SUBJECT: Chronic Hepatitis C (Pegasys, Peg- Intron, Ribavirin, Victrelis, Olysio, Sovaldi, Harvoni, Viekira, Daklinza, Zepatier).

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DESCRIPTION:

Hepatitis C Drug Coverage Criteria – For all Regimens (see individual drugs for drug specific requirements)

Based upon our assessment of the peer-reviewed literature, the drugs for Hepatitis C have been medically proven to be effective and therefore medically necessary in the treatment of Chronic Hepatitis C.

The request for coverage must meet ALL of the following criteria:

1. Treatment must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or HCV/HIV specialist.
   a. Treatment may also be prescribed by a Primary Care Provider if they have received additional training in the treatment and management of Hepatitis C and/or are working in conjunction with one of the above specialists.

2. HCV genotype and quantitative baseline viral load must be provided with a collection date within twelve months before the start of therapy.
   A. If a patient has received hepatitis c treatment within the past 12 months, recent genotype test results taken after the completion of the previous treatment regimen, will be required to rule out re-infection.

3. Disease Severity and liver/ risk documentation - While disease severity criteria or Fibrosis scores are not considered a threshold for coverage decisions, documentation of those scores is requested to aid in the evaluation and for case reporting and documentation. The following testing results can be used:
   a. Liver biopsy confirming a METAVIR score
   b. Ishak score
   c. Transient elastography (Fibroscan) score
   d. FibroTest (FibroSURE) score
   e. Radiological imaging demonstrating cirrhosis (e.g. evidence of portal hypertension or ascites)

OR

A. Documentation of high risk conditions for liver-related complications would include the following:

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1. HIV coinfection where **HIV viral load must be <200 copies/mL for the past 6 months**

2. Patients co-infected with HBV **with detectable viremia**

3. Other coexistent liver disease (e.g., nonalcoholic steatohepatitis)

4. Type 2 diabetes mellitus with evidence of F1 fibrosis or higher

5. Porphyria cutanea tarda

6. Persons who have undergone a liver transplant

7. Debilitating fatigue impacting quality of life (e.g., secondary to extra-hepatic manifestations and/or liver disease)

8. Healthcare worker whose daily activities put them in contact with blood and/or needles

9. Extrahepatic manifestations as defined:
   
   1. Cryoglobulinemia – must have lab work to confirm presence of cryoglobulins AND physical symptoms (such as vasculitis, blotching skin, joint pain, peripheral neuropathy, Reynaud’s, Behcet’s) OR Neutropenia OR Thrombocytopenia (<100,000 cells/uL) OR Glomerulonephritis

4. Must demonstrate treatment readiness and ability to adhere to drug regimen.

   A. Patients must be **abstinent from substance abuse (Including IV drug, marijuana, or Alcohol use) for 3 months.** Physician attestation and urine testing documentation must be provided. For Ribavirin-containing regimens, female patients of child bearing potential must have a negative pregnancy test collected within 30 days prior to the initiation of therapy OR Medical records must be submitted documenting pregnancy status.
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5. Patients with limited life expectancy (<12 months due to non-liver related comorbidities) are not covered. Per AASLD guidelines, HCV therapy would not improve symptoms or prognosis in this patient population and do not require treatment.

6. Progress notes are required on all new starts and re-certifications.

7. For patients requiring peg-interferon therapy, Pegasys will be the required product in place of Peg-Intron.

8. Per IDSA/AASLD guidelines, Victrelis regimens are not recommended for any indication and therefore will only be authorized if there is documentation of a serious adverse reaction or contraindication to Olysio.

9. Patients who are previously cured will not be covered for any treatment upon reinfection.

POLICY GUIDELINES:

1. Prior-authorization is required for the Hepatitis C drug coverage.

2. Cirrhosis as defined as any one of the following:
   a. Liver biopsy showing cirrhosis (e.g., Metavir score = 4 or Ishak score ≥ 5) OR
   b. FibroTest® score of > 0.75 AND an APRI > 2 OR
   c. Nodular liver morphology on abdominal ultrasound or CT scan.

