HEPATITIS C TREATMENT GUIDELINES

Updated May 21, 2014

INSTRUCTIONS:
1. Review the posted Hepatitis C Treatment Guidelines document to validate that your patient meets the criteria for treatment.

2. Complete the online Hepatitis C Prior Authorization Form in its entirety.

3. Print, Sign and fax the completed Prior Authorization Form along with copies of laboratory results, required documentation from medical record, and all other supporting information to: PerformRx at 866-610-2775
**DRUGS PREFERRED**
PEGINTRON™ (peginterferon alfa-2b): 50mcg/0.5mL, 80mcg/0.5mL, 120mcg/0.5mL powder for injection in Redipens™ or glass vials
COPEGUS™ (ribavirin): 200mg tablet
REBETOL™ (ribavirin): 200mg capsule
SOVALDI™ (sofosbuvir): 400mg tablets
OLYSIO™ (simeprevir): 375mg capsules

**DRUGS NOT PREFERRED**
PEGASYS™ (peginterferon alfa-2a): 180mcg/ml single use glass vials or prefilled syringe
INCIVEK® (telaprevir): 375mg tablets
VICTRELIS® (boceprevir): 200mg capsules

**All Initial requests MUST meet the following requirements:**
1. Patient Age 18 or older, **AND**
2. Medical history:
   - Past medical history and co-morbidities
   - Complications of chronic liver disease
   - Symptoms, **AND**
3. Psychiatric history:
   - Psychiatric disorders, past and present
   - Substance abuse (if there is a history of substance abuse, an attestation that the patient is drug and alcohol free)
   - Conditions affecting compliance, **AND**
4. Lab testing **within three (3) months** of starting treatment (copy of results required):
   - ALT/AST, albumin, bilirubin, total and direct, prothrombin time
   - Genotype
   - HCV RNA viral load
   - CBC, ferritin, iron saturation
   - TSH, ANA
   - Serum creatinine, glucose, uric acid
   - ECG, echocardiogram, stress test in the presence of heart disease
5. Lab testing **within one (1) month** of starting treatment (copy of results required):
   - Urine drug screen
   - Blood alcohol level
   - Pregnancy test in women of childbearing age, with patient agreeing to use two or more forms of contraception, and will have monthly pregnancy tests during therapy, **AND**
6. Serum HBsAg, anti-HBc, anti-HBs, anti-HAV, **AND**

7. HIV serology (CD4+ T cell count and HIV RNA are required for patients co-infected with HIV, **AND**
   *In patients with lower CD4 counts (e.g., <200 cells/mm3), it may be preferable to delay HCV therapy until CD4 counts increase* **AND**

8. The patient has had a Liver biopsy showing advanced to severe fibrosis. Either Ishak Stage >3 or Metavir Score >2, **AND**
   - **Ishak stage > 3**
     | Category | Fibrous measurement | Histologic description |
     |----------|---------------------|------------------------|
     | 0        | 1.9%                | No fibrosis            |
     | 1        | 3.0%                | Fibrous expansion of some portal areas (+/-) short fibrous septa |
     | 2        | 3.6%                | Fibrous expansion of most portal areas (+/-) short fibrous septa |
     | 3        | 6.5%                | Fibrous expansion of some portal areas with occasional portal to portal (P-P) bridging |
     | 4        | 13.7%               | Fibrous expansion of portal areas with marked P-P and portal to central (P-C) bridging |
     | 5        | 24.3%               | Marked P-P and/or P-C bridging with occasional nodules |
     | 6        | 27.8%               | Cirrhosis, probable or definite |
   - **Metavir score > 2**
     | Stage 1 | Portal / periportal fibrosis |
     | Stage 2 | Septal fibrosis |
     | Stage 3 | Bridging fibrosis with architectural distortion |
     | Stage 4 | Cirrhosis, probable cirrhosis |

9. Patient is sofosbuvir treatment naïve (no claims history or reference in medical records to previous trial and failure of sofosbuvir), **AND**

10. The dose that has been prescribed for the patient is consistent with the dosing recommendations listed below, and the prescriber is a hepatologist / gastroenterologist / infectious disease specialist/transplant specialist, **AND**

11. For a pegylated interferon alpha product, Peglntron is the preferred agent

12. Presence of previous treatment, treatment regimen and response
   - Treatment Naïve / Previous Relapsed
   - Previous Partial Responders / Null Responders
APPROVAL CONSIDERATIONS:

Compliance:
1. A nurse case manager will reach out to all members approved for treatment, with the intent to educate and ensure successful completion of the regimen.
2. The nurse case manager will guide and reinforce compliance through ongoing interaction with the member.
3. Demonstrated non-compliance with the treatment regimen, defined as two consecutive missed doses or more than four missed doses in a four week period, renders the treatment ineffective and may result in denial of additional authorizations.

In the presence of previous substance abuse (including alcohol and prescription drugs), ALL:
1. No alcohol or illicit drug use within 6 months of treatment onset, AND
2. Negative drug and / or blood alcohol level 30 days prior to treatment onset, AND
3. Physician attestation of patient abstinence from drugs and alcohol, and is compliant with treatment program participation as documented by a copy of the note in the patient’s medical record.

