.
  - ✓ Complete blood count.
  - ✓ Serum creatinine test.
  - ✓ Albumin test.
  - ✓ International normalized ratio.
  - ✓ Liver biopsy, scan, or ultrasound results (if performed).
- 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.
  - ✓ Clinical assessment of presence or absence of cirrhosis.
  - ✓ If cirrhotic, documentation of the following:
    - o Child-Turcotte-Pugh score.
    - o Clinical evidence of the state of compensation.
    - o Hepatocellular carcinoma status based on an imaging study within the last six months.
  - ✓ Fibrosis stage or score.

- Hepatitis C medication treatment history, including the following:
  - ✓ Details of when treatment occurred.
  - ✓ Medications taken and compliance.
  - ✓ Treatment results (e.g., null response, partial response, or relapse).
- Current medication list.
- Relevant medical history not related to hepatitis C, including the following:
  - ✓ Other liver disease.
  - ✓ Transplant history.
  - ✓ Hepatitis A, hepatitis B, or Human Immunodeficiency Virus (HIV) coinfection.
  - ✓ Autoimmune disease.
  - ✓ Current and historical alcohol abuse or illicit drug use. (*Note:* Documentation of at least six months of abstinence from alcohol abuse or illicit drug use must be submitted with the PA request.)
  - ✓ Other significant or uncontrolled diseases (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).
- 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 Viekira Pak™ may be approved for up to a maximum of eight weeks. Depending on the treatment course that has been approved, PA requests may be renewed for additional weeks if the member's HCV-RNA is less than 25 IU/ml.

Renewal Prior Authorization Requests

For renewal PA requests for Viekira Pak™, 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 Viekira Pak™. 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, F-11042 (07/12). A PA/RF should not be submitted.

Olysio™

Olysio™, a hepatitis C agent, requires PA.

Prior authorization requests for Olysio™ must be completed and signed by prescribers. Initial PA requests for Olysio™ must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents form. Renewal PA requests for Olysio™ must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form. Prior authorization requests for Olysio™ may be submitted on the Portal, by fax, or by mail. Prior authorization requests for Olysio™ may not be submitted via STAT-PA.

In addition, only HCV treatment prescribed by a gastroenterologist or infectious disease provider practice for a member who has chronic hepatitis C genotype 1 infection and is 18 years of age or older will be considered for review. Members with hepatitis C genotype 1a must be screened for the NS3 Q80K polymorphism. If the NS3 Q80K polymorphism is detected, treatment will not be considered for review.

Clinical Criteria for use of Olysio™ with Pegylated Interferon and Ribavirin

Clinical criteria that must be documented for approval of a PA request for Olysio™ for use with pegylated interferon and ribavirin are *all* of the following:

- The member has a diagnosis of chronic hepatitis C genotype 1.
- The member is 18 years of age or older.
- The member is not pregnant.
- The member has not had a liver transplant.
- The member has not received a prior course of therapy with a treatment regimen that includes the requested agent or any other HCV NS3/4A protease inhibitor.

- The member's treatment includes concurrent use of pegylated interferon and ribavirin.
- The member has compensated liver disease.
- The member is not taking any contraindicated drugs.

Clinical Information That Must Be Documented on Initial Prior Authorization Requests for Use of Olysio™ with Pegylated Interferon and Ribavirin

For initial PA requests for Olysio™ for use with pegylated interferon and ribavirin, 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.

Renewal Prior Authorization Requests for Use of Olysio™ with Pegylated Interferon and Ribavirin

For renewal PA requests for use of Olysio™ with pegylated interferon and ribavirin, 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 Olysio™. 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.

Approval Periods for use of Olysio™ with Pegylated Interferon and Ribavirin

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

Treatment with Olysio™ may be approved for up to a maximum treatment period of 12 weeks.

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

Requests for Use of Olysio™ as a Combined Treatment with Sovaldi™

Prior authorization requests for the use of Olysio™ and Sovaldi™ as a combined treatment must be completed and signed by prescribers. Initial PA requests for the use of Olysio™ and Sovaldi™ as a combined treatment must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents form. Renewal PA requests for the use of Olysio™ and Sovaldi™ as a combined treatment must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form.

