# Criteria for Prior Approval of Zepatier™ (elbasvir/ grazoprevir)

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 or 4 confirmed by lab documentation and quantitative baseline HCV-RNA level.

3. The patient must submit baseline hepatic laboratory testing prior to initiation of treatment.

4. If genotype 1a, the patient must submit testing for the presence of virus with NS5A resistance-associated polymorphisms.

5. Zepatier 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.

6. 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.

7. The patient does not have decompensated liver disease as defined by Child-Pugh Class B or C.

8. The patient is not taking an efavirenz-containing therapy such as Atripla or Sustiva.

9. The patient is not taking an organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitor. e.g., atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine

10. The patient is not taking a strong cytochrome P450 3A (CYP 3A) inducer. e.g., phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz

11. The patient is not taking prescribed or over-the-counter products known to be harmful while taking Zepatier. Please see Zepatier package insert for further information: **http://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf**