UnitedHealthcare®
COMMUNITY & STATE

Prior Authorization Guideline

Guideline Name Sovaldi (sofosbuvir)

Formulary UnitedHealthcare Community & State

Formulary Note

Approval Date 2/19/2014

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1 . Indications

Drug Name: Sovaldi (sofosbuvir)

Indications

Chronic Hepatitis C (CHC)
Indicated for the treatment of CHC infection as a component of a combination antiviral treatment regimen. - Sovaldi efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection. The following points should be considered when initiating treatment with Sovaldi: - Monotherapy of SOVALDI is not recommended for treatment of CHC. - Treatment regimen and duration are dependent on both viral genotype and patient population. - Treatment response varies based on baseline host and viral factors.

2 . Criteria

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 1 – Interferon Eligible – Sovaldi + Alfa Interferons + Ribavirin Treatment Regimen
Approval Length	12 Week
Guideline Type	Prior Authorization

Approval Criteria

1 Both of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1 [1]

AND

1.2 One of the following:

1.2.1 Evidence of stage 3 or stage 4 hepatic fibrosis, including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting HCV reinfection following liver transplantation [2]

OR

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.2.4 Patient is co-infected with HIV [1, 2]

AND

2 Used in combination with peginterferon alfa and ribavirin [1]

AND

3 Prescribed by one of the following: [3]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine

drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

6 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

Notes	*Refer to Background Section for alternative scoring equivalents.

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 1- Interferon Ineligible - Sovaldi + Olysio Treatment Regimen
Approval Length	12 Week
Guideline Type	Prior Authorization

Approval Criteria

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

1.1.2 One of the following:

1.1.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting evidence of stage 3 or stage 4 hepatic fibrosis including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.1.2.3 Patient is co-infected with HIV [2]

AND

1.1.3 Submission of medical records (e.g., chart notes, laboratory values) documenting patient is ineligible for treatment with peginterferon alfa, defined by at least one of the following: [2, 3, 5]

- Autoimmune hepatitis or autoimmune disorders (eg, dermatomyositis, immune [idiopathic)] thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
- Major uncontrolled depressive illness
- History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation
- Uncontrolled seizures
- Moderate or severe retinopathy
- Poorly controlled diabetes
- Baseline neutrophil count below 1,500/ uL
- Baseline platelet count below 70,000/ uL
- Baseline hemoglobin below 10 g/dL
- Significant ischemic cardiac disease
- Prior intolerance or hypersensitivity (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) to interferon therapy

OR

1.2 Submission of medical records (e.g., chart notes, laboratory values) documenting

genotype 1 HCV reinfection following liver transplantation [2]

AND

2 Used in combination with Olysio (simeprevir) [6, C]

AND

3 Prescribed by one of the following: [3]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

6 One of the following:

6.1 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

OR

6.2 Patient has demonstrated intolerance to interferon or ribavirin requiring discontinuation of triple therapy including Sovaldi plus peginterferon alfa plus ribavirin

Notes	*Refer to Background Section for alternative scoring equivalents.

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 1– Interferon & Olysio Ineligible - Sovaldi + Ribavirin Treatment Regimen
Approval Length	24 Week
Guideline Type	Prior Authorization

Approval Criteria

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

1.1.2 One of the following:

1.1.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting evidence of stage 3 or stage 4 hepatic fibrosis including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.1.2.3 Patient is co-infected with HIV

AND

1.1.3 Submission of medical records (e.g., chart notes, laboratory values) documenting patient is ineligible for treatment with peginterferon alfa, defined by at least one of the following: [2, 3, 5]

- Autoimmune hepatitis or autoimmune disorders (eg, dermatomyositis, immune [idiopathic)] thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
- Major uncontrolled depressive illness
- History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation
- Uncontrolled seizures
- Moderate or severe retinopathy
- Poorly controlled diabetes
- Baseline neutrophil count below 1500/ uL

- Baseline platelet count below 70,000/ uL
- Baseline hemoglobin below 10 g/dL
- Significant ischemic cardiac disease
- Prior intolerance or hypersensitivity (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) to interferon therapy

OR

1.2 Submission of medical records (e.g., chart notes, laboratory values) documenting genotype 1 HCV reinfection following liver transplantation [2]

AND

2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has a contraindication to Olysio (simeprevir) (Sovaldi plus Olysio combination therapy is the preferred regimen in patients with interferon ineligibility) [2, D]

AND

3 Used in combination with ribavirin [1]

AND

4 Prescribed by one of the following: [3]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

5 One of the following:

5.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

5.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

5.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

5.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

6 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

7 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

Notes	*Refer to Background Section for alternative scoring equivalents.

