Sovaldi (Sofosbuvir)-HFS Criteria for Prior Approval
Final: July 10, 2014

1. Patient is 18 years of age or over and enrolled in IL Medicaid.
2. Patient must have diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, or 4 confirmed by HCV RNA level and a metavir score ≥ 4 or equivalent.
3. The patient has not been denied Sovaldi from another insurance carrier for an acceptable cause. If approved for coverage by another carrier, HFS will only pay as a secondary payer after the primary payer has paid.
4. If patient is female, she must not currently be pregnant and may not become pregnant while taking Sovaldi. A negative pregnancy test must be obtained within the previous 30 days, and monthly thereafter during treatment with Sovaldi.
5. If patient is male, patient must not have a female partner who is currently pregnant, and agrees to use adequate contraception to avoid pregnancy during treatment.
6. The patient is mentally competent, able to make appropriate decisions about this treatment, comply with dosing and other instructions, and is capable of completing therapy.
7. The patient does not have end stage renal disease requiring dialysis.
8. The patient does not have glomerular filtration rate < 30 mL/minute/1.73m^2.
9. The patient, if Genotype 1, is not considered interferon-ineligible.
10. The patient does not have evidence or known diagnosis of malignancy of any body organ diagnosed within the last 12 months, or currently receiving or planning to receive chemotherapy or radiation therapy. Exceptions will be made for hepatocellular carcinoma if patient has been cleared by HFS for liver transplant.
11. The patient does not have evidence of known terminal disease, with life expectancy < 12 months.
12. The patient is not currently enrolled in hospice.
13. The patient is not taking rifampin, anticonvulsants, St. John's Wort or other prescribed or over-the-counter products known to be harmful while taking Sovaldi.
14. The treatment with Sovaldi is NOT for an indication outside of the FDA approved labeling and is prescribed with FDA-approved combination therapy. Further, no contraindications for use of Sovaldi exist as specified in the product labeling.
15. The patient does not have evidence of substance abuse diagnosis or treatment (alcohol, illicit drugs or prescription opioids and other drugs listed on the schedule of controlled drugs maintained by the Drug Enforcement Administration) in the past 12 months based on department claims records, prescriber's knowledge, medical record entry, state's narcotic prescription registry database, reports from a hospital, an Emergency Department visit, an urgent care clinic, a physician's office or practice or another setting.
16. The patient has a documented negative standard urine drug screen report within 15 days prior to submission of prior approval request.
17. The patient has no history of a full or incomplete course of Sovaldi treatment ("Once in a lifetime" treatment policy).
18. A full course of Sovaldi will usually consist of 12 weeks of therapy. The prescriber will submit additional information to justify a request for more than 12 weeks of therapy.
19. Sovaldi will be dispensed for 2 weeks at a time with further refills being available every 2 weeks for a total of 12 weeks (or longer if indicated).*

20. Non-compliance with the regimen or patient's failure to obtain refills every 2 weeks will result in discontinuation of previous prior approval, and no further therapy with Sovaldi will be approved by the department.
21. Lost or misplaced Sovaldi will not be replaced, and further treatment with Sovaldi will not be approved. Exceptions will be made only in cases of an extreme hardship such as a house fire.
22. The prescriber can be any 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 board-certified gastroenterologist, transplant hepatologist or infectious disease specialist, a one-time written consultation report from a board-certified gastroenterologist, transplant hepatologist or infectious disease specialist will be required within the past 3 months. This consulting specialist must have recommended Sovaldi therapy prior to approval. Requests will not be accepted from mid-level practitioners and pharmacies.
23. The prescriber agrees to obtain all FDA recommended tests and to monitor therapy with Sovaldi for the entire duration of therapy.
24. The prescriber agrees to submit progress notes and HCV RNA level to HFS on patients prescribed Sovaldi within the first 8 weeks of treatment, upon completion of therapy, and at 12 months post-treatment.
25. Provider must provide a copy of a signed patient commitment letter for Sovaldi treatment.

* Product stability testing suggests the medication is stable for 45 days and should be protected from light