**TO: Pharmacy Providers, Physicians, Nurse Practitioners, Physician Assistants, Long Term Care Providers, Clinics, and Hospitals**
**RE: New Hepatitis C Prior Authorization Criteria - Sovaldi™**

The purpose of this bulletin is to inform prescribing providers that, effective December 10, 2014, Prior Authorization (PA) is required for prescription benefit coverage of Sovaldi™ for HUSKY A, HUSKY C, and HUSKY D clients starting therapy.

Sovaldi™ is a Hepatitis C Virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of Chronic Hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen.

Approval durations differ by baseline characteristics; a full course of Sovaldi™ usually consists of 12 weeks of therapy. The prescriber must submit additional information to justify a request for more than 12 weeks of therapy. Sovaldi™ will be dispensed for a 2 week supply, which limits the fill quantity to 14 tablets at a time, with further refills being available every 2 weeks for a total of 12 weeks (or longer if indicated, with approved request).

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sovaldi™, approval requires Sovaldi™ to be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or liver transplant physician.

The efficacy of Sovaldi™ has been established in patients with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma (HCC) meeting Milan criteria (awaiting liver transplantation) and those with HCV/human immunodeficiency virus (HIV)-1 co-infection.

Coverage of Sovaldi™ is provided to those who meet the following criteria:

- Patient is 18 years of age or older
- Patient has a diagnosis of CHC infection genotype 1, 2, 3, or 4 confirmed by HCV Ribonucleic acid (RNA) level and a metavir score ≥ 4 or equivalent
- Female patients must not be currently pregnant and must also agree to use adequate birth control during treatment. This must be documented with a negative pregnancy test obtained within the previous 30 days, and monthly thereafter during treatment with Sovaldi™
- Male patients must not have a female partner who is currently pregnant, and must agree to use adequate birth control to avoid pregnancy during treatment
- Patient does not have end stage renal disease requiring dialysis
- Patient does not have glomerular filtration rate < 30mL/minute/1.73$m_2$
- If Genotype 1, documentation is maintained demonstrating why the patient is not considered "interferon-ineligible"
- Patient must not have evidence or known diagnosis of any malignancy diagnosed within the last 12 months, or be currently receiving or planning to

receive chemotherapy or radiation therapy. Exceptions will be made for hepatocellular carcinoma patients upon request

- Patient is not enrolled in Hospice
- 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™
- Patient must undergo treatment with Sovaldi™ for an FDA approved indication and is prescribed with FDA approved combination therapy. Further, no contraindications for use of Sovaldi™ exist as specified in the product labeling
- Patient has no history of a full or incomplete course of Sovaldi™ treatment

Effective December 10, 2014, the newly developed Sovaldi™ PA Request Form must be used to request a PA for Sovaldi™.

Please note: Early Refill requests for any Sovaldi™ prescription in which less than 85% of the medication should have been utilized at the time the prescription is submitted for refill will not be considered.

The new Sovaldi™ PA form is attached below and will be available on the www.ctdssmap.com Web site. From the Home page, go to Information → Publications → Forms → Authorization/Certification Forms → Sovaldi™ PA Form; or to Pharmacy Information → Pharmacy Program Publications → Sovaldi™ PA Form.

**STATE OF CONNECTICUT DEPARTMENT OF SOCIAL SERVICES**
**PO BOX 2943 HARTFORD, CT 06104**
**TELEPHONE: 1-866-409-8386 FAX: 1-866-759-4110 OR (860) 269-2035**

# Connecticut Medical Assistance Program Hepatitis C Prior Authorization (PA) Request Form- Sovaldi™ (Sofosbuvir)

**[This and other pharmacy PA forms are available at www.ctdssmap.com]**

## To Be Completed By Prescriber

| Prescriber Information | Patient Information |
|---|---|
| Prescriber's NPI: | Client Medicaid ID Number: |
| Prescriber Name: | Patient Name: |
| Phone # ( ) | Patient DOB: / / |
| Fax # ( ) | |

## Important message for Providers

- The prescriber can be any physician who holds a current unrestricted license to practice medicine AND who is enrolled in the Connecticut Medical Assistance Program. If the prescriber is NOT a board certified gastroenterologist, hepatologist or infectious disease specialist, a one-time written consultation from one of these will be required within the past 3 months. This consulting specialist must have recommended Sovaldi™ therapy prior to approval. **Documentation of the written consultation must be retained in the patient's medical record and be available upon request.**
- A full course of Sovaldi™ usually consists of 12 weeks of therapy. The prescriber will submit additional information to justify a request for more than 12 weeks of therapy.
- 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, with approved request).
- 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.
- The prescriber agrees to obtain all FDA recommended tests and to monitor therapy with Sovaldi™ for the entire duration of therapy.
- **Prescriber must maintain a copy of a signed patient commitment letter for Sovaldi™ treatment, which includes the appropriate information listed above.**

## Criteria for Medical Necessity Review

| | |
|---|---|
| Patient is 18 years of age or older. | □ Yes □ No |
| Patient has a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, or 4 confirmed by HCV RNA level and a metavir score ≥ 4 or equivalent. | □ Yes □ No |
| Female patients must not be currently pregnant which must be documented with a negative pregnancy test obtained within the previous 30 days, and monthly thereafter during treatment with Sovaldi™. **Documentation of the negative pregnancy tests must be retained in the patient's medical record and be available upon request.** | □ Yes □ No |
| Male patients must not have a female partner who is currently pregnant, and must agree to use adequate birth control to avoid pregnancy during treatment. | □ Yes □ No |

*Continued →*

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| | |
|---|---|
| Patient does not have end stage renal disease requiring dialysis. | □ Yes □ No |
| Patient does not have glomerular filtration rate < 30mL/minute/1.73$m_2$. | □ Yes □ No |
| If Genotype 1, documentation is maintained demonstrating why the patient is not considered "interferon-ineligible." | □ Yes □ No |
| Patient must not have evidence or known diagnosis of any malignancy diagnosed within the last 12 months, or be currently receiving or planning to receive chemotherapy or radiation therapy. Exceptions will be made for hepatocellular carcinoma patients upon request. | □ Yes □ No |
| Patient is not enrolled in Hospice. | □ Yes □ No |
| 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™. | □ Yes □ No |
| Patient must undergo treatment with Sovaldi™ for an FDA approved indication and is prescribed with FDA-approved combination therapy. Further, no contraindications for use of Sovaldi™ exist as specified in the product labeling. | □ Yes □ No |
| Patient has no history of a full or incomplete course of Sovaldi treatment. | □ Yes □ No |

**I certify that use of Sovaldi™ for this patient is consistent with the above criteria/guidelines.**

**Prescriber Signature: _____Date:_____**

(By his/her signature, the prescriber confirms the criteria/guideline information above is accurate and verifiable in patient records.)

Please complete the information below **only** if the prescriber who signed above is <u>not</u> a gastroenterologist, hepatologist or infectious disease specialist.

**Board Certified Specialist Name:_____**
(please indicate specialty)

☐ Gastroenterologist ☐ Hepatologist ☐ Infectious disease specialist

**Phone Number:_____**