3. In the absence of a definitive diagnosis of presence or absence of cirrhosis by the above criteria, a liver biopsy is required; liver biopsy results will supersede blood test results and be considered definitive.

4. Ineligibility to ribavirin is defined as:
   a. Neutrophils < 750 cells/mm³, results within the past month
   b. Hemoglobin < 10g/dL, results within the past month
   c. Platelets < 50 000 cells/ mm³, results within the past month
   d. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by Ribavirin.

5. Ineligibility to interferon therapy are defined as:

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a. comorbid autoimmune hepatitis or other autoimmune disorders or
b. decompensated hepatic disease or history of preexisting cardiac disease or
c. a baseline neutrophil count below 1500/μL or
d. a baseline platelet count below 90,000/μL or
e. baseline hemoglobin below 10 g/dL or
f. major uncontrolled depressive illness despite pharmacologic treatment, or
g. severe intolerance to past IFN therapy (such as urticaria, angioedema, broncho constriction, anaphylaxis, Stevens-Johnson syndrome, ophthalmologic disorder, thyroid disorder or refractory diabetes mellitus).

6. No early refills will be allowed without a prior authorization to document necessity.
7. Treatment regimens that are not listed within the policy will be evaluated based on current treatment guidelines for safety and efficacy.
   a. Treatment regimens must be listed as a class IIa or higher recommendation in the AASLD HCV guidance or DrugDex to be considered for coverage.
8. Triple therapy with Olysio is not recommended for any genotype and therefore is not included in the policy.

Recertification Criteria
1. Patient must be compliant with the treatment drug(s) on recertification documented by progress notes and fill history.
   a. Recertification for any genotype requires a viral load of ≥ 2 log reduction in HCV RNA from baseline collected two or more weeks after starting therapy. AND
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b. No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.

2. Requests for treatment durations longer than any FDA or guideline approved duration will be reviewed as off-label.

INDIVIDUAL POLICY GUIDELINES:

Zepatier (elbasvir and grazoprevir tablets):
Note: Zepatier is the preferred drug within its approved/guideline indications.

Coverage Criteria

- Patient must have genotype 1 or 4 and must be 18 years or older
  - For genotype 1 patients, the specific subtype (genotype 1a or 1b) must be provided.
- Zepatier will not be covered for patient with moderate or severe hepatic impairment (Child-Pugh B or C).
- Zepatier will not be covered when being prescribed in patients who are on OATP1B1/3 inhibitors, strong CYP3A inducers, or efavirenz. e.g. carbamazepine, cyclosporine, phenytoin, rifampin

1. For genotype 1a patients:
   a. For treatment naïve or peg-interferon/ribavirin experienced patients without baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93, approval will be for 12 weeks of Zepatier monotherapy.
   b. For treatment naïve or peg-interferon/ribavirin experienced patients WITH baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93, approval will be for 16 weeks in combination with ribavirin.
   c. For genotype 1a patients who are Peg-interferon/ribavirin/protease inhibitor
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experience, approval will be for 12 weeks of Zepatier in combination with Ribavirin.

2. For genotype 1b patients who are treatment naive or peg-interferon/ribavirin experienced, approval will be for 12 weeks of Zepatier monotherapy.

3. For genotype 1b patients who are peg-interferon/ribavirin/protease inhibitor experienced, approval will be for 12 weeks in combination with ribavirin.

4. For genotype 4 patients who are treatment naive, approval will be for 12 weeks of Zepatier monotherapy.

5. For genotype 4 patients who are peg-interferon/ribavirin experienced, approval will be for 16 weeks of Zepatier in combination with ribavirin.
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Harvoni (ledipasivi/sofosbuvir tablets):

Note: Coverage of Harvoni requires documentation/description of failure of Zepatier, clinical inappropriateness of Zepatier or inability to tolerate Zepatier.

