Hepatitis C Therapy

MO HealthNet Pharmacy Program
Preferred Drug List

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Preferred/Non-Preferred Agents

Preferred Agents	Non-Preferred Agents
• Pegasys® Vial/Syringe • Pegasys® Convenience Pack • Pegasys® Proclick • Peg-Intron® • Peg-Intron® RediPen • Victrelis® • Incivek® • Viekira Pak™	• Sovaldi® • Olysio™ • Harvoni®

Approval Criteria

Viekira Pak™

- Diagnosis of Hepatitis C
- Must have Genotype 1
- Adult patients age ≥ 18 years old
- Fibrosis score equal to or greater than F3
- Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months
- Baseline viral load must be submitted
- Must be prescribed with ribavirin for Genotype 1a with or without cirrhosis and for Genotype 1b with cirrhosis
- Maximum length of therapy approval of 12 weeks for Genotype 1a without cirrhosis and Genotype 1b with or without cirrhosis – subject to Clinical Consultant approval
- Maximum length of therapy approval of 24 weeks for Genotype 1a with cirrhosis dependent on prior treatment history – subject to Clinical Consultant approval
- Viral load results submitted at week 12 and week 24 (week 12 results must be less than 25 IU/mL if duration of treatment is 24 weeks)
- Prescription claim for Viekira Pak™ with billed units = 112 tablets for 28 day supply.
- No more than a 7 day gap between prior claim and incoming claim with a 168 day look back

Harvoni®

- Diagnosis of Hepatitis C
- Must have Genotype 1
- Trial and failure of Viekira Pak™
- Adult patients age ≥ 18 years old
- Fibrosis score equal to or greater than F3
- Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months
- Baseline viral load must be submitted
- Maximum length of therapy approval of 12 weeks for treatment-naïve with or without cirrhosis and treatment-experienced without cirrhosis – subject to Clinical Consultant approval.
- Maximum length of therapy approval of 24 weeks for treatment-experienced with cirrhosis – subject to Clinical Consultant approval
- Viral load results submitted at week 12 and week 24 (week 12 results must be less than 25 IU/mL if duration of treatment is 24 weeks)
- Prescription claim for Harvoni® with billed units = 28 tablets for 28 day supply.
- No more than a 7 day gap between prior claim and incoming claim with a 168 day look back

Sovaldi®

- Diagnosis of Hepatitis C
- Adult patients age ≥ 18 years old
- Must have Genotype 1 or 2 or 3 or 4
- **If Genotype 1 a trial and failure of Viekira Pak™**
- Fibrosis score equal to or greater than F3 for Genotype 1, 2, or 4
- Fibrosis score equal to or greater than F2 for Genotype 3
- Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months
- Baseline viral load must be submitted
- Must be prescribed with ribavirin or ribavirin + PEG
- Maximum length of therapy approval of 24 weeks – subject to Clinical Consultant approval
- For Sovaldi and Olysio combination therapy consideration
  - Must be defined interferon ineligible (see Appendix A)
  - Must be Genotype 1
  - **Trial and failure of Viekira Pak™**
  - Must be prescribed with Ribavirin
  - Max approval 12 weeks
- Ongoing therapy – Must be submitted at week 12 and week 24:
  - Negative Urine Alcohol and Illicit Drug Screen results submitted done within 7 days prior to refill request
  - Viral load results submitted and less than 25 IU/mL
- Prescription claim for Sovaldi® (sofosbuvir) with billed units = 28 tablets for 28 day supply.
- No more than a 7 day gap between prior claim and incoming claim with a 168 day look back.

Olysio™

- Diagnosis of Hepatitis C
- Adult patients age ≥ 18 years old
- Must be Genotype 1 or 4
  - If Genotype 1 must have Subtype
    - If Subtype 1A must be negative for polymorphism Q80K
    - **Trial and failure of Viekira Pak™**
- Fibrosis score equal to or greater than F3
- Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months
- Baseline viral load must be submitted
- Must be prescribed with ribavirin + PEG
- Maximum length of therapy approval of 24 weeks – subject to Clinical Consultant approval
- For Olysio and Sovaldi combination therapy consideration
  - **Trial and failure of Viekira Pak™**
  - Must be defined interferon ineligible (see Appendix A)
  - Must be Genotype 1
  - Must be prescribed with Ribavirin
  - Max approval 12 weeks
- Must not have been treated with an oral protease inhibitor indicated for HCV in the past
- Ongoing therapy – Must be submitted at week 12 and week 24:
  - Negative Urine Alcohol and Illicit Drug Screen results submitted done within 7 days prior to refill request
  - Viral load results submitted and less than 25 IU/mL
- Prescription claim for Olysio™ (simeprevir) with billed units = 28 tablets for 28 day supply.
- No more than a 7 day gap between prior claim and incoming claim with a 168 day look back.

Denial Criteria

Denial Criteria

- Lack of appropriate diagnosis
- Less than 18 years of age
- Pregnancy
- Sovaldi or Olysio as monotherapy
- Olysio therapy for Genotype 1a with Q80K polymorphism
- Viral load greater than 25 IU/mL at treatment week 4 or beyond
- Evidence of alcohol or illicit drugs use anytime during treatment
- Positive alcohol and illicit drug urine screen (without current prescription)
- Combination of Sovaldi and Olysio for genotypes 2, 3, 4, 5 or 6
- Metavir fibrosis score of less than F3 for genotypes 1, 2 or 4
- Metavir fibrosis score of less than F2 for genotype 3
- For Olysio therapy - previous treatment with an oral protease inhibitor indicated for HCV
- Lack of approval criteria

Denial Criteria

- For Viekira Pak™:
  - Billed units on the claim <112 tablets for 28 days and
  - Billed units on the claim >112 tablets for 28 days.
  - Gap in therapy >7 days from previous claim

- For Sovaldi®, Olysio™ and Harvoni®:
  - Billed units on the claim <28 tablets for 28 days and
  - Billed units on the claim >28 tablets for 28 days.
  - Gap in therapy >7 days from previous claim

- For Sovaldi®, Olysio™and Harvoni®:
  - Lack of trial and failure of Viekira Pak™ if treating genotype 1