

NC Pharmacy Prior Approval Request for Sovaldi

Beneficiary Information

1. Beneficiary Last Name: _____ 2. First Name: _____
 3. Beneficiary ID #: _____ 4. Beneficiary Date of Birth: _____ 5. Beneficiary Gender: _____

Prescriber Information

6. Prescribing Provider NPI #: _____ Provider Fax #: _____
 7. Requester Contact Information - Name: _____ Phone #: _____ Ext. _____

Drug Information

8. Drug Name: _____ 9. Strength: _____ 10. Quantity Per 30 Days: _____
 11. Length of Therapy (in days): 12 Weeks 24 Weeks 48 Weeks

Clinical Information

Total Length of Therapy (Check ONE):

12 weeks = Genotype 1, 2, or 4 for treatment-naïve and treatment-experienced adult beneficiaries without cirrhosis or with compensated cirrhosis (child-pugh A); or genotype 2 for treatment-naïve and treatment-experienced pediatric patients, 3 years of age or older, without cirrhosis or with compensated cirrhosis (child-pugh A).

Genotype 1 and previously treated with a regimen containing an NS3/4A PI₂ without prior treatment with an NS5A inhibitor

24 weeks = Genotype 1 adult beneficiaries that are PEG-interferon ineligible; genotype 3 for treatment-naïve and treatment-experienced adults without cirrhosis or with compensated cirrhosis (child-pugh A); Or genotype 3 for treatment-naïve and treatment-experienced pediatric patients, 3 years of age or older, without cirrhosis or with compensated cirrhosis (child-pugh A)

48 weeks = Genotype 1,2,3, or 4 for adult beneficiaries with a diagnosis of Hepatocellular Carcinoma awaiting liver transplantation (up to 48 weeks or until liver transplantation, whichever comes first)

1. Does the beneficiary have a diagnosis of chronic hepatitis C infections with one of the following confirmed diagnosis':

Genotype 1 or 4 without cirrhosis or with compensated cirrhosis and beneficiary is 18years of age or older

Genotype 2 or 3 without cirrhosis or with compensated cirrhosis and beneficiary is 3 years of age or older

Beneficiary has CHC infection with hepatocellular carcinoma awaiting liver transplant

2. Are medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype being submitted with this request? Yes No ****Lab test results MUST be attached to the PA to be approved.****

3. Does the beneficiary have a documented quantitative HCV RNA at baseline that was tested within the past 6 months (medical documentation required)? Yes No **HCN RNA (IU/ml): _____ and/or log10 value: _____**

4. As the provider, are you reasonably certain that treatment will improve the beneficiary's overall health status?

Yes No

5. Is Sovaldi being prescribed in combination with ribavirin and pegylated interferon alfa for genotypes 1 and 4? Yes No

6. Is Sovaldi being prescribed in combination with ribavirin for beneficiaries with genotype 1 who are peginterferon-ineligible (medical record documentation of previous peginterferon therapy or reason for ineligibility must be submitted for review)?

Yes No

7. Is Sovaldi being prescribed in combination with ribavirin for genotypes 2 and 3 and/or in CHC beneficiaries with hepatocellular carcinoma awaiting liver transplant? Yes No

8. Is Sovaldi being used as monotherapy? Yes No

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9. Is Sovaldi being used with any other sofosbuvir containing regimen? Yes No
10. Does the beneficiary have any FDA labeled contraindications to sofosbuvir (Sovaldi)? Yes No
11. Is the Beneficiary pregnant? Yes No
12. Does the beneficiary have severe renal impairment (CrCl less than 30 mL/min), end stage renal disease, or require dialysis (AASLD/IDSA 2014)? Yes No
13. Is the beneficiary a non-responder to sofosbuvir? Yes No
14. Has the beneficiary previously failed therapy with a treatment regimen that included sofosbuvir? Yes No
15. Does the beneficiary have hepatocellular carcinoma and is not awaiting a liver transplant? Yes No

Signature of Prescriber: _____ Date: _____

(Prescriber Signature Mandatory)

I certify that the information provided is accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.