PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Sovaldi (sofosbuvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Sovaldi is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor initially approved by the FDA in 2013. It is indicated for the treatment of adult patients with genotype 1, 2, 3 or 4 chronic HCV infection as well as pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection.

Sovaldi (sofosbuvir) will be considered for coverage when the following criteria are met:

Hepatitis C

For **initial** authorization:

1. Member must be 3 years of age or older;
2. Must have one of one of the following:
   a) Adult patient aged 18 and older: Member is treatment-naïve or treatment-experienced with genotype 1,2,3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis (laboratory documentation required); OR
   b) Pediatric patient aged 3 and older: Member is treatment-naïve or treatment-experienced with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated (laboratory documentation required);
3. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
4. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
5. Member must have tried and failed course of treatment with sofosbuvir/velpatasvir (generic for Epclusa) and with Mavyret (Dates and HCV RNA values must be documented in chart notes);
6. Member dose is not at least 35 kg

	One 400mg tablet once daily or Two 200mg tablets once daily or Two 200mg packets of pellets once daily	400 mg per day
17 to less than 35 kg	One 200mg tablet once daily or One 200 mg packet of pellets once daily	200 mg per day
Less than 17 kg	One 150mg packet of pellets once daily	150 mg per day

Appendix I. Treatment Duration for Adults

Genotype	Adult Patient Population	Regimen and Duration
Genotype 1 or 4	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + peginterferon alfa + ribavirin 12 weeks
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)	