Hepatitis C

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-249-6155**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____Date: _____
Patient's ID: _____Patient's Date of Birth: _____
Physician's Name: _____
Specialty: _____ NPI#: _____
Physician Office Telephone: _____Physician Office Fax: _____
Request Initiated For: _____

1. What is the prescribed regimen for patient's course of treatment?
   Indicate ALL drugs for this course of treatment.
   - ❑ Epclusa
   - ❑ Harvoni
   - ❑ Mavyret
   - ❑ Pegasys
   - ❑ Ribasphere RibaPak
   - ❑ ribavirin
   - ❑ Sovaldi
   - ❑ Viekira Pak
   - ❑ Vosevi
   - ❑ Zepatier
   - ❑ sofosbuvir/velpatasvir (generic Epclusa)
   - ❑ ledipasvir/sofosbuvir (generic Harvoni)
   - ❑ Other _____

2. What is the ICD-10 code? _____

3. What is the diagnosis?
   - ❑ Chronic hepatitis C
   - ❑ Acute hepatitis C
   - ❑ Hairy cell leukemia
   - ❑ Erdheim-Chester disease
   - ❑ Chronic myeloid leukemia in pregnancy
   - ❑ Systemic mastocytosis, *skip to Section H.*
   - ❑ Adult T-cell leukemia/lymphoma, *skip to Section H.*
   - ❑ Mycosis fungoides/Sezary syndrome, *skip to Section H.*
   - ❑ Chronic hepatitis B virus (HBV) infection, including hepatitis D virus (HDV) co-infection, *no further questions.*
   - ❑ Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower risk myelofibrosis), *skip to Section H.*
   - ❑ Primary cutaneous CD30+ T-cell lymphoproliferative disorders, *skip to Section H.*
   - ❑ Other _____

Section A: Preferred Product - *complete the following section if generic sofosbuvir/velpatasvir or ledipasvir/sofosbuvir is bring prescribed*

1. The preferred products for your patient's health plan are brand-name Epclusa and Harvoni. *Please note that the generic versions are not available on your patient's plan, but they would have access to the brand-name version.* Can the patient's treatment be switched to brand Epclusa or Harvoni?
   If Yes, skip to Section E: All Requests. ❑ Yes - Brand Epclusa ❑ Yes - Brand Harvoni
   - ❑ No - continue request for non-preferred product
   - ❑ Not applicable - prescribed medication is not listed above, *skip to next section.*

Send completed form to: Case Review Unit, CVS Caremark Prior Authorization Fax: 1-866-249-6155

2. Given that brand-name Epclusa/Harvoni and their respective generics are the same products, is there a documented clinical reason that the patient must use generic over brand? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).*** ❑ Yes ❑ No

Section B: Preferred Product - *complete the following section if Viekira PAK or Zepatier is prescribed*

1. Is the patient currently receiving treatment with the requested product?
   If Yes, skip to Section E: All Requests. ❑ Yes ❑ No

2. These are the preferred products for which coverage is provided for the treatment of the following genotypes:
   a) Genotype 1, 4, 5, or 6: **brand-name Epclusa, brand-name Harvoni, and Vosevi**
   b) Genotype 2, or 3: **brand-name Epclusa, and Vosevi**
   Vosevi is specifically preferred for those who failed prior treatment with an HCV NS5A inhibitor-containing regimen.

   Can the patient's treatment be switched to a preferred product? *If Yes, skip to Section D: All Requests.*
   ❑ Yes, *please specify:* _____ ❑ No - continue request for non-preferred product
   ❑ N/A - question does not apply

Section C: Preferred Product - *complete the following section if Mavyret is prescribed*

1. Is the patient currently receiving treatment with the requested product?
   If Yes, skip to Section E: All Requests. ❑ Yes ❑ No

2. These are the preferred products for which coverage is provided for the treatment of the following genotypes:
   a) Genotype 1, 4, 5, or 6: **brand-name Epclusa, brand-name Harvoni, and Vosevi**
   b) Genotype 2, or 3: **brand-name Epclusa, and Vosevi**
   Vosevi is specifically preferred for those who failed prior treatment with an HCV NS5A inhibitor-containing regimen.

