Hepatitis C Therapy

Effective 01/10/2013
Revised 01/05/2017

Preferred Agents for Genotype 1
- Incivek® (Discontinued)
- Pegasys® Vial/Syringe
- Pegasys® Convenience Pack
- Pegasys® Proclick
- Peg-Intron®
- Peg-Intron® RediPen
- Victrelis® (Discontinued)
- Viekira Pak®
- Viekira XR®
- Zepatier®

Non-PREFERRED Agents for Genotype 1
- Daklinza®
- Epclusa®
- Harvoni®
- Olysio®
- Sovaldi®
- Technivie® (not FDA indicated)

Preferred Agents for Genotype 2
- Epclusa®
- Pegasys® Vial/Syringe
- Pegasys® Convenience Pack
- Pegasys® Proclick
- Peg-Intron®
- Peg-Intron® Redipen

Non-PREFERRED Agents for Genotype 2
- Daklinza® (not FDA indicated)
- Harvoni® (not FDA indicated)
- Olysio® (not FDA indicated)
- Sovaldi®
- Technivie® (not FDA indicated)
- Viekira Pak® (not FDA indicated)
- Viekira XR® (not FDA indicated)
- Zepatier® (not FDA indicated)

Preferred Agents for Genotype 3
- Epclusa®
- Pegasys® Convenience Pack
- Pegasys® Proclick
- Pegasys® Vial/Syringe
- Peg-Intron®
- Peg-Intron® RediPen

Non-PREFERRED Agents for Genotype 3
- Daklinza®
- Harvoni® (not FDA indicated)
- Olysio® (not FDA indicated)
- Sovaldi®
- Technivie® (not FDA indicated)
- Viekira Pak (not FDA indicated)
- Viekira XR® (not FDA indicated)
- Zepatier® (not FDA indicated)
### Preferred Agents for Genotype 4
- Pegasys® Vial/Syringe
- Pegasys® Convenience Pack
- Pegasys® Proclick
- Peg-Intron®
- Peg-Intron® RediPen
- Technivie® (if no cirrhosis)
- Zepatier®

### Preferred Agents for Genotype 5
- Harvoni®
- Pegasys® Convenience Pack
- Pegasys® Proclick
- Pegasys® Vial/Syringe
- Peg-Intron®
- Peg-Intron® RediPen

### Preferred Agents for Genotype 6
- Harvoni®
- Pegasys® Convenience Pack
- Pegasys® Proclick
- Pegasys® Vial/Syringe
- Peg-Intron®
- Peg-Intron® RediPen

### Non-Preferred Agents for Genotype 4
- Daklinza® (not FDA indicated)
- Epclusa®
- Harvoni®
- Olysio®
- Sovaldi®
- Viekira Pak® (not FDA indicated)
- Viekira XR® (not FDA indicated)

### Non-Preferred Agents for Genotype 5
- Daklinza® (not FDA indicated)
- Epclusa®
- Olysio® (not FDA indicated)
- Sovaldi® (not FDA indicated)
- Viekira Pak® (not FDA indicated)
- Viekira XR® (not FDA indicated)
- Zepatier® (not FDA indicated)

### Non-Preferred Agents for Genotype 6
- Daklinza® (not FDA indicated)
- Epclusa®
- Olysio® (not FDA indicated)
- Sovaldi® (not FDA indicated)
- Viekira Pak® (not FDA indicated)
- Viekira XR® (not FDA indicated)
- Zepatier® (not FDA indicated)
Approval Criteria

For Viekira Pak® or Viekira XR®
- Diagnosis of Hepatitis C
- Must have Genotype 1 and if cirrhotic only a Child-Pugh score of A
- Adult patients age ≥ 18 years old
- Metavir fibrosis score equal to or greater than F3
- 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 10 and week 24 (week 10 results must be less than 25 IU/mL if duration of treatment is 24 weeks) for 24 week approvals
- Viral load results submitted upon completion and week 24 for 12 week approvals
- 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
- 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 10 and week 24 (week 10 results must be less than 25 IU/mL if duration of treatment is 24 weeks) for 24 week approvals
- Viral load results submitted upon completion and week 24 for 12 week approvals
- 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
Approval Criteria (continued)

