



## Drug Quantity Management – Per Days Hepatitis C – Sovaldi® (sofosbuvir tablets and oral pellets)

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### Product Identifier(s)

**Effective 1/1/23 to 2/27/23:** 109892  
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#### INSTRUCTIONS FOR USE

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### National Formulary Medical Necessity

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 Maximum Quantity per 365 days*	Home Delivery Maximum Quantity per 365 days
Sovaldi® (sofosbuvir tablets and pellet packets)	150 mg pellet packets	84 packets	84 packets
	200 mg pellet packets	168 packets	168 packets
	200 mg tablets	168 tablets	168 tablets
	400 mg tablets	84 tablets	84 tablets

\* 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.

## Criteria

**Cigna covers quantities as medically necessary when the following criteria are met:**

### Sovaldi 150 mg pellet packet, Sovaldi 400 mg tablet

- 1. Chronic Hepatitis C Virus, Genotype 3 Pediatrics.** Approve 168 tablets per 365 days at retail or home delivery if the individual meets all of the following criteria (A, B, and C):
  - A)** Individual is < 18 years of age; AND
  - B)** The individual does not have decompensated cirrhosis (Child-Pugh B or C); AND  
Note: Coverage is provided for individuals 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 individual 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 Pediatrics.** Approve 336 tablets per 365 days at retail or home delivery if the individual meets all of the following criteria (A, B, and C):
  - A)** Individual is < 18 years of age; AND
  - B)** The individual does not have decompensated cirrhosis (Child-Pugh B or C); AND  
Note: Coverage is provided for individuals 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 individual has received 12 weeks 12 weeks of therapy (168 tablets), approve 168 tablets to complete a total of 24 weeks of treatment (total of 336 tablets).

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

### Overview

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

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

### Dosing

The recommended dose of Sovaldi in pediatric patients ≥ 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).<sup>1</sup> Sovaldi pellets can be taken by pediatric patients who cannot swallow the tablet formulation.

**Table 1. Sovaldi Dosing in Pediatric Patients ≥ 3 Years of Age.<sup>1</sup>**

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).<sup>1</sup>**

	Patient Population	Treatment and Duration
<b>Genotype 2</b>	Treatment-naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin x 12 weeks
<b>Genotype 3</b>	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.<sup>1</sup> Sovaldi is also available as 200 mg and 400 mg tablets in bottles containing 28 tablets.

### Guidelines

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.<sup>2</sup> Regimens with Sovaldi + peginterferon + ribavirin or Sovaldi + weight-based ribavirin are no longer recommended in treatment guidelines. Previously, Sovaldi was the only DAA available for children from 3 to 5 years of age. It may still have a small role in pediatric patients.

## References

1. Sovaldi® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead Sciences; 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 October 5, 2021. Accessed on: September 26, 2022.

## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.  Policy was updated to include the existing quantity limits when the product is obtained via home delivery.	09/26/2022

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