

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 December 1, 2014

This *ForwardHealth Update* provides new information for prescribers and pharmacy providers regarding pharmacy policies for hepatitis C agents effective for dates of service on and after December 1, 2014.

This *ForwardHealth Update* provides new information for prescribers and pharmacy providers regarding pharmacy policies for hepatitis C agents effective for dates of service on and after December 1, 2014. This *Update* announces the following:

- Prior Authorization Drug Attachment for Sovaldi™, F-01247 (10/14), and Prior Authorization Drug Attachment for Sovaldi™ Renewal, F-01248 (07/14), have been revised and renamed.
- Clinical criteria for Harvoni® have been established.
- Clinical criteria for Olysio™ and Sovaldi™ combined treatment are currently being assessed.

Prior Authorization Drug Attachment for Sovaldi™ and Prior Authorization Drug Attachment for Sovaldi™ Renewal Have Been Revised and Renamed

Prior authorization requests for Harvoni® or Sovaldi™ should be submitted using the Prior Authorization Drug Attachment for Hepatitis C Agents, F-01247 (12/14). This form was previously named the Prior Authorization Drug Attachment for Sovaldi™. The form has been revised and renamed. Prior authorization requests for renewal of

Harvoni® or Sovaldi™ should be submitted using the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal, F-01248 (12/14). This form was previously named the Prior Authorization Drug Attachment for Sovaldi™ Renewal. The form has been revised and renamed.

Note: The member's hepatitis C virus-ribonucleic acid (HCV-RNA) levels and a copy of the actual laboratory report are required to be submitted with each renewal prior authorization (PA) request for Harvoni® or Sovaldi™.

The Attachment of this *Update* lists the PA forms and completion instructions that have been revised and renamed. The previous versions of these forms and completion instructions 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 may refer to the Forms page of the Portal for the revised completion instructions and forms. Prior authorization requests processed on and after December 1, 2014, must be submitted on the revised forms or they will be returned.

Approved PAs on file with ForwardHealth dated prior to December 1, 2014, will be honored until they expire or until the approved days' supply is used up.

Harvoni®

Harvoni®, a hepatitis C agent, requires PA until further notice.

Harvoni® is a non-preferred drug that is scheduled to be reviewed by the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee as part of the 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 Harvoni®.

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

Prior authorization requests for Harvoni® may be submitted on the ForwardHealth Portal, by fax, or by mail. Prior authorization requests for Harvoni® may not be submitted via Specialized Transmission Approval Technology-Prior Authorization.

Prior Authorization Requests That Will Be Considered for Review

Only PA requests for Harvoni® 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).

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.

Note: For treatment-experienced members with cirrhosis who meet the previously referenced criteria for PA review consideration, requests for 24 weeks of treatment with Harvoni® will not be considered. In these cases, if the member meets the previously explained review criteria, the provider and member may decide to proceed with a treatment course of Sovaldi™ with ribavirin.

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

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 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 is co-infected with Human Immunodeficiency Virus (HIV).
- The member has taken or is currently taking Sovaldi™.
- Non-compliance with approved hepatitis C treatment regimen (for renewals only).

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

Clinical Information That Must Be Documented on Initial Prior Authorization Requests

For initial PA requests for Harvoni®, prescribers should complete and sign the Prior Authorization Drug

Attachment for Hepatitis C Agents 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 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 Harvoni® 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:
 - Child-Turcotte-Pugh score.
 - Clinical evidence of the state of compensation.
 - 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, the PA request will be considered incomplete and will be returned to the provider or denied.

Initial PA requests for Harvoni® 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 Harvoni®, prescribers should complete and sign the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal 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 Harvoni®. Pharmacy providers are required to submit to ForwardHealth the completed Prior Authorization Drug Attachment for Hepatitis C Agents Renewal and a completed Prior Authorization Amendment Request, F-11042 (07/12). A PA/RF should not be submitted.

Olysio™ and Sovaldi™ Combined Treatment

Olysio™ is a non-preferred drug in the hepatitis C, protease inhibitors, drug class and requires combined treatment with pegylated interferon or ribavirin. Clinical criteria for Olysio™ have not changed. For more information about coverage of Olysio™, providers may refer to the Hepatitis C, Protease Inhibitors topic (topic #12937) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook..

Providers should continue to submit PA requests for Olysio™ on the Prior Authorization Drug Attachment for Hepatitis C Protease Inhibitors, F-00583 (07/14).

ForwardHealth is also currently assessing the clinical criteria for the recent approval by the Food and Drug Administration (FDA) of Olysio™ and Sovaldi™ as a combined treatment for hepatitis C. Providers should not submit PA requests for the combined use of Olysio™ and Sovaldi™ to ForwardHealth until published guidance is issued. Prior authorization requests received before clinical criteria and submission requirements are issued will be returned to providers.

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 Web site at www.forwardhealth.wi.gov/.

P-1250

ATTACHMENT

Changes to Pharmacy Prior Authorization Forms and Completion Instructions

The table below lists the pharmacy prior authorization (PA) forms and completion instructions that have been revised and renamed as a result of pharmacy policy changes. Providers should refer to the Forms page of the ForwardHealth Portal at www.forwardhealth.wi.gov/ for current copies of these forms and completion instructions. All form changes listed are effective December 1, 2014. The previous versions of these forms and completion instructions will be moved to the Pharmacy-Related Forms and Completion Instructions archive page that is linked under the Archives section on the Pharmacy Resources page of the Portal.

Form Name	Form Number	Revised, Renamed, Discontinued, or New	Effective Date
Prior Authorization Drug Attachment for Sovaldi™	F-01247	Revised and Renamed: Prior Authorization Drug Attachment for Hepatitis C Agents	12/01/14
Completion Instructions	F-01247A	Revised and Renamed: Prior Authorization Drug Attachment for Hepatitis C Agents Completion Instructions	12/01/14
Prior Authorization Drug Attachment for Sovaldi™ Renewal	F-01248	Revised and Renamed: Prior Authorization Drug Attachment for Hepatitis C Agents Renewal	12/01/14
Completion Instructions	F-01248A	Revised and Renamed: Prior Authorization Drug Attachment for Hepatitis C Agents Renewal Completion Instructions	12/01/14