

Sovaldi Rule changes as discussed on January 20, 2015

- Patient must be 18 years of age or over and enrolled in IL Medicaid.
- Patient must have diagnosis of Chronic Hepatitis C infection genotype 1,2,3, or 4 confirmed by HCV RNA level and a metavir $\geq 2-4$ or equivalent,
- The patient has not been denied interferon-free therapy for Hepatitis C Virus Sovaldi.
- ~~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. This decision should be made by the practitioner.~~
- ~~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. This decision should be made by the practitioner.~~
- ~~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. May violate the Affordable Care Act.~~
- The patient does not have end stage renal disease requiring dialysis.
- The patient does not have glomerular filtration rate < 30 mL/minute/ 1.73^2 .
- ~~The patient, if Genotype 1, is not considered interferon ineligible.~~
- ~~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.~~
- The patient does not have evidence of known terminal and incurable disease, with life expectancy < 12 months.
- The patient is not currently enrolled in hospice.
- The patient is not taking rifampin, anticonvulsants, St. John's Wort or other prescribed over-the-counter products known to be harmful while taking any interferon-free therapy for Hepatitis C Virus Sovaldi.
- 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 ~~18~~ 6 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. This limitation is subject to review in cases where there is a drug interaction that would indicate a positive reading from a urine test or other drug test.
- The patient has a documented negative standard urine drug screen report within 15 days prior to submission of prior approval request.
- ~~The patient has no history of a full or incomplete course of Sovaldi treatment ("Once in a lifetime" treatment policy).~~

- ~~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.~~
- 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, hepatologist, or infectious disease specialist, a one-time written consultation report from a board-certified gastroenterologist, hepatologist or infectious disease specialist will be required within the past ~~3~~ 6 months. This consulting specialist must have recommended any interferon-free therapy for Hepatitis C Virus ~~Sovaldi therapy~~ prior to approval. ~~Requests will not be accepted from mid-level practitioners and pharmacies.~~
- The prescriber agrees to obtain all FDA recommended tests and to monitor therapy with any interferon-free therapy for Hepatitis C Virus for the entire duration of therapy.
- The prescriber agrees to submit lab results ~~progress notes~~ and HCV RNA level to HFS on patients prescribed any interferon-free therapy for Hepatitis C Virus ~~Sovaldi~~ representing the base line, end of therapy, and 12 weeks after treatment.
- Provider must provide a copy of a signed patient commitment letter for any interferon-free therapy for Hepatitis C Virus ~~Sovaldi treatment.~~
- The Department shall establish an appeals process for cases that may fail to meet this criteria but have a reasonable argument for continuing treatment.