Coverage Criteria
1. Patient is at least 18 years old
2. Diagnosis of chronic hepatitis C, genotype 1, 4, 5, or 6
3. Harvoni is being prescribed by a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g. hepatologist)
4. Patient does not have end stage renal disease or require dialysis (not covered if CrCl <30ml/min)
5. Patient been counseled regarding the potential for antacids, H2 blockers and proton pump inhibitors, including over-the-counter (OTC) medications, to decrease the efficacy of Harvoni
6. Patient is not currently taking any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simprevir, or sofosbuvir
7. Patient’s liver disease staging has been documented within the past 3 years using one of the following tests:
   a. Liver biopsy confirming a METAVIR score
   b. Ishak score
   c. Transient elastography (Fibroscan) score
   d. FibroTest (FibroSURE) score
   e. Radiological imaging demonstrating cirrhosis (e.g. evidence of portal hypertension or ascites)
8. HCV RNA viral load taken within the past 3 months
9. If patient has cirrhosis and is treatment-experienced, Harvoni will be taken in combination with ribavirin
10. Patient does not have decompensated cirrhosis
11. Patient was not previously treated with sofosbuvir-containing regimen
12. If patient is co-infected with HIV (in addition to criteria above):
   o Patient’s antiretroviral regimen is being managed by a physician

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During treatment with Harvoni, the patient will NOT be taking an antiretroviral regimen containing cobicistat (Tybost), elvitegravir (Vitekta) or tipranavir (Aptivus), including Striult (elvitegravir, cobicistat, tenofovir and emtricitabine)

If during treatment with Harvoni, the patient will be taking an antiretroviral regimen containing tenofovir (Viread) or an HIV protease inhibitor boosted by ritonavir (Norvir), the patient’s creatinine clearance (CrCl) is greater than 60mL/min

- If patient has recurrent HCV post-liver transplantation (in addition to criteria above):
  - Harvoni will be taken in combination with ribavirin
  - Note: fibrosis staging criteria do not apply to patients who have previously received a liver transplant.

13. Harvoni will be approved for individuals with hepatocellular carcinoma:

  - Must be managed in a liver transplant center
  - Must be awaiting liver transplantation (patient is on the list for liver transplant)
  - Patient meets Milan criteria defined as all of the following:
    - Presence of a tumor 5 cm or less in diameter in subjects with single hepatocellular carcinoma
    - No more than three tumor nodules, each 3 cm or less in diameter, in subjects with multiple tumors
    - No extrahepatic manifestation of cancer and no evidence of vascular invasion of the tumor.

<table>
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<th>Prior treatment status</th>
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<td>12 weeks</td>
</tr>
<tr>
<td>Recurrent HCV post-liver transplant</td>
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</table>

**Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)**

Note Coverage of Viekira Pak requires documentation/description of failure of Zepatier, clinical inappropriateness of Zepatier or inability to tolerate Zepatier.

**Coverage Criteria:**
1. Patient must have genotype 1 and must be 18 years or older
2. Must have compensated liver disease (Child-Pugh A). Moderate to severe hepatic impairment is a contraindication (Child-Pugh B and C).
4. Drug interactions must be assessed. Strong inducers of CYP3A and CYP2C8; and strong inhibitors of CYP2C8 are contraindicated.
5. Must be naïve to Viekira.
6. Viekira is covered as monotherapy or in combination with ribavirin only.
7. For indeterminate or mixed genotype 1, follow the genotype 1A dosing guidelines.
8. Please see policy guidelines for definition of cirrhosis.
9. For genotype 1A with or without cirrhosis, approval is for 12 weeks in combination with ribavirin. This includes treatment experienced patients who had a partial response or relapse on prior HCV therapy.

