

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 Sovaldi™

Sovaldi™, a hepatitis C agent, requires prior authorization until further notice.

Sovaldi™, a hepatitis C agent, requires prior authorization (PA). Sovaldi™ is a non-preferred drug that will be reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee as part of the Preferred Drug List (PDL) review in summer 2014 in the hepatitis C agents drug class. Until the summer PDL review has occurred, the following PA guidelines have been established for Sovaldi™.

Submitting Prior Authorization Requests for Sovaldi™

Prior authorization requests for Sovaldi™ must be submitted using the Prior Authorization/Drug Attachment (PA/DGA), F-11049 (10/13). The following information must be submitted with a PA request:

- Lab data, including the following:
 - ✓ Hepatitis C virus (HCV) genotype.
 - ✓ Hepatitis C virus ribonucleic acid (HCV-RNA) level.
 - ✓ Liver function tests (LFTs).
 - ✓ Complete blood count (CBC).
 - ✓ Serum creatinine test.
 - ✓ Albumin test.
 - ✓ International normalized ratio (INR).
 - ✓ Biopsy results (if performed).
- Hepatitis C virus clinical data, including the following:
 - ✓ Current medical records for hepatitis C assessment and treatment.

- ✓ History of liver transplant.
- ✓ Cirrhosis (including compensated and decompensated).
- Hepatitis C medication treatment history, including the following:
 - ✓ Details of when treatment occurred.
 - ✓ Medications taken.
 - ✓ Treatment results, such as 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.
 - ✓ Human Immunodeficiency Virus (HIV) co-infection.
 - ✓ Autoimmune disease.
 - ✓ Pregnancy status for women of child-bearing age, including whether the member is contemplating pregnancy, is willing to use contraceptives during treatment, and is willing to use contraceptives for the appropriate exclusion period following treatment.
 - ✓ Current and historical illicit drug and alcohol use.
 - ✓ Other severe or uncontrolled diseases (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).
- Planned hepatitis C treatment regimen.

Providers are required to document this information on the PA/DGA in Section VII (Clinical Information for Other Drug Requests) and may use Section VIII (Additional Information) if needed. The documentation can also be submitted as an attachment.

If the required information is not included on the PA/DGA form and attachments, the PA request will be returned as incomplete.

Only Urgent Prior Authorization Requests for Sovaldi™ Will Be Considered for Approval

Prior authorization requests for Sovaldi™ will be reviewed to identify urgent cases that necessitate approval prior to the summer PDL review of the hepatitis C agents drug class. Only PA requests for urgent cases, where the disease is rapidly progressing or where other clinical factors (e.g., a fibrosis score of F3 to F4) create risk for a negative outcome if treatment is not promptly started, will be approved. Prior authorization requests that are not urgent will be denied.

The decision to treat chronic hepatitis C is not always urgent and involves discussion with the member about the risks and benefits of treatment, the need for compliance with drug protocols, the side effects associated with prolonged use of a drug, and the rapidly changing breakthrough drug therapies that are currently in development for hepatitis C treatment.

In cases where the provider and member decide to immediately proceed with treatment for hepatitis C and the treatment is not considered urgent, the provider should refer to the Preferred Drug List Quick Reference located on the Pharmacy Resources page of the Providers area of the ForwardHealth Portal at www.forwardhealth.wi.gov/ for a list of preferred hepatitis C drugs that are available.

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 autoimmune hepatitis or other conditions exacerbated by interferon or Ribavirin.
- The member has a severe 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 an organ transplant.
- The member currently uses illicit drugs or alcohol.
- The member's treatment is not urgent.

Prior Authorization Requests for Extension of Treatment

If a PA request for Sovaldi™ was previously approved by ForwardHealth, a new PA request to extend treatment must follow the guidelines and documentation requirements outlined in this *Update* in order to be considered. The new PA request must be submitted using the guidelines detailed in this *ForwardHealth Update* until further information is published by ForwardHealth.

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/.

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This *Update* was issued on 3/4/2014 and information contained in this *Update* was incorporated into the Online Handbook on 3/6/2014.