Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Hepatitis C Products- Commercial/Exchange**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: **December 2016**

Last P & T Committee Approval Date: *May 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for peginterferon alfa-2a (Pegasys), peginterferon alfa-2b (Peg), sofosbuvir (Sovaldi), \ledipasvir/sofosbuvir (Harvoni), Ombitasvir/ritonavir/paritaprevir/dasabuvir (Viekira Pak™), daclatasvir (Daklinza), ombitasvir/paritaprevir/ritonavir (Technivie), elbasvir/grazoprevir (Zepatier), sofosbuvir/velpatasvir (Epclusa), Mavyret (glecaprevir/pibrentasvir), Vosevi (sofosbuvir/velpatasvir/voxilaprevir), and Olysio (simeprevir).

DEFINITIONS

Child-Pugh Score- assessment scale used in clinical staging of cirrhosis

HBV- Hepatitis B Virus

HCV RNA (Hepatitis C Virus Ribonucleic Acid) – are fragments of the replicating hepatitis C virus which can be detected by testing to determine levels of hepatitis C virus in the body.

HIV- Human Immunodeficiency Virus

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Milan Criteria – a basis for selecting patients with hepatocellular carcinoma for liver transplant that have a favorable prognosis for cure

METAVIR Fibrosis Score – assessment of liver biopsy for fibrosis (scarring) associated with hepatitis C

Score	Description
F0	Chronic hepatitis without fibrosis
F1	Portal fibrosis without septae
F2	Portal fibrosis with few septae
F3	Septal fibrosis without cirrhosis
F4	Complete cirrhosis

Nonstructural Protein 3 (NS3) Protease Inhibitor- includes telaprevir (Incivek), boceprevir (Victrelis), and simeprevir (Olysio)

Nonstructural Protein 5A (NS5A) Inhibitor- includes daclatasvir (Daklinza), ledipasvir (in Harvoin), ombitasvir (in Technivie and Viekira), elbasvir (in Zepatier), and velpatasvir (in Epclusa)

NS5A Resistance-Associated Polymorphisms - genetic variations in the viral NS5A gene, which may result in resistance and decreased clinical response to treatment with NS5A inhibitors

Null Responders – less than 2–$\log_{10}$ reduction in HCV-RNA at week 12 of prior treatment with peginterferon alfa and ribavirin (dual therapy).

Partial Responder – achieved greater than or equal to 2–$\log_{10}$ decrease in HCV-RNA at week 12 but never achieved SVR with previous treatment with peginterferon alfa and ribavirin (dual therapy).

Relapser – A member who obtains an initial response to therapy (complete elimination of HCV-RNA) with medications in this policy, however upon discontinuation of the medications has a return elevation of HCV-RNA.

Sustained Virological Response 24 (SVR24) – An absence of serum HCV RNA 24 weeks following the discontinuation of hepatitis C therapy.

Sustained Virological Response 12 (SVR12) – An absence of serum HCV RNA 12 weeks following the discontinuation of hepatitis C therapy.

Transient Elastography (Fibroscan) – measures liver stiffness through low-amplitude elastic waves that travel through skin and intercostal space into the liver. Ultrasound is

used to track the shear wave and to measure its speed, which is correlated with the elasticity of the liver.

PREFERRED – PA REQUIRED	NON-PREFERRED – PA REQUIRED
Hepatitis C Agents	
Mavyret (glecaprevir/pibrentasvir)	Viekira Pak / Viekira XR (ombitasvir/paritaprevir/ritonavir/dasabuvir)
Harvoni (ledipasvir/sofosbuvir)	Sovaldi (sofosbuvir)
Epclusa (velpatasvir/sofosbuvir)	Olysio (simeprevir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Daklinza (daclatasvir)
	Technivie (ombitasvir/paritaprevir/ritonavir)
	Zepatier (elbasvir/grazoprevir)

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, peginterferon alfa-2a (Pegasys®), peginterferon alfa-2b (PegIntron®),sofosbuvir (Sovaldi™), ledipasvir/sofosbuvir (Harvoni®), Ombitasvir/ritonavir/paritaprevir/dasabuvir (Viekira Pak™), daclatasvir (Daklinza), ombitasvir/paritaprevir/ritonavir (Technivie), elbasvir/grazoprevir (Zepatier), sofosbuvir/velpatasvir (Epclusa), Mavyret (glecaprevir/pibrentasvir), Vosevi (sofosbuvir/velpatasvir/voxilaprevir), and Olysio (simeprevir) are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the general criteria and product-specific criteria:

1. General Criteria (applies to all drugs):

- Must have a diagnosis of chronic hepatitis C
- Must be prescribed by a specialist in: infectious disease, gastroenterology, hepatology, transplant, or HIV

- Must submit documentation describing an assessment of both the patient's ability to comply with prescribed hepatitis C regimen, as well as potential risk of reinfection
- For members with a history of substance abuse, the following documentation must be submitted:
    - Documentation of prescriber counseling regarding the risk of alcohol or IV drug abuse and an offer of a referral for substance abuse disorder treatment.
- Member must have evidence of advanced disease, as defined as having one of the following:
    - Liver biopsy or fibrosis assessment confirming a fibrosis score of F2 to F4. Chart documentation of liver biopsy or fibrosis assessment within the past 3 years is required.
    - Transient Elastography (Fibroscan) must be ≥7.0 kPa Chart documentation of result is required.
    - Ultrasound, CT scan, or MRI confirming evidence of cirrhosis of the liver. Chart documentation of result confirming presence of cirrhosis is required.
    - An exception to the above advanced disease requirement can be made for members with one of the following:
        - Evidence of type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis). Chart documentation is required.
        - Evidence of proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis. Chart documentation is required.
        - HIV or HBV coinfection
        - History of liver transplant
- Must have a quantifiable hepatitis C virus titer (HCV RNA) at baseline. Chart documentation of baseline HCV RNA level, including date and reference range for assay, must be submitted.
- Must submit chart documentation of laboratory genotype result.

2. Mavyret:

- Must be age 18 years or older
- Must not have severe hepatic impairment (Child-Pugh C)
- Must not be used concomitantly with atazanavir or rifampin
- Approval length:

Mavyret Approval Length	
8 weeks	• GT 1, 2, 3, 4, 5, or 6, treatment-naïve, without cirrhosis • GT 1, 2, 3, 4, 5, or 6, previously treated with PEG-INF, RBV, or sofosbuvir (no prior experience with an NS5A or NS3/4A inhibitor), without cirrhosis
12 weeks	• GT 1, 2, 3, 4, 5, or 6, treatment-naive, with compensated cirrhosis (Child-Pugh A)

Mavyret Approval Length	
	• Genotype 1, 2, 4, 5, or 6, previously treated with PEG-INF, RBV, or sofosbuvir (no prior experience with an NS5A or NS3/4A inhibitor), with compensated cirrhosis (Child-Pugh A) • GT 1, previously treated with NS3/4A protease inhibitor, not previously treated with NS5A inhibitor, without cirrhosis or with compensated cirrhosis (Child-Pugh A)
16 weeks	• GT1, previously treated with NS5A inhibitor, not previously treated with NS3/4A protease inhibitor, without cirrhosis or with compensated cirrhosis (Child-Pugh A) • GT 3, previously treated with PEG-INF, RBV, or sofosbuvir (no prior experience with NS5A or NS3/4A inhibitor), without cirrhosis or with compensated cirrhosis (Child-Pugh A)

3. Epclusa:

- Must be age 18 years or older
- Must not be used in combination with ribavirin if member has a contraindication to ribavirin
- Must not have severe renal impairment/end stage renal disease (Creatinine Clearance < 30 mL/min)
- Approval length:

Epclusa Approval Length	
12 weeks	• GT 1, 4, 5, 6 without cirrhosis or with compensated cirrhosis; treatment naïve or PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced • GT 2 and 3 without cirrhosis or with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced
12 weeks + RBV	• GT 2 and 3 without cirrhosis or with compensated cirrhosis; Sofosbuvir + RBV experienced • GT 3 with compensated cirrhosis; PEG-INF + RBV experienced • GT 3 with compensated cirrhosis; treatment naïve; Y93H variant associated with velpatasvir resistance • GT 3 without cirrhosis; PEG-INF + RBV experienced; Y93H variant associated with velpatasvir resistance
24 weeks	• GT 1 and 4 with ***decompensated*** cirrhosis and RBV ineligible
24 weeks + RBV	• GT 1 and 4 with ***decompensated*** cirrhosis; sofosbuvir or NS5A inhibitor experienced

4. Harvoni:

- Must be 12 years of age or older
- Must have genotype (GT) 1, 4, 5, or 6
- Must not be used in combination with ribavirin if member has a contraindication to ribavirin
- Must not have severe renal impairment/end stage renal disease (Creatinine Clearance < 30 mL/min)
- Approval length:

Harvoni Approval Length	
8 weeks	• GT 1 without cirrhosis; treatment naïve; pre-treatment HCV RNA below 6 million IU/mL
12 weeks	• GT 1 and 4 without cirrhosis or with compensated cirrhosis; treatment naïve • GT 1 and 4 without cirrhosis; PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced • GT 5 and 6 without cirrhosis or with compensated cirrhosis; treatment naïve or PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced
12 weeks + RBV	• GT 1 and 4 with compensated cirrhosis; PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced • GT 1 without cirrhosis; Sofosbuvir + RBV ± PEG-INF experienced • GT 1 and 4 with *decompensated* cirrhosis • GT 1 and 4 with recurrent infection post liver transplantation
24 weeks	• GT 1 and 4 with compensated cirrhosis; PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced • GT 1 and 4 with *decompensated* cirrhosis and RBV ineligible • GT 1 and 4 with recurrent infection post liver transplantation and RBV ineligible; treatment naïve
24 weeks + RBV	• GT 1 with compensated cirrhosis; Sofosbuvir + RBV ± PEG-INF experienced • GT 1 with compensated cirrhosis; Simeprevir ± RBV experienced; without NS5A variant associated with ledipasvir resistance • GT 1 with compensated cirrhosis; NS5A inhibitor experienced; without NS5A variant associated with ledipasvir resistance • GT 1 and 4 with *decompensated* cirrhosis; Sofosbuvir-containing regimen experienced

5. Vosevi:

- Must be 18 years of age or older

- Must not have severe renal impairment/end stage renal disease (Creatinine Clearance < 30 mL/min)
- Must not have moderate to severe hepatic impairment (Child Pugh B or C)
- Must not be used concomitantly with rifampin
- Approval length:

Vosevi Approval Length	
12 weeks	• GT 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A); previously treated with an NS5A inhibitor • GT 1a or 3 previously treated with sofosbuvir without an NS5A inhibitor

6. Zepatier:

- Must be age 18 years or older
- Must not have moderate or severe hepatic impairment (Child Pugh B or C)
- Must not be used in combination with ribavirin if member has a contraindication to ribavirin
- Must not be used concomitantly with any of the following products:
    - OATP1B1/3 inhibitors such as:
        - Atazanavir (Reyataz)
        - Darunavir (Prezista)
        - Lopinavir (with ritonavir in Kaletra)
        - Saquinavir (Invirase)
        - Tipranivir (Aptivus)
    - CyclosporineStrong CYP3A inducers such as:
        - Phenytoin, carbamazepine
        - Rifampin
        - St. John's Wort
        - Efavirenz (Sustiva)
- Must have genotype (GT) 1 or 4
- For genotype 1a: must be assessed for NS5A resistance- associated polymorphism prior to initiation of treatment (documentation of result is required)
- Must have documentation for intolerance, contraindication, or clinical reasons (such as severe hepatic impairment) not to use Mavyret, Epclusa, Harvoni, and Vosevi
- Approval length:

