

Criteria for Prior Approval of Sovaldi® (sofosbuvir)

1. The patient must meet all General Criteria for Newer Direct Acting Antivirals (DAA) for Hepatitis C in addition to drug specific criteria, to be considered eligible for prior approval.
2. The patient must have a diagnosis of Chronic Hepatitis C infection genotype 2, 3, or 4 confirmed by lab documentation and baseline HCV-RNA level.
3. Sovaldi in combination with ribavirin is contraindicated in pregnancy. If patient is female she must not currently be pregnant and may not become pregnant while taking above combinations. A negative pregnancy test must be obtained within the previous 30 days, and monthly thereafter during treatment.
4. If the patient is male, he must not have a female partner who is currently pregnant, and he must agree to use adequate contraception to avoid pregnancy during treatment.
5. The patient does not have end stage renal disease requiring dialysis.
6. The patient does not have a glomerular filtration rate $< 30 \text{ mL/minute/1.73m}^2$.
7. The patient does not have decompensated liver disease as defined by Child-Pugh Class B or C.
8. The patient is not taking prescribed or over-the-counter products known to be contraindicated or harmful while taking Sovaldi. Please see Sovaldi package insert for further information:
https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf