Criteria for Prior Approval of EPCLUSA™

(Sofosbuvir/Velpatasvir)

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 or 3, confirmed by lab documentation and quantitative baseline HCV-RNA level.

3. The prescriber must provide documented clinical evidence supporting use of Epclusa over preferred agents for genotype 1 or 4 infection. Patients with genotype 5 or 6 will be evaluated on a case-by-case basis.

4. If patient is diagnosed with decompensated liver disease as defined by Child-Pugh Class B or C, Epclusa should be combined with ribavirin.

5. Epclusa 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.

6. If the patient is male and using Epclusa 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.

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

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