Zepatier Approval Length	
12 weeks	• GT 1a without cirrhosis or with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced; without NS5A polymorphisms • GT 1b or 4 without cirrhosis or with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced
12 weeks + RBV	• GT 1a without cirrhosis or with compensated cirrhosis; PEG-INF + RBV + boceprevir/simeprevir/telaprevir experienced; without NS5A polymorphisms • GT 1b without cirrhosis or with compensated cirrhosis; PEG-INF + RBV + boceprevir/simeprevir/telaprevir experienced
16 weeks + RBV	• GT 1a without cirrhosis or with compensated cirrhosis; treatment naïve or PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced; with NS5A polymorphisms • GT 4 without cirrhosis or with compensated cirrhosis; PEG-INF + RBV experienced

7. Daklinza:

- Must be 18 years of age or older
- Must not be used concomitantly strong inducers of CYP3A such as:
  - Phenytoin, carbamazepine
  - Rifampin
  - St. John's Wort
- Must have genotype (GT) 1, 2, 3, or 4
- Must have documentation for intolerance, contraindication, or clinical reasons (such as severe hepatic impairment) not to use Mavyret, Epclusa, Harvoni, and Vosevi
- Must be used in combination with Sovaldi
- Approval length:

Daklinza Approval Length	
12 weeks	• GT 1 without cirrhosis; treatment naïve or PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced • GT 2 and 3 without cirrhosis; treatment naïve or PEG-INF + RBV experienced • GT 3 without cirrhosis; Sofosbuvir + RBV experienced
12 weeks + RBV	• GT 3 without cirrhosis; PEG-INF + RBV experienced; Y93H variant associated with daclatasvir resistance

Daklinza Approval Length	
	• GT 1, 2, 3, 4 with *decompensated* cirrhosis • GT 1, 2, 3, 4 with recurrent infection post liver transplantation
24 weeks	• GT 1 with compensated cirrhosis; treatment naïve or PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced • GT 2 with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced • GT 2 without cirrhosis or with compensated cirrhosis; Sofosbuvir + RBV experienced • GT 3 with compensated cirrhosis; treatment naïve • GT 1 and 4 with *decompensated* cirrhosis and RBV ineligible • GT 1 and 4 with recurrent infection post liver transplantation and RBV ineligible; treatment naïve • GT 2 and 3 with recurrent infection post liver transplantation and RBV ineligible
24 weeks + RBV	• GT 1 with compensated cirrhosis; treatment naïve or PEG-INF + RBV ± boceprevir/simeprevir/telaprevir experienced • GT 2 without cirrhosis or with compensated cirrhosis; Sofosbuvir + RBV experienced • GT 3 with compensated cirrhosis; treatment naïve or PEG-INF + RBV or Sofosbuvir + RBV experienced

8. Sovaldi:

- Must be 12 years of age or older
- Must not have severe renal impairment/end stage renal disease (Creatinine Clearance < 30 mL/min)
- Must not be used in combination with ribavirin and/or peginterferon alfa if member has a contraindication to any product in the combination
- Must not have been previously treated with a regimen containing sofosbuvir (i.e. Sovaldi, Harvoni, Epclusa)
- Must have genotype (GT) 1, 2, 3, or 4
- Must have documentation for intolerance, contraindication, or clinical reasons (such as severe hepatic impairment) not to use Mavyret, Epclusa, Harvoni, and Vosevi
- Approval length: Only approve Sovaldi when Daklinza or Olysio is approved
    - With Daklinza: up to 24 weeks
    - With Olysio and compensated cirrhosis: up to 24 weeks
    - With Olysion and without cirrhosis: up to 12 weeks

9. Olysio (Exchange/SGFI ONLY)

- Must be 18 years of age or older
- Must have genotype (GT) 1
    - Must not have GT 1a with Q80K polymorphism
- Must have documentation for intolerance, contraindication, or clinical reasons (such as severe hepatic impairment) not to use Mavyret, Epclusa, Harvoni, and Vosevi
- Must be used with ONE of the following:
    - Ribavirin and Peg-interferon, OR
    - Sovaldi
- Approval length:
    - With compensated cirrhosis: up to 24 weeks
    - Without cirrhosis: up to 12 weeks