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a. Requests for 24 weeks of treatment are only approved for genotype 1A patients with cirrhosis who is a null responder to previous HCV therapy. Documentation of null response to HCV therapy is needed.

10. For genotype 1B without cirrhosis, approval is for 12 weeks monotherapy

11. For genotype 1B with cirrhosis, approval is for 12 weeks in combination with ribavirin

12. For post-liver transplant, patient must have mild fibrosis (Metavir fibrosis score 2 or lower). Approval is for 24 weeks in combination with ribavirin.

13. Viekira pak will not be authorized for new starts unless there is documentation of severe intolerance (that prevents completion of therapy) with Zepatier

Sovaldi (sofosbuvir tablet) Based Regimens

Note Coverage of Sovaldi Based Regimens requires documentation/description of failure of Zepatier, clinical inappropriateness of Zepatier or inability to tolerate Zepatier.

Coverage Criteria

- Patient must be 18 or older

- Must be naïve to Sovaldi. This includes patients who have not completed a course of therapy due to an adverse reaction or for other reasons.

- Sovaldi will not be authorized as monotherapy.

- The safety and efficacy of Sovaldi is not recommended in patients with severe renal impairment/ESRD (CrCl <30 mL/min) or hemodialysis-patients in treatment guidelines and therefore is not covered.

1. For genotype 1, Sovaldi is not covered based on IDSA/AASLD guidelines because newer and safer therapies are available for this genotype.
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2. For **genotype 2**, Sovaldi will be authorized as **dual therapy in combination with ribavirin** for completion of therapy (12 weeks from the start date).

3. For **genotype 3**, Sovaldi will be authorized as **triple therapy with Pegasys and ribavirin** for an **initial approval of 6 weeks**. Recertification is approved until the completion of therapy (12 weeks from the start date). This regimen is recommended in the IDSA/AASLD guidelines as a more effective and a shorter duration of therapy than the standard dual Sovaldi/Ribavirin for 24 weeks.

4. For **genotype 3**, please note the preferred regimen for interferon ineligible individuals is a combination of Sovaldi/Daklinza for 12 weeks. However, Sovaldi will be authorized as **dual therapy in combination with ribavirin** for those that are **ineligible to receive interferon (IFN)**, if they meet one of the following conditions:

   - Patient has cirrhosis (please see policy guidelines for a definition of cirrhosis OR
   - Patient is on moderate CYP3A inducers and is unable to take a standard dose of Daklinza 60mg daily.
   - **Initial approval will be for 6 weeks**. Recertification is approved until the completion of therapy (24 weeks from the start date).

Please see policy guidelines for definition of those who are considered interferon ineligible

5. For **genotype 4**, Sovaldi will be authorized as **triple therapy** in combination with peg-interferon (Pegasys) and ribavirin for **12 weeks** for the completion of therapy.

6. For **genotype 5, or 6**, Sovaldi will be authorized as **triple therapy** in combination with peg-interferon (Pegasys) and ribavirin for an **initial approval of 6 weeks**. Recertification is approved until the completion of therapy (12 weeks from the start date).

7. Sovaldi will be approved as **dual therapy** in combination with ribavirin for individuals...
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with hepatocellular carcinoma. Initial approval will be for 12 weeks or until the time of transplantation (whichever is less).

- Must be managed in a liver transplant center.
- Must be awaiting liver transplantation (patient is on the list for liver transplant)
- Patient meets Milan criteria defined as all of the following:
  - Presence of a tumor 5 cm or less in diameter in subjects with single hepatocellular carcinoma.
  - No more than three tumor nodules, each 3 cm or less in diameter, in subjects with multiple tumors
  - No extrahepatic manifestation of cancer and no evidence of vascular invasion of the tumor.

- Recertification will be required every 12 weeks with a maximum length of therapy of 48 weeks regardless of liver transplant status.

