

## General Criteria for Prior Approval of Newer Direct-Acting Antivirals (DAA) for Hepatitis C

1. The patient is 18 years of age or over and enrolled in IL Medicaid.
2. The patient must have a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, or 4 confirmed by lab documentation and quantitative baseline HCV-RNA.
3. The patient must have evidence of Stage 4 hepatic fibrosis documented with one of the following:
  - a. Liver biopsy confirming a Metavir score of F4; **OR**
  - b. Transient elastography (Fibroscan) score  $\geq 12.5$  kPa; **OR**
  - c. FibroTest score  $\geq 0.74$ ; **OR**
  - d. APRI score  $> 2.0$ ; **OR**
  - e. Radiological imaging consistent with cirrhosis (e.g. evidence of portal hypertension); **OR**
  - f. Physical findings or clinical evidence consistent with cirrhosis
4. The patient has not been denied Hepatitis C therapies from another insurance carrier. If approved for coverage by another carrier, HFS will only pay as a secondary payer after the primary payer has paid.
5. In the opinion of the prescriber, the patient is able to make appropriate decisions about treatment, comply with dosing and other instructions, and is capable of completing therapy.
6. The patient does not have evidence or known diagnosis of malignancy of any body organ diagnosed within the last 12 months, or is currently receiving or planning to receive chemotherapy or radiation therapy. Exceptions will be made for hepatocellular carcinoma if patient has been pre-approved by HFS for liver transplant.
7. The patient does not have evidence of known terminal disease, with life expectancy  $< 12$  months. The patient is not currently enrolled in hospice.
8. The treatment regimen prescribed is NOT for an indication outside of the FDA approved labeling and is prescribed as part of an FDA approved treatment regimen. Further, no contraindications or significant drug interactions to treatment exist as specified in the product labeling.
9. The patient does not have evidence of active substance abuse diagnosis or treatment in the past 12 months.
10. A documented negative standard urine drug screen report is required within 15 days before initiation of treatment.
11. The patient has no history of a full or incomplete course of treatment with newer DAAs (“Once in a lifetime treatment policy.”) Patients who were not cured of hepatitis C following treatment with newer DAA’s will not be considered for repeat treatment. (Newer DAAs do not include telaprevir and boceprevir regimens.)
12. The prescriber can be any practitioner licensed to prescribe, or licensed to prescribe in collaboration with a physician who holds a current unrestricted license to practice medicine, and is currently enrolled as an Illinois Medicaid Provider. If the prescriber is NOT a gastroenterologist, hepatologist or infectious disease specialist, a one-time consultation with one of these specialists will be

- required within the past 3 months. This consulting specialist must have recommended a newer DAA regimen prior to approval. Requests will not be accepted from pharmacies.
13. The provider must provide a copy of a signed patient commitment letter for all hepatitis C treatment regimens.
  14. Non-compliance with the regimen or patient's failure to obtain refills in a timely manner will result in discontinuation of previous prior approval, and no further hepatitis C therapy will be approved by the department.
  15. Lost or misplaced hepatitis C medications will not be replaced.
  16. The prescriber agrees to submit progress notes and HCV RNA levels to HFS on patients prescribed newer DAAs within the first 8 weeks of treatment, upon completion of therapy, and at 12 weeks and 12 months post-treatment.
  17. HFS will review requests from authorized prescribers for exceptions to these above criteria on a case by case basis.