



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Hepatitis C – Sovaldi Drug Quantity Management Policy – Per Days

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

REVIEW DATE: 10/07/2024

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 \geq 3 years of age without cirrhosis or with compensated cirrhosis in combination with ribavirin.

Dosing

The recommended dose of Sovaldi in pediatric patients \geq 3 years of age with genotype 2 or 3 HCV is based on weight, and is to be taken orally once daily in combination with ribavirin (Table 1).¹ Sovaldi pellets can be taken by pediatric patients who cannot swallow the tablet formulation.

Table 1. Sovaldi Dosing in Pediatric Patients \geq 3 Years of Age.¹

Body Weight	Dosing of Sovaldi Tablets or Oral Pellets	Sovaldi Daily Dose
< 17 kg	1 x 150 mg pellet packet QD	150 mg/day

≥ 17 kg to < 35 kg	1 x 200 mg pellet packet QD OR 1 x 200 mg tablet QD	200 mg/day
≥ 35 kg	2 x 200 mg pellet packets QD OR 2 x 200 mg tablets QD OR 1 x 400 mg tablet QD	400 mg/day

QD – Once daily.

The duration of therapy in pediatric patients with genotype 2 or 3 chronic HCV is provided in Table 2.

Table 2. 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

Availability

Sovaldi is available as 150 mg and 200 mg pellets in unit-dose packets in cartons of 28 packets.¹ Sovaldi is also available as 200 mg and 400 mg tablets in bottles containing 28 tablets.

Guidelines

According to the American Association for the Study of Liver Diseases (AASLD) guidelines, weight-based Sovaldi + ribavirin for treatment-naïve 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

This Drug Quantity Management program has been developed to prevent stockpiling and waste and address potential order entry error of Sovaldi. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail or Home Delivery Maximum Quantity per 365 days*
Sovaldi® (sofosbuvir tablets and pellet packets)	150 mg pellet packets	84 packets (28 packets per dispensing)
	200 mg pellet packets	168 packets (56 packets per dispensing)
	200 mg tablets	168 tablets (56 tablets per dispensing)
	400 mg tablets	84 tablets (28 tablets per dispensing)

* This is a quantity sufficient to treat for 12 weeks at a dose of 1 x 150 mg pellet packet QD, 1 x 200 mg pellet packet QD, 2 x 200 mg pellet packet QD, 2 x 200 mg tablets QD, or 1 x 400 mg tablet QD.

Hepatitis C – Sovaldi Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Sovaldi 150 mg pellet packet, Sovaldi 400 mg tablet

- 1. Chronic Hepatitis C Virus, Genotype 3** Approve 168 tablets per 365 days at retail or home delivery if the patient meets ALL of the following (A, B, and C):
 - A)** Patient is < 18 years of age; AND
 - B)** The patient does not have decompensated cirrhosis (Child-Pugh B or C); AND
Note: Coverage is provided for patients without cirrhosis or with compensated cirrhosis (Child-Pugh A).
 - C)** The medication will be prescribed in combination with ribavirin.
Note: This is a quantity sufficient to treat with one pellet packet or one tablet once daily for 24 weeks.
- 2.** For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 168 tablets to complete a course therapy.
Note: For example, if the patient has received 84 tablets (12 weeks), approve 84 tablets to complete a total of 24 weeks of treatment (total of 168 tablets).

Sovaldi 200 mg pellet packet, Sovaldi 200 mg tablet

- 1. Chronic Hepatitis C Virus, Genotype 3.** Approve 336 tablets per 365 days at retail or home delivery if the patient meets ALL of the following (A, B, and C):
 - A)** Patient is < 18 years of age; AND
 - B)** The patient does not have decompensated cirrhosis (Child-Pugh B or C); AND
Note: Coverage is provided for patients without cirrhosis or with compensated cirrhosis (Child-Pugh A).
 - C)** The medication will be prescribed in combination with ribavirin.
Note: This is a quantity sufficient to treat with two pellet packets or two tablets once daily for 24 weeks.

2. For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 336 tablets per 365 days at retail or home delivery, to complete a course therapy.

Note: For example, if the patient has received 12 weeks of therapy (168 tablets), approve 168 tablets to complete a total of 24 weeks of treatment (total of 336 tablets).

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: October 1, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/28/2023
Annual Revision	No criteria changes.	10/07/2024

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