Prior Authorization Criteria for the Hepatitis C Treatment

A. Member Coverage Criteria:

1. Age is equal to or greater than 18 year

2. Diagnosis of Hepatitis C confirmed by detectable serum HCV RNA by quantitative assay completed within the last 90 days

3. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician

4. Liver fibrosis/cirrhosis
   a. Imaging evidence of cirrhosis or severe fibrosis based upon ultrasound, CT or MRI of the abdomen describing a nodular-appearing liver, generally in combination with evidence of splenomegaly and portal hypertension.
   OR
   b. Elastography Score ≥ 11kPa
   OR
   c. Liver biopsy with METAVIR score ≥ F3
   OR
   d. Fibro sure (e.g. Fibro test) scoring ≥ F3 (0.58)
   OR
   e. Extrahepatic manifestations including leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease

5. Member has received Hepatitis A and B vaccinations or has laboratory evidence of immunity

6. If member has history of substance use disorder in the past 12 months, he/she must be in remission for six months prior to initiating treatment

7. If member has HIV-1:
   a. CD4 count >500 cells/mm³, if patient is not taking antiretroviral therapy: OR
   b. CD4 count >200 cells/mm³, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL)

8. Interferon ineligibility will be considered for the following:
   - Autoimmune hepatitis or other autoimmune disorders
   - Previous intolerance to IFN leading to treatment discontinuation
Pre-existing hematological disease as evidenced by:
- Baseline neutrophil count $< 1500/\mu$L, or
- Baseline platelet count $< 90,000/\mu$L, or
- Baseline hemoglobin of $< 10g/dL$

History of psychiatric disorders:
- Schizophrenia
- Bipolar Disorder
- Previous inpatient psychiatric admission
- History of a suicide attempt within the past 2 years
- Unstable major depressive disorder

Ischemic heart disease

B. Monitoring Requirements During Treatment:
1. HCV viral load laboratory results must be submitted to the Contractor/PBM after completion of 4 weeks of a 12-week therapy regimen.
   - Viral loads must be undetectable after 4 weeks of therapy by sensitive assay testing.
   - If the viral load is very low, but detectable, $<100$ IU’s, the test must be repeated.
   - If the viral load is still detectable ($>100$ IUs), treatment shall be discontinued.
2. HCV viral load laboratory results must be submitted to the Contractor/PBM after completion of 4 and 12 weeks of a 24-week therapy regimen.
   - Viral loads must be undetectable after 4 weeks of therapy by sensitive assay testing.
   - If the viral load is very low, but detectable, ($<100$ IUs), the test must be repeated.
   - If the viral load is still detectable ($>100$ IUs), treatment shall be discontinued.
   - Viral loads must be undetectable after 12 weeks of therapy by sensitive assay testing.
   - If the viral load is very low, but detectable, ($<100$ IUs), the test must be repeated.
   - If the viral load is still detectable ($>100$ IUs), treatment shall be discontinued
3. For members with a history of substance or alcohol abuse in the past 12 months, random blood alcohol and/or drug screens must be completed monthly during HCV treatment.
4. Members prescribed Sofosbuvir or Simeprevir must participate in a treatment adherence program.

C. Coverage is not provided for:
1. Monotherapy of Simeprevir (Olysio).
2. Monotherapy of Sofosbuvir (Sovaldi).
3. Sofosbuvir for greater than 12 weeks of therapy except for interferon ineligible genotype 3 members.
4. Sofosbuvir doses greater than 400mg/day.
5. Simeprevir doses greater than 150mg/day.
6. Harvoni doses greater than 90mg Ledipsavir / 400mg Sofosbuvir / day
7. Viekira doses greater than one Viekira Pak / day.
8. Previous therapy with Sofosbuvir or Simeprevir.
9. HCV Genotypes 5 & 6
10. Documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and procedures
11. Members declining to participate in a treatment adherence program.
12. Decompensated liver disease (i.e., Child-Pugh score >9)
13. Elastrography score <11kPa
14. METAVIR score < F3
15. Fibro Sure score <0.58.
16. Members who have engaged in substance abuse within 6 months from the date of the request for HCV treatment
17. Current use of a potent P-gp inducer (St. John’s wart, rifampin, carbamazepine, ritonavir, tipranavir
18. Members’ with severe renal impairment or end stage renal disease defined as CrCl ≤ 30ml/min
19. Members who do not meet the CD4 counts as stated in Section A 7.
20. Post-liver transplant treatment
21. Greater than one course of therapy per lifetime.
22. Lost or stolen medication absent good cause.
23. Fraudulent use of HCV medications.