10. Technivie:

- Must be 18 years of age or older
- Must not have moderate to severe hepatic impairment
- Must not be used in combination with ribavirin if member has a contraindication to ribavirin
- Must not have known hypersensitivity to ritonavir
- Must not be used concomitantly with any moderate or strong inducers of CYP3A such as:
    - Alfuzosin HCL
    - Colchicine
    - Ranolazine
    - Carbamazepine, phenytoin, phenobarbital
    - Rifampin
    - Lurasidone
    - Pimozide
    - Ergotamine, dihydroergotamine, methylergonovine
    - Ethinyl estradiol-containing medications such as combined oral contraceptives
    - Cisapride
    - St. John’s Wort
    - Atorvastatin, lovastatin, simvastatin
    - Everolimus, sirolumus, tacrolimus
    - Efavirenz (Sustiva)

  - Sildenafil (PAH dosing)
  - Triazolam, orally administered midazolam
- Must have genotype (GT) 4
- Must have documentation for intolerance, contraindication, or clinical reasons (such as severe hepatic impairment) not to use Mavyret, Epclisa, Harvoni, and Vosevi
- Approval length: 12 weeks

11. Viekira Pak/XR:

- Must be 18 years of age or older
- Must not have moderate to severe hepatic impairment
- Must not be used in combination with ribavirin if member has a contraindication to ribavirin
- Must not have known hypersensitivity to ritonavir
- Must not be used concomitantly with any moderate or strong CYP3A inducers and strong inducers or inhibitors of CYP2C8 such as:
  - Alfuzosin HCL
  - Ranolazine
  - Dronedarone
  - Carbamazepine, phenytoin, phenobarbital
  - Colchicine
  - Gemfibrozil
  - Rifampin
  - Lurasidone
  - Pimozide
  - Ergotamine, dihydroergotamine, methylergonovine
  - Ethinyl estradiol-containing medications such as combined oral contraceptives
  - Cisapride
  - St. John’s Wort
  - Atorvastatin, lovastatin, simvastatin
  - Everolimus, sirolimus, tacrolimus
  - Efavirenz (Sustiva)
  - Sildenafil (PAH dosing)
  - Triazolam, orally administered midazolam
- Must have genotype (GT) 1 or 4

- Must have documentation for intolerance, contraindication, or clinical reasons (such as severe hepatic impairment) not to use Mavyret, Epclusa, Harvoni, and Vosevi
- Approval length:

Viekira Pak / Viekira XR Approval Length	
12 weeks	• GT 1b without cirrhosis or with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced
12 weeks + RBV	• GT 1a without cirrhosis; treatment naïve or PEG-INF + RBV experienced • Mixed GT 1 without cirrhosis; treatment naïve or PEG-INF + RBV experienced • GT 1 (unknown subtype) without cirrhosis; treatment naïve or PEG-INF + RBV experienced
24 weeks + RBV	• GT 1a with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced • Mixed GT 1 with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced • GT 1 (unknown subtype) with compensated cirrhosis; treatment naïve or PEG-INF + RBV experienced • GT 1 with recurrent infection post liver transplantation; METAVIR score of 2 or lower

12. Ribavirin

- Must not be a female member who is pregnant or a male member with a female partner who is pregnant

13. Peginterferon

- Must be at least 3 years of age
- Must not have any of the following illnesses or conditions, which are contraindications for the use of peginterferons:
  - Autoimmune hepatitis or other conditions known to be exacerbated by interferon
  - Known hypersensitivity to alpha interferons
  - Hepatic decompensation in patients with cirrhosis
- For members meeting applicable criteria, approval is granted for peginterferon alfa-2b (PegIntron)

  - Peginterferon alfa-2a (Pegasys) may be approved for members who meet criteria AND who have had an adequate trial of peginterferon alfa-2b (PegIntron) with an inadequate response or significant side effects/toxicity or a contraindication to this therapy
- Approval length: 48 weeks (with ribavirin) for pediatric members (all genotypes)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	See each category for specific approval length
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Revised criteria and separation of CVS client policy to RX.062.1	*12/16*
Annual Review	*02/17, 02/18*
Addition of Vosevi and Mavyret and adoption as policy for all Commercial/Exchange clients	*12/17*
Revised Fibroscan criteria. Addition of Olysio	*05/18*