   Can the patient's treatment be switched to a preferred product? *If Yes, skip to Section E: All Requests.*
   ❑ Yes, *please specify:* _____ ❑ No - continue request for non-preferred product
   ❑ N/A - question does not apply

3. *If the request is for a patient who is at least 3 years old and less than 18 years old*, does the patient have genotype 1, 2, 3, 4, 5 or 6?
   ❑ Yes
   ❑ No
   ❑ N/A, patient is for at least 3 years old and less than 18 years old *If No or N/A, skip to Section E: All Requests.*

4. Did the patient fail prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni) without prior treatment with an NS3/4A protease inhibitor (PI) (e.g., Incivek, Olysio, Victrelis)?
   If Yes, skip to Section E: All Requests. ❑ Yes ❑ No

5. Did the patient fail prior treatment with a regimen containing an NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor? ❑ Yes ❑ No

Section D: Pegasys Requests

1. Is Pegasys being prescribed as monotherapy?
   ❑ Yes ❑ No ❑ N/A, request is NOT for Pegasys, *continue to next section*

2. *If the diagnosis is chronic hepatitis B virus (HBV) infection, including hepatitis D virus (HDV) co-infection,* how many weeks of therapy has the patient received? _____ weeks *No further questions.*

3. *If the diagnosis is myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower risk-myelofibrosis), systemic mastocytosis, mycosis fungoides/Sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease, or chronic myeloid leukemia in pregnancy,* is this a request for continuation of therapy with Pegasys?
   ❑ Yes ❑ No ❑ N/A, diagnosis is not listed above *If No or NA, no further questions.*

4. *If the diagnosis is myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower risk-myelofibrosis),* has the patient experienced benefit from therapy as evidenced by improvement in symptoms

and/or disease markers (e.g., morphological response, reduction or stabilization in spleen size, improvement of thrombocytosis/leukocytosis, etc.)?
If Yes or No, no further questions. ❑ Yes ❑ No ❑ N/A, diagnosis is not listed above

5. *If the diagnosis is systemic mastocytosis,* has the patient experienced benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., reduction in serum and urine metabolites of mast cell activation, improvement in cutaneous lesions, skeletal disease, bone marrow mast cell burden, etc.)?
If Yes or No, no further questions. ❑ Yes ❑ No ❑ N/A, diagnosis is not listed above

6. *If the diagnosis is adult T-cell leukemia/lymphoma, mycosis fungoides/Sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease, or chronic myeloid leukemia in pregnancy,* is there evidence of unacceptable toxicity or disease progression on the current regimen? ❑ Yes ❑ No

Section E: All Requests

1. Will the requested medication be prescribed by or in consultation with a prescriber specializing in one of the following: A) infectious disease, B) gastroenterology, C) hepatology, or D) transplant?
❑ Yes - Infectious disease ❑ Yes - Gastroenterology ❑ Yes - Hepatology
❑ Yes - Transplant ❑ No - None of the above

2. What is the patient's genotype? ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6
❑ Unknown genotype/genotype could not be determined
If genotype 1 or 6, specify the subtype: _____ ❑ Mixed ❑ Unknown

3. What is the patient's Metavir/Fibrosis score? ❑ F0 ❑ F1 ❑ F2 ❑ F3 ❑ F4 ❑ Unknown

4. Has the patient been screened for Hepatitis B virus (HBV)? ❑ Yes ❑ No ❑ Unknown

5. Has the patient been evaluated for alcohol and substance abuse using a validated screening tool? ❑ Yes ❑ No

6. Does the patient have a recent history (within the past 6 months) of alcohol or substance abuse?
❑ Yes ❑ No *If No, skip to #8*

7. Has the patient received alcohol or substance abuse counseling, completed or is participating in a recovery program, or currently seeing an addiction specialist? ❑ Yes ❑ No

8. Has the patient been counseled on the importance of adherence, confirmed readiness for treatment or retreatment and agrees to be compliant with regimen? ❑ Yes ❑ No

9. What is the **SPECIFIC** date (mm/dd/yyyy) the patient will start or has started this course of therapy?
_____ ***Please do NOT use ASAP. If treatment will be delayed after approval, please specify.***
❑ Unknown

10. What was the patient's treatment status prior to the requested regimen? *Indicate all that apply.*
List continues on next page.
❑ Treatment-naïve, *skip to #13*
❑ Failed prior treatment with PEG-IFN (with or without an HCV protease inhibitor (e.g., Victrelis, Incivek, Olysio)) with or without ribavirin
❑ Failed prior treatment with Mavyret
❑ Failed prior treatment with Vosevi
❑ Failed prior treatment with PEG-IFN + ribavirin
❑ Failed prior treatment with a direct-acting antiviral
❑ Failed prior treatment with Olysio + PEG-IFN + ribavirin
❑ Failed prior treatment with Victrelis + PEG-IFN + ribavirin
❑ Failed prior treatment with Incivek + PEG-IFN + ribavirin
❑ Failed 16 weeks of therapy with sofosbuvir (Sovaldi) and Mavyret

❑ Failed prior treatment with an interferon-based regimen with ribavirin
❑ Failed prior treatment with an interferon-based regimen without ribavirin
❑ Failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon)
❑ Failed prior treatment with PEG-IFN + ribavirin without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor

❑ Failed prior treatment with PEG-IFN + ribavirin without an HCV protease inhibitor (boceprevir, simeprevir, or telaprevir)
❑ Failed prior treatment with Sovaldi + PEG-IFN + ribavirin without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor
❑ Failed prior treatment with Sovaldi + ribavirin without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor
❑ Failed prior treatment with a sofosbuvir-based regimen (e.g., Sovaldi with PEG-IFN with RBV, Sovaldi with RBV, Sovaldi with Olysio, Sovaldi with Olysio with RBV)
❑ Failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon, sofosbuvir/ledipasvir (Harvoni), sofosbuvir/velpatasvir (Epclusa))
❑ Failed prior treatment with a direct-acting antiviral (DAA) regimen other than Mavyret (e.g., NS5A- or sofosbuvir-containing regimens (e.g., Epclusa, Harvoni, Technivie with or without ribavirin, Sovaldi plus PEG-IFN and ribavirin, Zepatier))
❑ Failed prior treatment with a direct-acting antiviral (DAA) regimen (e.g., NS5A- or sofosbuvir-containing regimen (e.g., Daklinza and Sovaldi with or without ribavirin, Epclusa with or without ribavirin, Sovaldi with ribavirin))
❑ Failed prior treatment with an NS5A inhibitor-based regimen (e.g., a regimen containing Daklinza, Harvoni, Mavyret, Technivie, Viekira Pak, Viekira XR, Vosevi, Zepatier)
❑ Failed prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni), excluding Mavyret, without prior treatment with a regimen containing an NS3/4A protease inhibitor (e.g., Olysio, Incivek, Victrelis)
❑ Failed prior treatment with a regimen containing an NS3/4A protease inhibitor (e.g., Olysio with Sovaldi; Olysio, Incivek or Victrelis in combination with ribavirin and peginterferon alfa) without prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni)
❑ Failed prior treatment with a regimen containing an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and ribavirin, simeprevir with sofosbuvir) without prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni)
❑ Failed prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni), excluding Mavyret, without prior treatment with an NS3/4A protease inhibitor
❑ Failed prior treatment with a regimen containing an NS5A inhibitor other than Mavyret (e.g., Daklinza, Epclusa, Harvoni, Viekira Pak, Viekira XR, Zepatier)
❑ Failed prior treatment with a sofosbuvir (Sovaldi)-based regimen (e.g., Sovaldi and Olysio with or without ribavirin, Sovaldi and ribavirin with or without PEG-IFN)
❑ Failed prior treatment with a direct-acting antiviral (DAA) regimen (e.g., NS5A- or sofosbuvir-containing regimens (e.g., Epclusa, Harvoni, Mavyret, Technivie with or without ribavirin, Sovaldi plus PEG-IFN and ribavirin, Zepatier))
❑ Other _____

11. Please specify the regimen, dates, and duration (number of weeks) of previous therapies.
_____
_____
❑ Unknown

12. What is the reason for retreatment?
❑ Non-compliance ❑ Reinfection ❑ Treatment failure ❑ Other _____

13. Prior to treatment, has hepatitis C been confirmed by the presence of a viral load (HCV-RNA) in the serum?
❑ Yes ❑ No

14. What is the patient's pretreatment HCV RNA level? _____ million IU/mL

15. What is the planned duration of therapy?
❑ Up to 6 weeks ❑ Up to 8 weeks ❑ Up to 12 weeks
❑ Up to 16 weeks ❑ Up to 24 weeks ❑ Up to 48 weeks

16. How long has the patient received therapy with the requested regimen? Indicate in weeks. Please do not indicate the planned duration of therapy. _____weeks

17. Does the patient have any of the following conditions?

❑ Decompensated cirrhosis (Child Turcotte Pugh (CTP) class B or C)
❑ Moderate or severe hepatic impairment (Child Turcotte Pugh (CTP) class B or C)
❑ None of the above

18. Has the patient failed prior treatment with a direct-acting antiviral? ❑ Yes ❑ No

19. Which, if any, of the following applies to the patient? *Indicate all that apply.*
❑ Received kidney transplant
❑ Received liver transplant from HCV-viremic donor
❑ Received non-liver organ transplant from HCV-viremic donor
❑ Has recurrent HCV infection post liver transplantation
❑ Has compensated cirrhosis
❑ Has HIV co-infection
❑ Has received an NS3/4A protease inhibitor or NS5A inhibitor
❑ None of the above

Complete the following section based on the prescribed regimen if applicable.

Section F: Harvoni +/- ribavirin
Harvoni monotherapy
1. Does the patient have documented anemia? ❑ Yes ❑ No *If No, skip to #3*

2. What is the patient's baseline hemoglobin level?
If less than 10 g/dL, no further questions. ❑ Less than 10 g/dL ❑ Greater than or equal to 10 g/dL

3. Is the patient ineligible to receive ribavirin? ❑ Yes ❑ No *If No, no further questions.*

4. Please indicate the reason for ribavirin ineligibility. *Indicate below and no further questions.*
❑ Intolerance to ribavirin
❑ Patient is a pregnant female or male whose female partner is pregnant
❑ Hemoglobinopathy
❑ Coadministration with didanosine
❑ History of significant or unstable cardiac disease
❑ Other _____

Section G: Epclusa +/- ribavirin
Epclusa monotherapy
1. Has the patient received a liver or non-liver organ transplant from an HCV-viremic donor?
❑ Yes ❑ No

2. Does the patient have documented anemia? ❑ Yes ❑ No *If No, skip to #4*

3. What is the patient's baseline hemoglobin level?
If less than 10 g/dL, no further questions. ❑ Less than 10 g/dL ❑ Greater than or equal to 10 g/dL

4. Is the patient ineligible to receive ribavirin? ❑ Yes ❑ No *If No, skip to #6*

5. Please indicate the reason for ribavirin ineligibility. *List continues on next page.*
❑ Intolerance to ribavirin
❑ Patient is a pregnant female or male whose female partner is pregnant
❑ Hemoglobinopathy
❑ Coadministration with didanosine
❑ History of significant or unstable cardiac disease
❑ Other _____

6. Which, if any, of the following characteristics does the patient have?
❑ HIV and the patient is on a tenofovir disoproxil fumarate (TDF)-containing regimen with an eGFR less than 60 mL/min
❑ HBsAG positive
❑ Current pregnancy

❑ Known or suspected hepatocellular carcinoma
❑ Prior liver transplantation
❑ None of the above

Epclusa + ribavirin

7. Has laboratory testing for presence of NS5A inhibitor resistance-associated substitutions been performed?
❑ Yes ❑ No ❑ Unknown *If No or Unknown, no further questions.*

8. Was the Y93H substitution associated with velpatasvir resistance detected? ❑ Yes ❑ No

Section H: Vosevi +/- ribavirin

Vosevi monotherapy

1. Does the patient have cirrhosis? ❑ Yes ❑ No

2. Has laboratory testing for presence of NS5A inhibitor resistance-associated substitutions been performed?
❑ Yes ❑ No ❑ Unknown *If No or Unknown, no further questions.*

3. Was the Y93H substitution associated with velpatasvir resistance detected? ❑ Yes ❑ No

Section I: Mavyret +/- Sovaldi +/- ribavirin

Mavyret monotherapy

1. *If patient received non-liver organ transplant from HCV-viremic donor*, will treatment be initiated in the first week after transplant? ❑ Yes ❑ No

2. Has the patient had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir (Zepatier))? ❑ Yes ❑ No

3. Did the patient receive an NS3/4A protease inhibitor or NS5A inhibitor? ❑ Yes ❑ No

4. Does the patient have sofosbuvir/NS5A inhibitor experience (e.g., sofosbuvir/ledipasvir (Harvoni), sofosbuvir/velpatasvir (Epclusa))? ❑ Yes ❑ No

5. Has the patient had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir (Zepatier))? ❑ Yes ❑ No

6. Has the patient received an NS3/4A protease inhibitor or NS5A inhibitor? ❑ Yes ❑ No

7. Has the patient received treatment with a regimen containing an NS3/4A protease inhibitor (e.g., Olysio, Incivek, Victrelis) or an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni)? ❑ Yes ❑ No

8. Which, if any, of the following characteristics does the patient have?
❑ HIV and the patient is on a tenofovir disoproxil fumarate (TDF)-containing regimen with an eGFR less than 60 mL/min
❑ HBsAG positive
❑ Current pregnancy
❑ Known or suspected hepatocellular carcinoma
❑ Prior liver transplantation
❑ None of the above

Mavyret + Sovaldi + ribavirin

9. Does the patient have an extremely difficult case (e.g., genotype 3 with cirrhosis)? ❑ Yes ❑ No

Section J: Sovaldi + ribavirin

1. Is the request for a patient with hepatocellular carcinoma awaiting liver transplantation?
❑ Yes ❑ No *If No, skip to #3*

2. Does the patient meet the MILAN criteria: A) tumor size 5 centimeters (cm) or less in diameter with single hepatocellular carcinomas OR 3 tumor nodules or less, each 3 cm or less in diameter with multiple tumors AND B) no extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor? ❑ Yes ❑ No

3. Does the patient have documented interferon ineligibility? ❑ Yes ❑ No *If No, no further questions.*

4. Please indicate the reason for IFN ineligibility.
   - ❑ Intolerance to interferon (IFN)
   - ❑ Autoimmune hepatitis and other autoimmune disorders
   - ❑ Hypersensitivity to PEG-IFN or any of its components
   - ❑ Major uncontrolled depressive illness
   - ❑ A baseline neutrophil count less than 1,500/mcL
   - ❑ A baseline platelet count less than 90,0000/mcL
   - ❑ A baseline hemoglobin count less than 10g/dL
   - ❑ History of pre-existing cardiac disease
   - ❑ Other _____

Section K: Zepatier +/- ribavirin

1. What is the patient's weight? _____ kg
2. Was the patient tested for baseline NS5A resistance-associated substitutions (RASs)/polymorphisms?
   ❑ Yes ❑ No ❑ Unknown
3. Is one or more baseline NS5A resistance-associated substitution (RAS)/polymorphism present?
   ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

***X*_____**
Prescriber or Authorized Signature **Date (mm/dd/yy)**

OFFICE CONTACT: _____ PHONE: _____ EXT: _____

Send completed form to: Case Review Unit, CVS Caremark Prior Authorization Fax: 1-866-249-6155