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 2 – Sovaldi + Ribavirin Treatment Regimen
Approval Length	12 Week
Guideline Type	Prior Authorization

Approval Criteria

1 Both of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 2 [1]

AND

1.2 One of the following:

1.2.1 Evidence of stage 3 or stage 4 hepatic fibrosis, including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting genotype 2 HCV reinfection following liver transplantation [2]

OR

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.2.4 Patient is co-infected with HIV [1, 2]

AND

2 Used in combination with ribavirin [1]

AND

3 Prescribed by one of the following: [3]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

6 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

Notes	*Refer to Background Section for alternative scoring equivalents.

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 3 – Interferon Eligible – Sovaldi + Alfa Interferons + Ribavirin Treatment Regimen
Approval Length	12 Week
Guideline Type	Prior Authorization

Approval Criteria

1 Both of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 3 [1]

AND

1.2 One of the following:

1.2.1 Evidence of stage 3 or stage 4 hepatic fibrosis, including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting

genotype 3 HCV reinfection following liver transplantation [2]

OR

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.2.4 Patient is co-infected with HIV [2]

AND

2 Used in combination with peginterferon alfa and ribavirin [7, E]

AND

3 Prescribed by one of the following: [3]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

6 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

Notes	*Refer to Background Section for alternative scoring equivalents.

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 3 – Interferon Ineligible – Sovaldi + Ribavirin Treatment Regimen
Approval Length	24 Week
Guideline Type	Prior Authorization

Approval Criteria

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting

diagnosis of chronic hepatitis C genotype 3

AND

1.1.2 One of the following:

1.1.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting evidence of stage 3 or stage 4 hepatic fibrosis including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.1.2.3 Patient is co-infected with HIV [2]

AND

1.1.3 Submission of medical records (e.g., chart notes, laboratory values) documenting patient is ineligible for treatment with peginterferon alfa, defined by at least one of the following: [2, 3, 5]

- Autoimmune hepatitis or autoimmune disorders (eg, dermatomyositis, immune [idiopathic)] thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
- Major uncontrolled depressive illness
- History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation
- Uncontrolled seizures
- Moderate or severe retinopathy
- Poorly controlled diabetes

- Baseline neutrophil count below 1,500/ uL
- Baseline platelet count below 70,000/ uL
- Baseline hemoglobin below 10 g/dL
- Significant ischemic cardiac disease
- Prior intolerance or hypersensitivity (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) to interferon therapy

OR

1.2 Submission of medical records (e.g., chart notes, laboratory values) documenting genotype 3 HCV reinfection following liver transplantation [2]

AND

2 Used in combination with ribavirin [1]

AND

3 Prescribed by one of the following: [3]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

6 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

Notes	*Refer to Background Section for alternative scoring equivalents.

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 4 – Interferon Eligible – Sovaldi + Alfa Interferons + Ribavirin Treatment Regimen
Approval Length	12 Week
Guideline Type	Prior Authorization

Approval Criteria

1 Both of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 4 [1]

AND

1.2 One of the following:

1.2.1 Evidence of stage 3 or stage 4 hepatic fibrosis, including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting genotype 4 HCV reinfection following liver transplantation [2]

OR

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.2.4 Patient is co-infected with HIV [2]

AND

2 Used in combination with peginterferon alfa and ribavirin [1]

AND

3 Prescribed by one of the following: [3]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

6 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

Notes	*Refer to Background Section for alternative scoring equivalents.

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without Decompensation) - Genotype 4 – Interferon Ineligible – Sovaldi + Ribavirin Treatment Regimen
Approval Length	24 Week
Guideline Type	Prior Authorization

Approval Criteria

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 4

AND

1.1.2 One of the following:

1.1.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting evidence of stage 3 or stage 4 hepatic fibrosis including one of the following: [2, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [9]

OR

1.1.2.3 Patient is co-infected with HIV [2]

AND

1.1.3 Submission of medical records (e.g., chart notes, laboratory values) documenting patient is ineligible for treatment with peginterferon alfa, defined by at least one of the following: [2, 3, 5]