For Zepatier®
- Diagnosis of Hepatitis C
- Must have Genotype 1 or 4 and if cirrhotic only a Child-Pugh score of A
- If Genotype 1A Must submit NS5A RAV polymorphism test results to determine if combined therapy with ribavirin is required and duration of treatment
- Adult patients age ≥ 18 years old
- Metavir fibrosis score equal to or greater than F3
- Metavir fibrosis scores F0-F2 with certain comorbidities
- Baseline viral load must be submitted
- For Genotype 1A treatment-naïve or PegIFN/RBV experienced without NS5A polymorphism at 28, 30, 31 or 93 – Zepatier 12 weeks duration
- For Genotype 1A treatment-naïve or PegIFN/RBV experienced with NS5A polymorphism at 28, 30, 31 or 93 – Zepatier + Ribavirin 16 weeks
- For Genotype 1B treatment-naïve or PegIFN/RBV experienced – Zepatier 12 weeks duration
- For Genotype 1A or 1B PegIFN/RBV/PI experienced – Zepatier + Ribavirin 12 wks
- For Genotype 4 treatment-naïve – Zepatier® 12 weeks duration
- For Genotype 4 PegIFN/RBV experienced – Zepatier® + Ribavirin duration 16 wks
- Maximum length of therapy approval of 12 weeks or 16 weeks based on the above
- For duration of 12 weeks Viral load results submitted at week 12 and week 24
- For duration of 16 weeks Viral load results submitted at week 16 and week 32
- Prescription claim for Zepatier® 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

For Daklinza®
- Diagnosis of Hepatitis C
- Must be prescribed with Sovaldi®
- For Genotype 1 non-cirrhotic or cirrhotic with Child-Pugh score of A trial and failure of Viekira Pak® or Zepatier®
- For Genotype 1 cirrhotic with Child-Pugh score of B or C or post-transplant a trial and failure of Harvoni® and must also be prescribed with ribavirin
- For Genotype 3 with cirrhosis must also be prescribed with ribavirin
- Adult patients age ≥ 18 years old
- Metavir fibrosis score equal to or greater than F3 for Genotype 1
- Metavir fibrosis scores F0-F2 with certain comorbidities for Genotype 1
- Metavir fibrosis score equal to or greater than F2 for Genotype 3
- Metavir fibrosis scores F0-F1 with certain comorbidities for Genotype 3
- Baseline viral load must be submitted
- Maximum length of therapy approval is 12 weeks (24 weeks with Clinical Consultant Approval)
- Prescription claim for Daklinza® 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
Approval Criteria (continued)

For Technivie®
- Diagnosis of Hepatitis C
- Must have Genotype 4 and non-cirrhotic
- Adult patients age ≥ 18 years old
- Should be prescribed with ribavirin for duration of 12 weeks unless the patient is treatment-naïve and cannot take or tolerate ribavirin.
- Metavir fibrosis score equal to or greater than F3
- Metavir fibrosis scores F0-F2 with certain comorbidities
- Baseline viral load must be submitted.
- Maximum length of therapy approval is 12 weeks
- Prescription claim for Technivie® with billed units = 56 tablets for 28 day supply
- No more than a 7 day gap between prior claim and incoming claim with a 168 day look back

For Harvoni®
- Diagnosis of Hepatitis C
- Must have Genotype 1, 4, 5 or 6
- If Genotype 1 - Trial and failure of Viekira Pak®, Viekira XR® or Zepatier® unless cirrhosis and Child-Pugh Score is B or C
- If Genotype 4 – Trial and failure of Technivie® or Zepatier® unless cirrhosis and Child-Pugh Score is B or C
- Adult patients age ≥ 18 years old
- Metavir fibrosis score equal to or greater than F3
- Metavir fibrosis scores F0-F2 with certain comorbidities
- 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 10 and week 24 (week 10 results must be less than 25 IU/mL) if duration is approved for 24 weeks
- Viral load results submitted upon completion and week 24 if duration is approved for 12 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
Approval Criteria (continued)