Daklinza (daclatasvir)/Sovaldi (sofosbuvir) combination

Note: Coverage of Daklinza/Sovaldi Based regimens requires documentation/description of failure of, clinical inappropriateness of or inability to tolerate Zepatier, Harvoni or Viekira Pak options.

Coverage Criteria

1. Daklinza will not be authorized as monotherapy

2. Daklinza is contraindicated in combination with drugs that strongly induce CYP3A and may lead to lower exposure and loss of efficacy. These medications include phenytoin, carbamazepine, rifampin, and St. John’s wort.

3. For genotype 3 patients without cirrhosis, who are ineligible to receive interferon, Daklinza will be authorized in combination with sofosbuvir at a dosage of 60mg (standard dose) or 30mg (reduced dose) for 12 weeks. For those individuals who are
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interferon eligible, please see the Sovaldi guidelines for the recommended regimen.

a. For patients taking moderate CYP3A inducers who require a 90mg dose, this increased dosage will only be considered for patients who are Ribavirin ineligible and cannot take dual therapy with Sovaldi and Ribavirin for 24 weeks.

4. Due to the availability of other more cost-effective FDA approved treatment regimens, Daklinza will NOT be covered for genotype 1 patients.

5. For genotype 2 patients, who are treatment naïve, Daklinza and sofosbuvir will only be approved for 12 weeks in patients who are ineligible to receive Ribavirin. Please see policy guidelines for definition of those who are considered ribavirin ineligible.

6. For genotype 2 patients, who have previously failed sofosbuvir and ribavirin treatment, Daklinza will be authorized in combination with sofosbuvir in patients who are ineligible to receive interferon. Please see policy guidelines for a definition of those who are considered interferon ineligible.

7. Initial approval will be for 6 weeks. Recertification is approved until the completion of therapy (24 weeks from the start date).

Technivie (ombitasvir, paritaprevir, and ritonavir tablets)

Note: Coverage of Technivie Based Regimens requires documentation/description of failure of, clinical inappropriateness of or inability to tolerate Zepatier, Harvoni or Viekira Pak options.

Coverage Criteria:

- Must have compensated liver disease (Child-Pugh A). Moderate to severe hepatic impairment is a contraindication (Child-Pugh B and C).

1. For Genotype 4 patients, without cirrhosis, approval will be for 12 weeks in

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combination with Ribavirin.

2. Due to higher relapse rates, Technivie will only be authorized as monotherapy in genotype 4 patients who are treatment Naïve AND who are ineligible to receive Ribavirin.

Please see policy guidelines for definition of those who are considered ribavirin ineligible.

SOVALDI / OLYSIO COMBINATION (sofosbuvir / simeprevir)

Note: Coverage of Sovaldi/Olysio Based regimens requires documentation/description of failure of, clinical inappropriateness of or inability to tolerate Zepatier, Harvoni or Viekira Pak options.

Coverage Criteria:

1. For Genotype 1, will be authorized as combination therapy for those that are ineligible to receive interferon (IFN) for an initial approval of 6 weeks. Please see policy guidelines for definition of those who are considered interferon ineligible. Recertification is approved until the completion of therapy (12 weeks from the start date).

2. This regimen will not be approved for patients who had therapeutic failure to any protease inhibitor (Incivek, Victrelis, Olysio).

3. Simeprevir use is limited to patients with compensated liver disease (Child-Pugh Class A). T4. This regimen will not be authorized for individuals with moderate to severe liver impairment (Child-Pugh Class B or C).

4. All other genotypes (2-6) utilizing Sovaldi/Olysio combination will be evaluated as off-label.

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References

1. Pegasys prescribing information- Hoffmann-Roche, Inc. May 2013
2. Peg-Intron prescribing information - Schering Corporation April 2008
10. Incivek Prescribing Information – Vertex Pharmaceuticals, April 2013

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16. www.europeanaidsclinicalsocociety.org/
23. www.hep-druginteractions.org/

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30. Technivie Prescribing Information- AbbVie Inc. August 2015


