



Division: Pharmacy Services	Subject: Prior Authorization Criteria – Sovaldi
Original Development Date: Original Effective Date: Revision Date:	December 17, 2013 May 12, 2014; June 30, 2014; August 8, 2014

SOVALDI® (sofosbuvir)

LENGTH OF AUTHORIZATION:

Initial Review: One month (28 days)

Completion of Therapy: 8 weeks, 12 weeks, 24 weeks (depending on genotype)

INITIAL REVIEW CRITERIA:

1. Adult patient age ≥ 18 years old; **AND**
2. Prescribed by a hepatologist, gastroenterologist, infectious disease specialist or transplant physician; **AND**
3. Patient is sofosbuvir treatment naïve (no claims history or reference in medical records to previous trial and failure of sofosbuvir).
4. **One of the following:**
 - ☐ Patient has abstained from the use of illicit drugs and alcohol for a minimum of one month as evidenced by negative urine or blood confirmation tests collected within the past 30 days, prior to initiation of therapy (results must be submitted with request);
 - If the test results submitted is positive the reviewer must review claims history or medical records to determine if medications are prescribed. If so proceed to next step (#5).

OR

- ☐ Patient is receiving substance or alcohol abuse counseling services or seeing an addiction specialist as an adjunct to HCV treatment and it is documented in the medical records; **AND**
5. Baseline HCV RNA must be submitted with a collection date within the past three months. **Prescriber must submit lab documentation indicating HCV genotype and quantitative viral load.**
 6. Patient meets the diagnosis and disease severity criteria outlined in Dosing and Administration below; **AND**
 7. Patient agreement to a complete regimen is documented in medical records submitted (*e.g., dual or triple therapy as outlined in Dosing and Administration below*); **AND**
 8. Patient verbally or in writing commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment; **AND**
 9. Female patients must have a negative pregnancy test collected within 30 days prior to the initiation of

therapy **OR** Medical records must be submitted documenting pregnancy status.

- *When Sovaldi is used in combination with ribavirin or peginterferon alfa/ribavirin, women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded. Routine monthly pregnancy tests must be performed during this time. There are no data on the effectiveness of systemic hormonal contraceptives in women taking Sovaldi, therefore, two non-hormonal methods of contraception should be used during treatment with Sovaldi and concomitant ribavirin.*

10. For HIV-1 co-infected patients, patients must have the following:

- Documented HIV-1 diagnosis, **AND**
- CD4 count greater than 500 cells/mm³, if patient is not taking antiretroviral therapy; **OR**
- CD4 count greater than 200 cells/mm³, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL)

11. No early refills will be allowed due to lost, stolen medications, or vacation override.

COMPLETION OF THERAPY REVIEW CRITERIA:

1. The initial review criteria must have been met or the patient is currently on therapy and has not completed the recommended regimen per genotype.
2. Lab results (HCV RNA) collected two or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted.
 - a. *Subsequent reauthorization is contingent upon subsequent HCV viral load results (refer to individual regimen requirements under the "Dosing & Administration" section).*
3. No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
4. Continuation of treatment may be authorized for members who are **100% compliant** to the regimen as verified by the Prescriber and member's medication fill history (review Rx history and dispensing for compliance)

DOSING & ADMINISTRATION:

- Dose: 400 mg tablet once daily

HCV & HCV/HIV-1 Co-Infection – Genotype 1 or 4	
TRIPLE THERAPY:	SOVALDI + peg-interferon alfa + ribavirin
Length of Prior Authorization (PA):	Up to 12 weeks (1 st PA length – 4 weeks; 2 nd PA length – 8 weeks) <i>For re-authorization for continuation of treatment with sofosbuvir, the member must have an HCV RNA viral load performed at or approaching 4 weeks after initiation of treatment to determine response to therapy. Requests for renewal will NOT be authorized in members who have not achieved a ≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml around 4 weeks.</i>

- Documentation of concurrent (or planning to start) therapy with ribavirin and peg-interferon when starting SOVALDI for a 12-week duration
- **Evidence of Stage 3 or Stage 4 hepatic fibrosis including one of the following:**
 - Liver biopsy confirming a METAVIR score of F3 or F4; **OR**
 - Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa; **OR**
 - FibroTest score of greater than or equal to 0.58; **OR**
 - APRI score greater than 1.5; **OR**
 - Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension); **OR**
 - Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician.

HCV & HCV/HIV-1 Co-Infection – Genotype 1 or 4 (Interferon Ineligible)	
DUAL THERAPY: SOVALDI + ribavirin	
Length of Prior Authorization (PA):	Up to 24 weeks (1 st PA length – 4 weeks; 2 nd PA length – 8 weeks; 3 rd PA length – 12 weeks)
	<i>For re-authorization for continuation of treatment with sofosbuvir, the member must have an HCV RNA viral load performed at or approaching 4 weeks and 12 weeks after initiation of treatment to determine response to therapy. Requests for renewal will NOT be authorized in members who have not achieved a ≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml around 4 weeks and maintained an undetectable HCV RNA (less than 25 IU/mL) around 12 weeks of Sovaldi (sofosbuvir) treatment.</i>
<ul style="list-style-type: none"> • Documentation of concurrent (or planning to start) therapy with ribavirin when starting SOVALDI for a 24-week duration; AND • <u>Evidence of Stage 3 or Stage 4 hepatic fibrosis including one of the following:</u> <ul style="list-style-type: none"> ○ Liver biopsy confirming a METAVIR score of F3 or F4; OR ○ Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa; OR ○ FibroTest score of greater than or equal to 0.58; OR ○ APRI score greater than 1.5; OR ○ Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension); OR ○ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician; AND • <u>Interferon Ineligible defined as one of the following:</u> <ul style="list-style-type: none"> ○ Prior intolerance to interferon therapy (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) ○ Autoimmune hepatitis and other autoimmune disorders (e.g., dermatomyositis, immune thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus) ○ Hypersensitivity to peginterferon alfa or any of its components ○ Decompensated hepatic disease (defined as Child-Pugh score of >6 - Class B or C) – these cases require individual case reviews ○ Major uncontrolled depressive illness ○ History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder or suicidal ideation 	

- A baseline neutrophil count below 1500/ μ L, a baseline platelet count below 90,000/ μ L or baseline hemoglobin below 10 g/dL
- A history of preexisting cardiac disease
- Refractory diabetes mellitus
- Untreated thyroid disease
- ***This regimen should be considered only in those patients who require immediate treatment, because it is anticipated that safer and more effective IFN-free regimens will be available by 2015.***

HCV & HCV/HIV-1 Co-Infection – Genotype 2	
DUAL THERAPY:	SOVALDI + ribavirin
Length of Prior Authorization (PA):	Up to 12 weeks (1 st PA length – 4 weeks; 2 nd PA length – 8 weeks) <i>For re-authorization for continuation of treatment with sofosbuvir, the member must have an HCV RNA viral load performed at or approaching 4 weeks and 12 weeks (if therapy exceeds 12 weeks) after initiation of treatment to determine response to therapy. Requests for renewal will NOT be authorized in members who have not achieved a ≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml around 4 weeks and maintained an undetectable HCV RNA (less than 25 IU/mL) around 12 weeks of Sovaldi (sofosbuvir) treatment.</i>
<ul style="list-style-type: none"> • Documentation of concurrent (or planning to start) therapy with ribavirin when starting SOVALDI for a 12-week duration; AND • <u>Evidence of Stage 3 or Stage 4 hepatic fibrosis including one of the following:</u> <ul style="list-style-type: none"> ○ Liver biopsy confirming a METAVIR score of F3 or F4; OR ○ Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa; OR ○ FibroTest score of greater than or equal to 0.58; OR ○ APRI score greater than 1.5; OR ○ Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension); OR ○ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician; 	
Note: <ul style="list-style-type: none"> • <i>Patients who are prior nonresponders and have cirrhosis (defined as METAVIR score of F4 or ISHAK score of 6) may benefit by extension of treatment to 16 weeks.</i> 	

HCV & HCV/HIV-1 Co-Infected – Genotype 3	
DUAL THERAPY:	SOVALDI + ribavirin
Length of Prior Authorization (PA):	Up to 24 weeks (1 st PA length – 4 weeks; 2 nd PA length – 8 weeks; 3 rd PA length – 12 weeks) <i>For re-authorization for continuation of treatment with sofosbuvir, the member must have an HCV RNA viral load performed at or approaching 4 weeks and 12 weeks after initiation of treatment to determine response to therapy. Requests for renewal will NOT be authorized in members who have not achieved a ≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml around 4 weeks and maintained an undetectable</i>

