Sovaldi (sofosbuvir)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the use of the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

When a referral is received for a non-preferred agent, the requested agent is paid at the client's standard specialty copay if the patient has a paid claim for the requested agent in the past 30 days. If the patient does not have a claim for the requested agent in the previous 30 days, the Post Step Therapy Criteria for Approval will be applied. If the patient meets the criteria for approval, then the requested agent is paid at the standard specialty copay.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Sovaldi is indicated for the treatment of:

A. Adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen.
   1. genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin
   2. genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

B. Chronic HCV genotype 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

Compendial Uses

Chronic hepatitis C genotype 5 or 6 infection (refer to Daklinza policy)

POLICY

Required Documentation

The following information is necessary to initiate the prior authorization review:

- Presence of viral load (HCV RNA) in the serum prior to treatment with the requested regimen
- Genotype and subtype (if applicable)
- Baseline or current viral load
- Laboratory testing for resistance-associated variants (if applicable)
- METAVIR fibrosis score (if applicable)
- Liver transplantation status
- Treatment plan including treatment regimen and duration
- Prior treatment regimen(s) and response
- Prescriber specialty

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

Criteria for Approval

*****The criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

A. Chronic hepatitis C virus infection, in combination with peginterferon alfa (PEG-IFN) and ribavirin

1. **Genotype 1 infection**
   Authorization of up to 12 weeks total may be granted for members who are treatment-naïve.
2. **Genotype 4 infection**
   Authorization of up to 12 weeks total may be granted for members who are treatment-naïve.

B. Chronic hepatitis C virus infection, in combination with ribavirin

1. **Genotype 1 infection**
   Authorization of up to 24 weeks total may be granted for members who have documented interferon (IFN) ineligibility (see Appendix A).
2. **Genotype 2 infection**
   Authorization of up to 12 weeks total may be granted for members who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.
3. **Genotype 3 infection**
   Authorization of up to 24 weeks total may be granted for members who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.
4. **Members with hepatocellular carcinoma awaiting liver transplantation**
   Authorization of up to 48 weeks total or until liver transplantation, whichever occurs first, may be granted for members with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma who meet the MILAN criteria, defined as the following:
   a) Tumor size 5 cm or less in diameter with single hepatocellular carcinomas OR 3 tumor nodules or less, each 3 cm or less in diameter with multiple tumors AND
   b) No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor

C. Chronic hepatitis C virus infection, in combination with Olysio (with or without ribavirin)
Authorization of up to 24 weeks total (as applicable) may be granted for members prescribed Sovaldi in combination with Olysio (with or without ribavirin as applicable) who meet the criteria for approval for the requested regimen. Refer to the Olysio SGM for the specific criteria for approval and approval durations.

D. Hepatitis C virus infection, in combination with Mavyret (with ribavirin)
Authorization of up to 16 weeks total (as applicable) may be granted for members prescribed Sovaldi in combination with Mavyret (with ribavirin) who meet the criteria for approval for the requested regimen. Refer to the Mavyret SGM for the specific criteria for approval and approval durations.

E. Chronic hepatitis C virus infection, in combination with Daklinza (with or without ribavirin)
Authorization of up to 24 weeks total (as applicable) may be granted for members prescribed Sovaldi in combination with Daklinza (with or without ribavirin as applicable) who meet the criteria for approval for the requested regimen. Refer to the Daklinza SGM for the specific criteria for approval and approval durations.

F. Chronic hepatitis C virus infection, in combination with Zepatier
Authorization of up to 12 weeks total (as applicable) may be granted for members prescribed Sovaldi in combination with Zepatier who meet the criteria for approval for the requested regimen. Refer to the Zepatier SGM for the specific criteria for approval and approval durations.

G. HCV and HIV coinfection
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section I., II., III. or IV. above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Appendices

Appendix A: Interferon Ineligibility

IFN ineligible is defined as one or more of the below:

- Intolerance to IFN
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to PEG-IFN or any of its components
- Major uncontrolled depressive illness
- A baseline neutrophil count < 1,500/mcL
- A baseline platelet count < 90,000/mcL
- A baseline hemoglobin < 10 g/dL
- History of pre-existing cardiac disease

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

- 28 tablets per 28 days

Dispensing Limits

- A 28-day supply dispense limit applies to all targeted hepatitis C agents in order to better manage the therapy regimen.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made August 27, 2020. Accessed September 18, 2020.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.98
Policy Creation: January 2016
Reviewed: October 2020
Revised: October 2020
Current Effective Date: January 22, 2021