The presence of ANY of the following excludes approval:
1. Severe or uncontrolled co-morbidities
2. Sever renal impairment or End Stage Renal Disease (ESRD)
3. Transplant (except liver)
4. Disorders of mood, thought, or cognition expected to negatively impact treatment compliance
5. Substance abuse (positive urine drug screen or blood alcohol level)
6. Less than severe fibrosis on biopsy
7. Contraindication to any component of the treatment regimen

Contraindications to treatment with interferon:
1. A baseline neutrophil count below 1500/uL, a baseline Platelet count below 90,000/uL or baseline hemoglobin below 10g/dL
2. Intolerance to IFN
3. Autoimmune Hepatitis and other autoimmune disorders
4. Hypersensitivity to PEG or any of its components
5. Decompensated Hepatic disease
6. History of depression or clinical features consistent with depression
7. History of preexisting cardiac disease
8. Transplant of kidney, heart, or other solid-organ (excluding liver transplant).
Contraindications to treatment with ribavirin:
1. Hypersensitivity to drug, class, or components
2. Autoimmune hepatitis
3. GFR < 50
4. Pregnancy
5. Hemoglobinopathy

Contraindications to treatment with Sovaldi:
1. Hypersensitivity to drug, class, or components
2. HCV monotherapy
3. Significant drug-drug interactions

Contraindications to treatment with Olysio:
1. Hypersensitivity to drug, class, or components
2. HCV monotherapy
3. Significant drug-drug interactions

WHEN CRITERIA FOR APPROVAL FOR THE TREATMENT OF HEPATITIS C INFECTION IS MET**:

The patient will be placed into one of the following categories:
Hepatitis C **Genotype 1 infection:** Go to section I
Hepatitis C **Genotype 2 infection:** Go to section II
Hepatitis C **Genotype 3 infection:** Go to section III
Hepatitis C **Genotype 4 infection:** Go to section IV
Hepatitis C **Genotypes 5 and 6 infections:** Go to section V
Hepatitis C **Genotypes 1, 2, 3, or 4 infections with Hepatocellular Carcinoma with Ribavirin and Sovaldi:** Go to section VI

**These treatment regimens are for patients that are treatment naïve, relapser with Pegylated interferon and Ribavirin, or coinfected with HIV. For partial responders or null responders, please refer to the most current dosing guidelines.**
Section I: Treatment for patients with Hepatitis C Genotype 1 infection:
Interferon-eligible patients:
- Approve Sovaldi 400mg tablet #28 for 28 days with Ribavirin and Pegylated Interferon for a total of 12 weeks.

Interferon-ineligible patients:
- Approve Sovaldi 400mg tablet #28 tablets for 28 day supply with Olysio #28 for 28 day supply for a total of 12 weeks.

Section II: Treatment for patients with Hepatitis C Genotype 2 infection:
- Approve Sovaldi 400mg tablet #28 tablets for a 28 day supply with Ribavirin for 12 weeks.

Section III: Treatment for patients with Hepatitis C Genotypes 3 infection:
Interferon-eligible patients:
- Approve Sovaldi 400mg tablet #28 for a 28 day supply with Ribavirin and Pegylated Interferon for a total of 12 weeks.

Interferon-ineligible patients:
- Approve Sovaldi 400mg tablet #28 tablets for 28 day supply with Ribavirin for a total of 24 weeks.

Section IV: Treatment for patients with Hepatitis C Genotype 4 infection:
Interferon-eligible patients:
- Approve Sovaldi 400mg tablet #28 for 28 days with Ribavirin and Pegylated Interferon for a total of 12 weeks.

Interferon-ineligible patients:
- Approve Sovaldi 400mg tablet #28 for 28 days with Ribavirin for a total of 24 weeks.

Section V: Treatment for patients with Hepatitis C Genotypes 5 or 6 infections with Ribavirin and Sovaldi:
- Approve Sovaldi 400mg tablet #28 for 28 days with Ribavirin and Pegylated Interferon for a total of 12 weeks.

Per AASLD guidelines: No data are available to support the use of a non-PEG containing regimen for patients with HCV genotype 5 or 6 infection.

Section VI: Treatment for patients with Hepatitis C Genotypes 1, 2, 3, or 4 infections with Hepatocellular Carcinoma with Ribavirin and Sovaldi:
All initial requests must meet the following additional requirement:
- Documentation of testing confirming the diagnosis of Hepatocellular Carcinoma through either Imaging Testing (such as Ultrasound, Computed Tomography, Magnetic Resonance Imaging), Laparoscopy, or Biopsy.
- Approve Ribavirin and Sovaldi for 24 weeks (Sovaldi 400mg tablet #28 tablets for a 28 day supply with five refills).
  - The patient may be approved for an additional 24 weeks after receiving confirmation the patient has not yet received a transplant.
  - If the patient has received a transplant, treatment is stopped. Deny with the appropriate rationale.
REFILL CONSIDERATIONS:

- Demonstrated non-compliance with the treatment regimen, defined as two (2) consecutive missed doses or more than four (4) missed doses in a four week period, renders the treatment ineffective and may result in denial of additional authorizations
- Evidence of substance abuse may result in denial of additional authorizations
- Failure to submit follow-up pregnancy result for patient of child bearing age every 30 days, or a result demonstrating pregnancy may result in denial of additional authorizations

REFERENCES:


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