Sovaldi® (sofosbuvir) – Expanded orphan indication, new formulation approval

- On August 28, 2019, the FDA approved Gilead's Sovaldi (sofosbuvir), for the treatment of chronic hepatitis C virus (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.
    - Sovaldi was previously approved for this indication in pediatric patients 12 years of age and older or weighing at least 35 kg.
- Sovaldi is also approved for the treatment of adult patients with chronic HCV infection as a component of a combination antiviral treatment regimen:
    - Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin.
    - Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.
- Along with the expanded indication, the FDA also approved a new oral pellet formulation of Sovaldi and a new strength (200 mg) of the oral tablet formulation. Previously, Sovaldi was only available as a 400 mg tablet.
- The efficacy of Sovaldi was evaluated in 41 patients 6 years to < 12 years of age with HCV genotype 2 or genotype 3 infection. The sustained virologic response (SVR12) or cure rate was 100% (13/13) in genotype 2 and 100% (28/28) in genotype 3 patients. No patients experienced on-treatment virologic failure or relapse.
- The efficacy of Sovaldi was also evaluated in 13 patients 3 years to < 6 years of age with HCV genotype 2 or genotype 3 infection. The SVR12 rate was 80% (4/5) in genotype 2 patients and 100% (8/8) in genotype 3 patients. No patients experienced on-treatment virologic failure or relapse. One patient prematurely discontinued study treatment due to an adverse event.
- Sovaldi carries a boxed warning for risk of hepatitis B virus reactivation in patients coinfected with HCV and hepatitis B virus.
- When used in combination with peginterferon alfa/ribavirin or ribavirin alone, all contraindications to peginterferon alfa and/or ribavirin also apply to Sovaldi combination therapy.
- Additional warnings and precautions for Sovaldi include serious symptomatic bradycardia when coadministered with amiodarone, risk of reduced therapeutic effect due to use with P-gp inducers, and risks associated with combination treatment.
- The most common adverse event observed with Sovaldi use in combination with ribavirin oral solution in pediatric patients was decreased appetite.
- The recommended treatment regimen, duration, and recommended dosage for Sovaldi combination therapy in pediatric patients 3 years of age and older with genotype 2 and 3 are provided in the tables below.
    - Sovaldi pellets should not be chewed. If Sovaldi pellets are administered with food, the pellets should be sprinkled on one or more spoonfuls of non-acidic soft food at or below room temperature.

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— Refer to the Sovaldi label for additional dosing and administration recommendations, including dosing in adult patients.

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

* Treatment-experienced patients have failed an interferon based regimen with or without ribavirin

Body weight	Dosing of Sovaldi	Sovaldi daily dose
At least 35 kg	one 400 mg tablet once daily or two 200 mg tablets once daily or two 200 mg packets of pellets once daily	400 mg per day
17 kg to less than 35 kg	one 200 mg tablet once daily or one 200 mg packet of pellets once daily	200 mg per day
Less than 17 kg	one 150 mg packet of pellets once daily	150 mg per day

- Gilead's launch plans for Sovaldi oral pellets and the new oral tablet strength (200 mg) are pending. Sovaldi oral pellets will be available in 150 mg and 200 mg strengths.