



Drug Quantity Management – Per Days Sovaldi® (sofosbuvir tablets) Duration Limit

Table of Contents

National Formulary Medical Necessity	1
Conditions Not Covered.....	2
Background.....	2
References	3
Revision History	3

Product Identifier(s)

47521

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. 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.

National Formulary Medical Necessity

<u>Sovaldi</u> 400 mg tablets	Maximum quantity per 365 days = 84 tablets (28 tablets/28 days)
<u>Sovaldi</u> 200 mg tablets	Maximum quantity per 365 days = 168 tablets (56 tablets/28 days)
<u>Sovaldi</u> 200 mg pellet packets	Maximum quantity per 365 days = 168 packets (56 packets/28 days)
<u>Sovaldi</u> 150 mg pellet packets	Maximum quantity per 365 days = 84 packets (28 packets/28 days)

A quantity sufficient for 12 weeks of treatment per 365 days will be covered without prior authorization. For coverage of additional quantities (for example, a 24 week regimen), a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse while providing a sufficient quantity for indications covered.

Criteria

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

- Chronic HCV Genotype 3, Pediatrics. Approve for 24 weeks according to the table below IF the individual meets all of the following criteria (A and B):**
 - Sovaldi will be prescribed in combination with ribavirin; AND
 - The individual does not have decompensated cirrhosis (Child-Pugh B or C). [Coverage is provided for individuals without cirrhosis or with compensated {Child-Pugh A} cirrhosis].

Sovaldi strength/formulation	Three additional fills of the quantity below	Total treatment duration
Sovaldi 400 mg tablet	28 tablets	24 weeks = 168 tablets/365 days
Sovaldi 200 mg tablet	56 tablets	24 weeks = 336 tablets/365 days
Sovaldi 200 mg pellet packet	56 packets	24 weeks = 336 packets/365 days
Sovaldi 150 mg pellet packet	28 packets	24 weeks = 168 packets/365 days

- Individual Has Been Started on Sovaldi (brand or generic).** For an indication or condition addressed as an approval in the above criteria section, approve the duration described above to complete a course therapy (e.g., an individual 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

Any other exception is considered not medically necessary.

Background

Overview

Sovaldi is a hepatitis C virus (HCV) nucleotide analog non-serine (NS)5B polymerase inhibitor indicated for the treatment of genotype 1, 2, 3 or 4 chronic HCV infection as a component of a combination antiviral treatment.¹ Sovaldi is also indicated in pediatric patients ≥ 3 years of age with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin. Sovaldi is a direct acting antiviral agent (DAA) against HCV and an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication.¹ Sovaldi is a nucleotide prodrug that undergoes intracellular metabolism to form the pharmacologically active uridine analog triphosphate (GS-461203), which can be incorporated into HCV RNA by the NS5B polymerase and acts as a chain terminator. The place in therapy for Sovaldi has greatly lessened or is non-existent in some cases due to the availability of other DAAs with greater efficacy for many genotypes. However, Sovaldi is the only DAA indicated in pediatric patients with genotype 2 or 3 chronic HCV.

The current web-based treatment recommendations by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) in collaboration with the International Antiviral Society–USA (IAS–USA) provide guidance for treating patients with chronic HCV infection. Regimens with Sovaldi + PR or Sovaldi + WBR 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. Sovaldi + WBR is indicated in pediatric patients with genotype 2 or 3 chronic HCV and has a unique role in such patients. Daklinza® (daclatasvir tablets) is indicated in combination with Sovaldi for the treatment of genotypes 1 and 3 HCV in adults.^{1, 2}

Sovaldi is available as a 200 mg and 400 mg tablet. It is also available as 150 mg and 200 mg pellet packets. The recommended dose for adults is one 400 mg tablet taken orally once daily (QD) with or without food.¹ The recommended dosage in pediatric patients 3 years of age and older with genotype 2 or 3 HCV is based on weight.

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

Table 2. Daklinza + Sovaldi Treatment Regimens (Adults).³

	Patient Population	Treatment and Duration
Genotype 1	No Cirrhosis	Daklinza + Sovaldi x 12 weeks
	Compensated (Child-Pugh A) Cirrhosis	
	Post-Transplant	Daklinza + Sovaldi + ribavirin x 12 weeks
	Decompensated (Child-Pugh B or C) Cirrhosis	
Genotype 3	No Cirrhosis	Daklinza + Sovaldi x 12 weeks
	Compensated (Child Pugh A) Cirrhosis	Daklinza + Sovaldi + ribavirin x 12 weeks
	Decompensated (Child-Pugh B or C) Cirrhosis	
	Post-Transplant	

References

1. Sovaldi® [prescribing information]. Foster City, CA: Gilead Sciences, Inc., August 2019.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. Accessed September 12, 2019.
3. Daklinza™ tablets [prescribing information]. Princeton, NJ: Bristol-Meyers Squibb; November 2017.

Revision History

Type of Revision	Summary of Changes	Date
Selected Revision	Add criteria to complete course of treatment. Reviewed and approved at TAC.	02/12/2020

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2021 Cigna.