Criteria for Prior Approval of Harvoni®
(sofosbuvir/ledipasvir)

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 1, 4, 5, or 6 confirmed by lab documentation and baseline HCV-RNA level.

3. The prescriber must provide documented clinical evidence supporting use of Harvoni over preferred agents.

4. Harvoni 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 combination. A negative pregnancy test must be obtained within the previous 30 days, and monthly thereafter during treatment.

5. If the patient is male and using Harvoni in combination with ribavirin, he must not have a female partner who is currently pregnant, and he must agree to use adequate contraception to avoid pregnancy during treatment.

6. The patient does not have end stage renal disease requiring dialysis or a glomerular filtration rate < 30 mL/minute/1.73m^2.

7. The patient is not taking prescribed or over-the-counter products known to be contraindicated or harmful while taking Harvoni. Please see Harvoni package insert (pdf) for further information.