Prior authorization requests for the use of Olysio™ and Sovaldi™ as a combined treatment may be submitted on the Portal, by fax, or by mail. Prior authorization requests for the use of Olysio™ and Sovaldi™ as a combined treatment may not be submitted via STAT-PA.

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 whose hepatitis C liver disease has advanced to any of the following stages may be considered for review:

- Compensated cirrhosis.
- Metavir score of F3 or greater or evidence of bridging fibrosis.
- Serious extra-hepatic manifestations of HCV.

In addition, only HCV treatment prescribed by a gastroenterologist or infectious disease provider practice for a member who has chronic hepatitis C genotype 1 infection and is 18 years of age or older will be considered for review.

Members with hepatitis C 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 has autoimmune hepatitis.
- The member has a significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).
- The member has decompensated cirrhosis.
- The member has acute hepatitis C.
- The member has received a liver transplant.
- The member is currently abusing drugs or alcohol.
- The member has taken Sovaldi™, Harvoni®, Olysio™, Viekira Pak™, Incivek®, or Victrelis®.
- Non-compliance with approved hepatitis C treatment regimen (for renewals only).

Note: Use of Olysio™ and Sovaldi™ as a combined treatment will *only* be considered for members who have contraindications to the use of interferon, Harvoni®, ribavirin, and Viekira Pak™. Providers are required to clearly document why the member is unable to take interferon, Harvoni®, ribavirin, and Viekira Pak™.

Clinical Information That Must Be Documented on Initial Prior Authorization Requests for Use of Olysio™ as a Combined Treatment with Sovaldi™

If applicable, the clinical information that must be documented on an initial PA request for the use of Olysio™ and Sovaldi™ as a combined treatment are *all* of the following:

- Lab data, including the following:
  - ✓ Hepatitis C virus genotype.
  - ✓ Hepatitis C virus-ribonucleic acid level.
  - ✓ Liver function tests.
  - ✓ Complete blood count.
  - ✓ Serum creatinine test.
  - ✓ Albumin test.
  - ✓ International normalized ratio.
  - ✓ Liver biopsy, scan, or ultrasound results (if performed).
- 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.
  - ✓ Clinical assessment of presence or absence of cirrhosis.
  - ✓ If cirrhotic, documentation of the following:
    - o Child-Turcotte-Pugh score.
    - o Clinical evidence of the state of compensation.
    - o Hepatocellular carcinoma status based on imaging study within the last six months.
  - ✓ Fibrosis stage or score.
- Hepatitis C medication treatment history, including the following:
  - ✓ Details of when treatment occurred.
  - ✓ Medications taken and compliance.
  - ✓ Treatment results (e.g., null response, partial response, or relapse).
- Current medication list.
- Relevant medical history not related to hepatitis C, including the following:
  - ✓ Other liver disease.
  - ✓ Transplant history.
  - ✓ Hepatitis A, hepatitis B, or HIV coinfection.
  - ✓ Autoimmune disease.
  - ✓ Current and historical alcohol abuse or illicit drug use. (*Note:* Documentation of at least six months of abstinence from alcohol abuse or illicit drug use must be submitted with the PA request).

- ✓ Other significant or uncontrolled diseases (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).

- 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 the use of Olysio™ and Sovaldi™ as a combined treatment may be approved for up to a maximum of eight weeks. Depending on the treatment course that has been approved, PA requests may be renewed for additional weeks if the member's HCV-RNA is less than 25 IU/ml.

Renewal Prior Authorization Requests for Use of Olysio™ as a Combined Treatment with Sovaldi™

For renewal PA requests for the use of Olysio™ and Sovaldi™ as a combined treatment, 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 the use of Olysio™ and Sovaldi™ as a combined treatment. 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.

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.

This *Update* was issued on 03/18/2014 and information contained in this *Update* was incorporated into the Online Handbook on 04/01/2015.