For Epclusa®
- Diagnosis of Hepatitis C
- Must have Genotype 1, 2, 3, 4, 5, 6
- If Genotype 1 without cirrhosis or with cirrhosis Child Pugh Score A – Trial and failure of Viekira Pak®, Viekira XR® or Zepatier®
- If Genotype 1 with cirrhosis Child Pugh Score B or C – Trial and failure of Harvoni®
- If Genotype 4 without cirrhosis – Trial and failure of Technivie®
- If Genotype 4 with cirrhosis Child Pugh Score A – Trial and failure of Zepatier®
- If Genotype 4 with cirrhosis Child Pugh Score B or C – Trial and failure of Harvoni®
- If Genotype 5 or 6 – Trial and failure of Harvoni®
- Adult patients age ≥ 18 years old
- Metavir fibrosis score equal to or greater than F3 for Genotype 1, 2, 4, 5, or 6
- Metavir fibrosis scores F0-F2 with certain comorbidities for Genotype 1, 2, 4, 5, or 6
- Metavir fibrosis score equal to or greater than F2 for Genotype 3
- Baseline viral load must be submitted
- Maximum length of therapy approval of 12 weeks
- Viral load results submitted upon completion and week 24
- Prescription claim for Epclusa® 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

For 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® or Zepatier®
- If Genotype 2 or 3 – a trial and failure of Epclusa®
- If Genotype 4 – a trial and failure of Zepatier® or Technivie®
- Metavir fibrosis score equal to or greater than F3 for Genotype 1, 2, or 4
- Metavir fibrosis scores F0-F2 with certain comorbidities for Genotype 1, 2, or 4
- Metavir fibrosis score equal to or greater than F2 for Genotype 3
- Baseline viral load must be submitted
- Must be prescribed with ribavirin or ribavirin + PEG
- Max length of therapy approval of 24 wks – 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®, Viekira XR® or Zepatier®
  - Must be prescribed with Ribavirin
  - Max approval 12 weeks
- Ongoing therapy – Must be submitted at week 12 and week 24:
  - Viral load results submitted and less than 25 IU/mL
For Sovaldi® (continued)
- 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.

Approval Criteria (continued)

For 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®, or Viekira XR® or Zepatier®
  - If Genotype 4
    - Trial and failure of Technivie® or Zepatier®
- Metavir fibrosis score equal to or greater than F3
- Metavir fibrosis scores F0-F2 with certain comorbidities
- 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:
  - 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

- Lack of appropriate diagnosis
- Less than 18 years of age
- Pregnancy
- Genotype 5 or 6
- Sovaldi® or Olysio® as monotherapy
- For Olysio® therapy for Genotype 1a with Q80K polymorphism
- Viral load greater than 25 IU/mL at treatment week 4 or beyond
- Combination of Sovaldi® and Olysio® for genotypes 2, 3, 4, 5 or 6
- Metavir fibrosis score\(^1\) of less than F3 for genotypes 1, 2 or 4
- Metavir fibrosis score\(^1\) of less than F2 for genotype 3
- For Olysio® therapy - previous treatment with an oral protease inhibitor indicated for HCV
- Lack of approval 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 Viekira XR® and Technivie®
  - Billed units on the claim <56 tablets for 28 days and
  - Billed units on the claim >56 tablets for 28 days
  - Gap in therapy >7 days from previous claim
- For Sovaldi®, Olysio®, Daklinza®, Zepatier®, Epclusa® 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®, Epclusa® and Harvoni®:
  - Lack of trial and failure of Viekira Pak®, Viekira XR®, or Zepatier® if treating genotype 1, Child Pugh Score A

\(^1\)In addition to Metavir fibrosis score, Clinical Consultant will review all therapy requests for documentation of comorbidities that may result in approval.
Appendix A

Defined Interferon Alpha Ineligible Patients *(include any of the following)*

- Intolerance to interferon alpha
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to peginterferon alfa or any of its components
- Decompensated hepatic disease
- Baseline neutrophil count below 1,500/µl
- Baseline platelet count below 90,000/µl
- Baseline hemoglobin below 10 g/dl
- The following clinical conditions – Subject to Clinical Consultant Review and must be actively treated
  - Major Depressive Disorder
  - Psychosis
  - Schizophrenia, Schizoaffective Disorder
  - Bipolar Disorder
  - Suicidal Ideation
  - Cardiac Disease
  - Myocardial Infarction
  - Congestive Heart Failure
  - Cardiac Arrhythmias

Drug Prior Authorization Hotline: (800) 392-8030