ILLINOIS DEPARTMENT OF Healthcare and Family Services

Criteria for Prior Approval of Direct-Acting Antivirals (DAAs) for Hepatitis C

1. The patient is 12 years of age or over, and has a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5 or 6 confirmed by lab documentation and quantitative baseline HCV-RNA.

2. Patient's Metavir/fibrosis score must be documented in the request for prior approval. The patient's Metavir/fibrosis score can be determined based on Liver Biopsy, Transient Elastography (FibroScan ®), FibroTest®/FibroSure®, or FibroMeter™.

   And

   Prescriber must provide a copy of the following lab test reports, completed within 3 months prior to the 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. INR, albumin, and bilirubin, for stage 4 fibrosis only
   f. Negative HBV screen; or, if positive, quantitative HBV DNA and verification of treatment regimen

   And

   Prescriber must provide clinic or consultation notes from specialist consultation (see #7).

3. In the opinion of the prescriber, the patient is able to make appropriate decisions about treatment and comply with dosing and other instructions, and is capable of completing therapy as prescribed. The prescriber must provide a copy of a signed patient commitment letter for all hepatitis C treatment regimens.

4. The treatment regimen prescribed is not for an indication outside of the FDA approved labeling, and no contraindications or significant drug interactions to treatment exist as specified in the product labeling.

5. Prescribing provider is responsible for addressing ongoing misuse of alcohol and/or continued use of illicit IV drugs (if appropriate).

6. The patient has no history of an incomplete course of treatment with DAAs. (Prior treatment with telaprevir, boceprevir, and DAA regimens used in combination with interferons is not taken into consideration for purposes of this criterion.) HFS will review requests and pertinent clinical information for an additional course of DAA, after previous such therapy, on a case-by-case basis, considering whether the person has received counseling for or otherwise addressed the cause of non-adherence, where applicable.

7. 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. If the prescriber is NOT a gastroenterologist, hepatologist, transplant hepatologist, or infectious disease specialist, the prescriber must engage in a one-time consultation with one of these specialists within the 3 months prior to the request for prior authorization. This one-time consultation may be via telephone, video-conference, or tele-health technology. The records containing a specialist recommendation for treatment with a DAA regimen must be submitted with the request for prior approval.

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8. Non-adherence with the regimen (> 7 days) or patient's failure to obtain refills in a timely manner may result in discontinuation of current prior approval. Non-adherence or failure to obtain refills that result from situations that are beyond the patient's control will not result in discontinuation of a prior approval.

9. The prescriber agrees to submit HCV RNA levels to HFS for patients prescribed DAAs within 8 weeks after beginning treatment, 12 weeks post treatment, and 24 weeks post treatment. If at any point the patient's viral load is undetectable, the prescriber is not required to submit any subsequent test. Prescriber's failure to submit a lab report in a timely fashion due to patient's non-cooperation may result in denial of re-treatment, should that situation arise. However, situations beyond the control of the prescriber or the patient will not result in a denial of re-treatment under this criteria.

10. Requests for exceptions to these criteria can be made when the services are medically necessary to meet the medical needs of the patient. Requests for exceptions to these criteria can be made on the prior approval form itself and will be reviewed on a case-by-case basis.