

### **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 genotype 1 confirmed by lab documentation and baseline HCV-RNA level.
3. In pregnant women, documentation is provided justifying potential benefit versus risk to the fetus.
4. The patient does not have end stage renal disease requiring dialysis.
5. The patient does not have a glomerular filtration rate  $< 30 \text{ mL/minute}/1.73\text{m}^2$ .
6. The patient does not have decompensated liver disease as defined by Child-Pugh Class B or C.
7. The patient is not taking prescribed or over-the-counter products known to be harmful while taking Harvoni. Please see Harvoni package insert for further information: [http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni\\_pi.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf)