

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 a Fee for Service medical program administered by the Department of HFS.
2. The patient must have a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5 or 6 confirmed by lab documentation and quantitative baseline HCV-RNA.
3. The patient must have evidence of either Stage 3 or Stage 4 hepatic fibrosis documented with physical findings or clinical evidence consistent with significant fibrosis **AND**:

One of the following:

- a) Liver biopsy confirming a Metavir score of F3 or F4; **OR**
- b) Transient elastography (Fibroscan) score ≥ 9.5 kPa; **OR**
- c) FibroTest/Fibrosure score ≥ 0.59 ; **OR**
- d) APRI score > 1.5 ; **OR**

AND

A copy of the following lab test reports, completed within 3 months of request for prior approval, unless otherwise noted:

- a. Baseline quantitative HCV RNA level (within 1 year of request for prior approval)
 - b. ALT and AST
 - c. CBC
 - d. GFR
 - e. For Stage 4 fibrosis only: INR, albumin, and bilirubin
 - f. Negative standard urine drug screen (within 15 days of request for prior approval)
4. If patient has other insurance coverage besides IL Medicaid, 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 as prescribed.
 6. The patient does not have evidence or diagnosis of a terminal disease, with life expectancy less than 12 months. No coverage will be available for a patient currently enrolled in hospice or a palliative care program.
 7. 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.
 8. The patient does not have evidence of active substance abuse.
 9. The patient has no history of a full or incomplete course of treatment with newer DAAs. 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.)

10. 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 within the past 3 months is required. The report containing a recommendation for treatment with a newer DAA regimen must be submitted with the request for prior approval. Requests will not be accepted from pharmacies.
11. The provider must provide copy of a signed patient commitment letter for all hepatitis C treatment regimens.
12. Non-compliance with the regimen (> 7 days) 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 with a DAA will be approved by the department.
13. Lost or misplaced hepatitis C medications will not be replaced.
14. The prescriber agrees to submit HCV RNA levels to HFS on patients prescribed newer DAAs within 8 weeks of treatment, upon completion of therapy, and at 12 weeks and 12 months post-treatment.
15. HFS will review requests from authorized prescribers for exceptions to these criteria on a case-by-case basis.