- Autoimmune hepatitis or autoimmune disorders (eg, dermatomyositis, immune [idiopathic)] thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
- Major uncontrolled depressive illness
- History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation
- Uncontrolled seizures
- Moderate or severe retinopathy
- Poorly controlled diabetes
- Baseline neutrophil count below 1,500/ uL
- Baseline platelet count below 70,000/ uL
- Baseline hemoglobin below 10 g/dL
- Significant ischemic cardiac disease
- Prior intolerance or hypersensitivity (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) to interferon therapy

OR

1.2 Submission of medical records (e.g., chart notes, laboratory values) documenting genotype 4 HCV reinfection following liver transplantation

AND

2 Used in combination with ribavirin [8, F]

AND

3 Prescribed by one of the following: [3]

- Hepatologist

- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

6 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

Notes	*Refer to Background Section for alternative scoring equivalents.

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, or 4 - Patients with Hepatocellular Carcinoma Awaiting Liver Transplantation OR Decompensated Liver Disease- Sovaldi + Ribavirin Treatment Regimen
Approval Length	48 Week
Guideline Type	Prior Authorization

Approval Criteria

1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4

AND

2 Used in combination with ribavirin [1, 2]

AND

3 One of the following:

3.1 Both of the following: [1]

3.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of hepatocellular carcinoma

AND

3.1.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is an active candidate on the waiting list for a liver transplant

OR

3.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has decompensated liver disease (defined as Child-Pugh Class B or C) [2]

AND

4 One of the following: [2, 3]

4.1 Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist with expertise in decompensated liver disease

OR

4.2 Patient is being managed in a liver transplant center

AND

5 One of the following:

5.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

5.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

5.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

5.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

6	Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

3 . Background

Clinical Practice Guidelines

Comparison of Scoring Systems for Histological Stage (Fibrosis)

METAVIR	Batts-Ludwig	Knodell	Ishak
0	0	0	0
1	1	1	1
1	1	1	2
2	2	--	3
3	3	3	4
4	4	4	5
4	4	4	6

4 . Endnotes

A. Based on the 2014 AASLD/IDSA Treatment Guidelines, it may be advisable to delay treatment for some patients with documented early fibrosis stage (F 0-2), because waiting for future highly effective, pangenotypic, DAA combinations in IFN-free regimens may be prudent. [2]
B. Patients who use illicit drugs should receive continued support from drug abuse and psychiatric counseling services as an important adjunct to treatment of HCV infection. [4]
C. An interim analyses of a phase II trial (COSMOS) found that simeprevir and sofosbuvir for 12 or 24 weeks resulted in SVR12 rates of 79% to 96% with RBV and 93% without RBV in prior null responders to PegIFN and RBV with HCV genotype 1 and METAVIR scores of F0 to F2 (cohort 1). In addition, SVR4 rates were 96% with RBV and 100% without RBV in treatment-naïve and prior null responder patients with HCV genotype 1 and METAVIR scores of F3 or F4 (cohort 2). [6]
D. Based on the 2014 AASLD/IDSA treatment guidelines, Sovaldi plus Olysio is the recommended treatment regimen for treatment-naive patients with interferon ineligibility.

In addition, the regimen is the preferred treatment regimen for patients who failed prior therapy with interferon alfa and ribavirin (regardless of interferon ineligibility). [2]

E. LONESTAR-2 was a Phase 2 study that evaluated 12 weeks of treatment with sofosbuvir plus PegIFN/RBV in patients with HCV genotype 2 or 3 who did not achieve SVR with prior treatment of PegIFN/RBV. Overall, SVR was achieved in 83% (20/24) of patients infected with genotype 3. [7]
F. In a small study of Egyptian patients in the United States treated with sofosbuvir plus weight-based RBV (1000 mg to 1200 mg), SVR12 was achieved in 11 of 14 (79%) treatment-naive patients treated for 12 weeks; SVR24 was achieved in 100% of the 14 treatment-naive patients treated for 24 weeks. [8]

5 . References

1. Sovaldi Prescribing Information, Gilead Sciences, Inc., 2013.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. January 2014. http://www.hcvguidelines.org/full-report-view. Accessed March 13, 2014.
3. Per clinical consultation with hepatologist, March 11, 2014.
4. Ghany MG, Strader DB, Thomas DL, Seeff LB, American Association for the Study of Liver Diseases. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009;49(4):1335-74.
5. Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. N Engl J Med. 2013;368:1867-77.
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