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
   - ❑ Moderiba
   - ❑ 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 E*
   - ❑ Adult T-cell leukemia/lymphoma, *skip to Section E*
   - ❑ Mycosis fungoides/Sezary syndrome, *skip to Section E*
   - ❑ Chronic hepatitis B, including HDV co-infection, *no further questions.*
   - ❑ Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower risk myelofibrosis), *skip to Section E*
   - ❑ Primary cutaneous CD30+ T-cell lymphoproliferative disorders, *skip to Section E*
   - ❑ Other _____

4. *If generic sofosbuvir/velpatasvir or ledipasvir/sofosbuvir is being prescribed,* 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 #6 ❑ Yes - Brand Epclusa ❑ Yes - Brand Harvoni
   - ❑ No - continue request for generic sofosbuvir/velpatasvir or ledipasvir/sofosbuvir
   - ❑ Not applicable - preferred product is being requested, *skip to #6*

5. Given that brand 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

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

7. Indicate patient's weight: _____ kg or lb ***(circle one)***

8. Indicate pretreatment viral load (HCV-RNA) and date of lab work:

Pretreatment viral load: _____ IU/mL Date: _____ ❑ Unknown

9. Indicate patient's genotype. _____
If genotype 1 or 6, specify the subtype: _____ ❑ Mixed ❑ Unknown

10. These are the preferred products for which coverage is provided for the treatment of the following genotypes:
a) Genotype 1, 4, 5, or 6: **Epclusa, Harvoni, Vosevi**
b) Genotype 2, or 3: **Epclusa, 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?
❑ Yes, *please specify:* _____ ❑ No - continue request for non-preferred product
❑ N/A - question does not apply

11. Indicate planned duration of therapy: _____ weeks

12. Indicate **SPECIFIC** date (mm/dd/yyyy) the patient will start or has started this course of therapy:

_____ ***Do NOT indicate ASAP. If treatment will be delayed after approval, please specify.***

If patient has started this requested regimen, how long has the patient received therapy?
Please do not indicate the planned duration of therapy. _____ weeks

13. Is the patient an adult? ❑ Yes ❑ No

14. Please indicate which, if any, of the following applies to the patient.
Indicate ALL that apply or mark "None of the above."
❑ Awaiting liver transplantation ❑ Compensated cirrhosis ❑ Current pregnancy
❑ HBsAG positive ❑ HIV co-infection ❑ Kidney transplant recipient
❑ Received an NS3/4A protease inhibitor or NS5A inhibitor
❑ Known or suspected hepatocellular carcinoma
❑ Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)
❑ Moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C)
❑ HIV and the patient is on a tenofovir disoproxil fumarate (TDF)-contaning regimen with a eGFR less than 60 ml/min
❑ Received liver or non-liver organ transplant from HCV-viremic donor
❑ Prior liver transplantation
❑ Recurrent HCV infection post liver transplantation
❑ Extremely difficult case (e.g., genotype 3 with cirrhosis)
❑ Documented anemia - *Indicate baseline hemoglobin level:* _____ g/dL
❑ Documented interferon ineligibility - *Indicate reason:* _____
❑ Ineligible/Intolerance to receive ribavirin - *Indicate reason:* _____
❑ None of the above

15. What was the patient's treatment status prior to the requested regimen? ***Indicate ALL that apply.***
List continues on next page.
❑ Treatment-naive
❑ Failed prior treatment with PEG-IFN (with or without an HCV protease inhibitor [e.g., Victrelis, Incivek, Olysio]) with or without ribavirin, *specify:* _____
❑ Failed prior treatment with PEG-IFN and ribavirin without an HCV protease inhibitor (boceprevir, simeprevir, or telaprevir), *specify:* _____
❑ Failed prior treatment with a direct-acting antiviral (DAA) regimen, *specify:*
_____

❑ Failed prior treatment (or exposure) containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni), *specify:* _____
❑ Failed prior treatment (or prior exposure) with an NS3/4 A protease inhibitor, *specify:* _____
❑ Failed prior treatment with an interferon-based regimen with or without ribavirin, *specify:* _____
❑ Failed prior treatment (or prior exposure) with a sofobuvir-based regimen, *specify:* _____
❑ Failed other prior treatment(s) - *Please indicate regimen(s) and date(s) of treatment below.*
Regimen 1: _____
Dates of treatment: _____
Regimen 2: _____
Dates of treatment: _____
❑ Other _____

16. *If the requested regimen includes Mavyret, Viekira Pak, or Zepatier,* does the patient have documented end-stage renal disease (ESRD) or severe renal impairment (estimated glomerular filtration rate [eGFR] of less than 30 mL/min/1.73m^2)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) of the patient's renal function and skip to regimen section, if applicable.*** ❑ Yes ❑ No ❑ Not applicable

Complete the following section based on the prescribed regimen and/or diagnosis, if applicable.

Section A: Epclusa +/- Ribavirin **OR** Vosevi Monotherapy

17. *If patient has genotype 3,* has laboratory testing for presence of NS5A inhibitor resistance-associated substitutions been performed? ❑ Yes ❑ No ❑ Unknown

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

Section B: Sovaldi +/- Ribavirin

19. Does the patient meet the MILAN criteria? ❑ Yes ❑ No
A) Tumor size 5 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

Section C: Viekira Pak +/- Ribavirin

20. What is the patient's Metavir fibrosis score? ❑ F0 ❑ F1 ❑ F2 ❑ F3 ❑ F4 ❑ Other _____

Section D: Zepatier +/- Ribavirin - Genotype 1

21. Was the patient tested for baseline NS5A resistance-associated substitutions (RASs)/polymorphisms? ❑ Yes ❑ No ❑ Unknown

22. Is one or more baseline NS5A resistance-associated substitutions (RASs)/polymorphisms present? ❑ Yes ❑ No

Section E: Myeloproliferative Neoplasm, Systemic Mastocytosis, Adult T-Cell Leukemia/Lymphoma, Mycosis Fungoides/Sezary Syndrome, Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders

23. Is Pegasys being prescribed as monotherapy? ❑ Yes ❑ No *If No, no further questions.*

24. Is this a request for continuation of therapy with Pegasys? ❑ Yes ❑ No *If No, no further questions.*

25. *If patient's diagnosis is myeloproliferative neoplasm,* 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.)? ❑ Yes ❑ No

26. *If patient's 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.)? ❑ Yes ❑ No

27. *If patient's diagnosis is adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome or primary cutaneous CD30+ T-cell lymphoproliferative disorders,* is there evidence of unacceptable toxicity or disease progression while on the current regimen? ❑ 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: _____

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