<i>HCV RNA (less than 25 IU/mL) around 12 weeks of Sovaldi (sofosbuvir) treatment.</i>	
<ul style="list-style-type: none"> Documentation of concurrent (or planning to start) therapy with ribavirin when starting SOVALDI for a 24-week duration; AND Evidence of Stage 3 or Stage 4 hepatic fibrosis including one of the following: <ul style="list-style-type: none"> Liver biopsy confirming a METAVIR score of F3 or F4; OR Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa; OR FibroTest score of greater than or equal to 0.58; OR APRI score greater than 1.5; OR Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension); OR Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician; 	

HCV Genotypes 1, 2, 3, or 4	
Diagnosis of Hepatocellular Carcinoma Awaiting Liver Transplantation	
DUAL THERAPY:	SOVALDI + ribavirin
Length of Prior Authorization (PA):	Up to 48 weeks (1 st PA length – 4 weeks; 2 nd PA length – 8 weeks; 3 rd PA length – 12 weeks; 4 th PA length – 24 weeks)
<p><i>For re-authorization for continuation of treatment with sofosbuvir, the member must have an HCV RNA viral load performed at or approaching 4 weeks, 12 weeks, and 24 weeks after initiation of treatment to determine response to therapy. Requests for renewal will NOT be authorized in members who have not achieved a ≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml around 4 weeks and maintained an undetectable HCV RNA (less than 25 IU/mL) around 12 weeks of Sovaldi (sofosbuvir) treatment.</i></p>	
<ul style="list-style-type: none"> Documentation of concurrent (or planning to start) therapy with ribavirin when starting SOVALDI for a 48-week duration or until the time of liver transplantation, whichever occurs first; AND One of the following: <ul style="list-style-type: none"> Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist; OR Patient is being managed in a liver transplant center; AND Documentation of hepatocellular carcinoma; AND Patient meets Milan criteria and awaiting liver transplantation; <p>Milan criteria defined as:</p> <ul style="list-style-type: none"> Presence of a tumor 5 cm or less in diameter in subjects with single hepatocellular carcinoma; AND No more than three tumor nodules, each 3 cm or less in diameter, in subjects with multiple tumors; AND No extrahepatic manifestations of the cancer and no evidence of vascular invasion of the tumor 	

HCV & HCV/HIV-1 Co-Infection – Genotype 1 (Interferon Ineligible)	
DUAL THERAPY:	SOVALDI + OLYSIO
Length of Prior Authorization (PA):	Up to 12 weeks (1 st PA length – 4 weeks; 2 nd PA length – 8 weeks)
<p><i>For re-authorization for continuation of treatment with sofosbuvir, the member must have an HCV RNA viral load performed at or approaching</i></p>	

*4 weeks after initiation of treatment to determine response to therapy. Requests for renewal will **NOT** be authorized in members who have not achieved a ≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml around 4 weeks.*

- Documentation of concurrent (or planning to start) therapy with Olysio when starting SOVALDI for a 12-week duration; **AND**
- **Evidence of Stage 3 or Stage 4 hepatic fibrosis including one of the following:**
 - Liver biopsy confirming a METAVIR score of F3 or F4; **OR**
 - Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa; **OR**
 - FibroTest score of greater than or equal to 0.58; **OR**
 - APRI score greater than 1.5; **OR**
 - Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension); **OR**
 - Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician; **AND**
- **Interferon Ineligible defined as one of the following:**
 - Prior intolerance to interferon therapy (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome)
 - Autoimmune hepatitis and other autoimmune disorders (e.g., dermatomyositis, immune thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
 - Hypersensitivity to peginterferon alfa or any of its components
 - Decompensated hepatic disease (**defined as Child-Pugh score of >6 - Class B or C**) – **these cases require individual case reviews**
 - Major uncontrolled depressive illness
 - History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder or suicidal ideation
 - A baseline neutrophil count below $1500/\mu\text{L}$, a baseline platelet count below $90,000/\mu\text{L}$ or baseline hemoglobin below 10 g/dL
 - A history of preexisting cardiac disease
 - Refractory diabetes mellitus
 - Untreated thyroid disease
- *This regimen should be considered only in those patients who require immediate treatment, because it is anticipated that safer and more effective IFN-free regimens will be available by 2015.*

DENIAL CRITERIA:

HCV – Genotype 5 or 6
THERAPY REFERRAL: PEG-INTERFERON ALFA + RIBAVIRIN FOR 48 WEEKS
<i>Insufficient data to recommend use in patients with HCV genotypes 5 or 6</i>

Decompensated Cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C])
--

<i>Safety and efficacy of Sovaldi have not been established in patients with decompensated cirrhosis.</i>

Post Liver Transplantation

<i>Safety and efficacy of Sovaldi have not been established in post-liver transplant patients.</i>
--