Sofosbuvir (Sovaldi®)

Goal(s) :

- Approve cost effective treatments of chronic hepatitis C which are supported by the medical literature when there is available evidence. When evidence is lacking, consult with local specialists and the community standard.

Length of Authorization

- Initial trial of 8weeks
- Continuation of therapy up to 24 weeks of total therapy based on therapy regimen, genotype, and patient population

Requies PA:

- Sofosbuvir

Approval Criteria		
1. What diagnosis is being treated?	**Record ICD9 code**	
2. Is the request for treatment of Chronic Hepatitis C Virus?	**Yes:** Go to #3	**No:** Pass to RPh, Deny For Appropriateness
3. Is the request for continuation of therapy?	**Yes:** Go to "Continuation of Therapy"	**No:** Go to #4
4. Has the patient had previous treatment (full or incomplete course) with an oral direct acting antiviral that was FDA approved after 2012 (including sofosbuvir and simeprevir)?	**Yes:** Pass to RPh; Deny For Appropriateness	**No:** Go to #5
5. Is the medication being prescribed by or in consultation with a hepatologist or gastroenterologist with experience in Hepatitis C?	**Yes:** Go to #6	**No:** Pass to RPh, Deny For Appropriateness Forward to DMAP for further review to determine appropriateness of prescriber
6. Does the patient have a biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate severe fibrosis (stage 4) OR radiologic, laboratory, or clinical evidence of cirrhosis without ongoing progressive decompensation (MELD score between 8 and 11), and expected survival from non-HCV associated morbidity should be greater than 5 years?	**Yes:** Go to #11	**No:** Go to #7 **Note**: Patients with a MELD score >11 may be eligible for therapy, but only after review by the DMAP medical director. Forward fee-for-service cases to

		DMAP for Medical Director Review and notify requesting provider of pending review.
7. Does the patient have one of the following extrahepatic manifestations of hepatitis C and who have formal documentation from a relevant specialist that their condition is HCV related, and expected survival from non-HCV associated morbidity should be greater than 5 years? a. Vasculitis b. Glomerulonephritis c. Cryoglobulinemia d. Lymphoma	**Yes:** Go to #11	**No:** Go to #8
8. Does the patient have a HIV coinfection with cirrhosis (Stage 4 disease), and expected survival from non-HCV associated morbidity should be greater than 5 years?	**Yes:** Go to #9	**No:** Go to #10
9. Is the patient under the supervision of an HIV specialist?	**Yes:** Go to #11	**No:** Pass to RPh; Deny (medical appropriateness)
10. Does the patient have Hepatitis C Virus in the transplant setting, including the following scenarios: a. Patient is listed for a transplant and it is essential to prevent recurrent hepatitis C infection post-transplant b. Post-transplant patients with Stage 4 fibrosis c. Post-transplant patients with fibrosing cholestatic hepatitis due to HCV infection **and** expected survival from non-HCV associated morbidity should be greater than 5 years?	**Yes:** Go to #11 **Note**: Patients in the transplant setting may be eligible for therapy, but only after review by the DMAP medical director. Forward fee-for-service cases to DMAP for Medical Director Review and notify requesting provider of pending review.	**No:** Pass to RPh: Deny (medical appropriateness) **Note:** Other Scenarios not included can be brought to the Medical Director on a case by case basis
11. , Has the patient been abstinent from IV drug, illicit drugs and marijuana use, AND alcohol abuse for ≥ 6 months?	**Yes**: Go to #12	**No:** Pass to RPh, Deny for appropriateness
12. Does the patient have significant renal impairment (CrCl < 30 ml/min) or end stage renal disease (ESRD)?	**Yes:** Pass to RPh; Deny for appropriateness	**No:** Go to #13
13. Does the patient have a baseline HCV RNA level?	**Yes:** Record value and go to #14 Note: Next HCV RNA level required at week 4 of treatment (see continuation criteria	**No:** Pass to RPh; request provider obtain baseline lab value
14. What Hepatitis C genotype is the patient? Record Genotype:	Record Genotype and go to #15	
15. Does the patient have genotype 1 or 4 chronic hepatitis C?	**Yes:** Go to # 16	**No:** Go to #19
16. Is the medication being used as triple therapy with	**Yes:** Approve for initial 8	**No:** Go to #17

