PRIOR AUTHORIZATION POLICY

POLICY: Hepatitis C – Sovaldi Prior Authorization Policy
- Sovaldi® (sofosbuvir tablets and oral pellets – Gilead)

REVIEW DATE: 01/24/2024; selected revision 02/28/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Sovaldi, a hepatitis C virus (HCV) nucleotide analog non-serine (NS)5B polymerase inhibitor, is indicated for the following uses:[1]

- **Chronic HCV genotype 1, 2, 3 or 4 infection**, in adults without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment.
- **Chronic HCV genotype 2 or 3 infection**, in pediatric patients ≥ 3 years of age without cirrhosis or with compensated cirrhosis in combination with ribavirin.

The place in therapy for Sovaldi has greatly lessened or is non-existent in most cases due to the availability of other direct-acting antivirals (DAAs) with greater efficacy for many genotypes. Regimens with Sovaldi + peginterferon + ribavirin or Sovaldi + weight-based ribavirin are no longer recommended in treatment guidelines with the exception of pediatric patients due to inferior efficacy compared with other all-oral regimens for all genotypes. Table 1 provides pediatric recommendations.

Table 1. Sovaldi Treatment Regimen in Pediatric Patients (≥ 3 years of age).[1]

	Patient Population	Treatment and Duration

Genotype 2	Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin x 12 weeks
Genotype 3	Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin x 24 weeks

Guidelines

According to the American Association for the Study of Liver Diseases (AASLD) guidelines, weight-based Sovaldi + ribavirin for treatment-naive or interferon-experienced (± ribavirin) children aged ≥3 years with genotype 2 or 3, without cirrhosis or with compensated cirrhosis (Child-Pugh A) is no longer favored because pangenotypic ribavirin-free treatments are now available for children as young as 3 years of age.[2] The AASLD recommends Epclusa® (sofosbuvir/velpatasvir tablets and oral pellets) and Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets) for the treatment of patients ≥ 3 years of age with genotypes 1 through 6 chronic HCV who are treatment-naïve or interferon-experienced, with or without compensated cirrhosis; Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets) is also an option for children ≥ 3 years of age with genotypes 1, 4, 5, or 6 chronic HCV.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Sovaldi. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sovaldi as well as the monitoring required for adverse events and efficacy, approval requires Sovaldi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED

- **Sovaldi® (sofosbuvir tablets and oral pellets (Gilead)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

AUTHORIZATION CRITERIA

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 2.** Approve for 12 weeks if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 3 years of age and < 18 years of age; AND
   - **B)** Patient does not have decompensated cirrhosis (Child-Pugh B or C); AND
     Note: Coverage is provided for patients without cirrhosis or with compensated (Child-Pugh A) cirrhosis.
   - **C)** The medication will be prescribed in combination with ribavirin; AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus (HCV) Genotype 3.** Approve for 24 weeks if the patient meets the following (A, B, C, and D):
   A) Patient is ≥ 3 years of age and < 18 years of age; AND
   B) Patient does not have decompensated cirrhosis (Child-Pugh B or C); AND
   Note: Coverage is provided for patients without cirrhosis or for patients with compensated (Child-Pugh A) cirrhosis.
   C) The medication will be prescribed in combination with ribavirin; AND
   D) The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Other Uses with Supportive Evidence

3. **Patient Has Been Started on Sovaldi.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

CONDITIONS NOT COVERED

- **Sovaldi® (sofosbuvir tablets and oral pellets (Gilead)**

is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):
Sovaldi is not recommended in the following situations:

1. **HCV (Any Genotype), Combination Use with Direct-Acting Antivirals (DAAs) Other than Ribavirin.** In adults with any genotype chronic HCV with or without compensated cirrhosis who have failed treatment with Mavyret, retreatment with Mavyret + Sovaldi + ribavirin is a recommended regimen based on data from a Phase IIIb study evaluating the safety and efficacy of Mavyret + Sovaldi + weight-based ribavirin as a 12- or 16-week retreatment regimen for patients who experienced virologic failure to Mavyret within the context of a previous clinical trial. Non-cirrhotic Mavyret non-responders with genotype 1, 2, 4, 5, or 6 who were naïve to protease and NS5A inhibitors received 12 weeks Mavyret + Sovaldi and weight-based ribavirin. Patients with genotype 3, and/or compensated cirrhosis, and/or protease/NS5A experience (prior to their initial Mavyret treatment) received 16 weeks of therapy with the same regimen. In a preliminary analysis, 96% (n = 22/23) of these patients achieved SVR with a single relapse in a cirrhotic patient with genotype 1a. Vosevi is also a recommended regimen in this instance, and it is FDA-approved for such use.
2. **Monotherapy with Sovaldi.** Sovaldi is indicated as a component of a combination antiviral treatment regimen for HCV.[1]

3. **Pediatric Patients (Age < 3 years).** The safety and efficacy of Sovaldi have not been established in pediatric patients < 3 years of age.[1]

REFERENCES

1. Sovaldi® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: http://www.hcvguidelines.org. Updated December 19, 2023. Accessed on: January 11, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria change.	01/18/2023
Annual Revision	No criteria change.	01/24/2024
Selected Revision	**Conditions Not Covered : Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities**. This condition was removed.	02/28/2024