both ribavirin and peginterferon alfa and meets criteria for pegylated interferon-alfa and ribavirin?	weeks for 12 weeks of total therapy	
17. Is the medication being used with ribavirin or simeprevir?	**Yes:** Go to #18	**No:** Pass To RPh; Deny for Appropriateness
18. Is the patient interferon ineligible defined by having one of the following conditions: • Previous adverse reaction or hypersensitivity to interferon • Decompensated liver disease • Severe or uncontrolled psychiatric disorder in consult with a psychiatrist • Autoimmune hepatitis or other autoimmune disorders • Unstable cardiac disease • Severe cytopenias • Other comorbidities that would be exacerbated by interferon use Note: Patient's or prescribers not wanting to go through treatment with interferon does not meet the criteria for being "interferon ineligible"	**Yes:** Approve initial trial of 8 weeks for total therapy of 12 weeks for sofosbuvir + simeprevir combination **OR** a total of 24 weeks for sofosbuvir + ribavirin therapy	**No:** Pass To RPh; Deny for Appropriateness
19. Does the patient have genotype 2 chronic hepatitis C?	**Yes:** Go to #20	**No:** Go to #21
20. Is the medication being used with ribavirin?	**Yes:** Approve for initial 8 weeks for12 weeks total therapy	**No:** Pass To RPh; Deny for Appropriateness
21. Does the patient have genotype 3 chronic hepatitis C?	**Yes:** Go to #22	**No:** Pass To RPh; Deny for Appropriateness
22. Is the medication being used with both ribavirin and peginterferon alfa and meets criteria for pegylated interferon-alfa and ribavirin?	**Yes:** Approve for initial 8 weeks for 12 weeks total therapy	**No:** Go to #23
23. Is the medication being used with only ribavirin and the patient is interferon ineligible as defined by the conditions listed above in #18?	**Yes:** Approve for 8 weeks initial fill for a total 24 weeks of therapy	**No:** Pass To RPh; Deny for Appropriateness

P&T Board Action: 1/30/13 (MH)
Revision(s): 3/27/13, 7/31/13 (MH)
Initiated:

Continuation of Therapy- Sofosbuvir (Assess after 4 weeks of treatment)

1. Has the patient been adherent to and tolerated initial therapy?	**Yes**: Go to #2	**No:** DENY (Medical Appropriateness)
2. Is the HCV RNA level at week 4 detectable (HCV RNA is ≥25 IU/mL),?	**Yes:** reassess HCV RNA in 2 weeks. Go to #3	**No:** Go to #4
3. Has the HCV RNA increased (i.e., >1 log10 IU/mL from nadir)?	**Yes:** Discontinue treatment	**No:** Recheck in 2 weeks (week 8 of treatment). Go to #4
4. Is the 8 week HCV RNA detectable (HCV RNA is ≥25 IU/mL),?	**Yes:** Discontinue treatment	**No:** Approve for additional 4-16 weeks based on genotype and regimen

Dosage and Administration:

Genotype 1 and 4	Sofosbuvir + peginterferon alfa + ribavirin	12 weeks
Genotype 2	Sofosbuvir + ribavirin	12 weeks
Genotype 3*	Sofosbuvir + ribavirin	24 weeks
Genotype 1 and interferon ineligible	Sofosbuvir + ribavirin	24 weeks

*****Certain patients with genotype 3 (nonresponders with advanced fibrosis) can also be treated with sofosbuvir + peginterferon alfa + ribavirin for 12 weeks if deemed appropriate by physician.