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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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.
   ❑ Daklinza ❑ Epclusa ❑ Harvoni ❑ Mavyret ❑ Moderiba
   ❑ Olysio ❑ Pegasys ❑ Ribasphere RibaPak ❑ ribavirin ❑ Sovaldi
   ❑ Technivie ❑ Viekira Pak ❑ Viekira XR ❑ 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
   ❑ Chronic hepatitis B, including HDV co-infection, *no further questions.*
   ❑ Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, primary myelofibrosis and post-polycythemia vera or post-essential thrombocythemia myelofibrosis), *skip to Section F.*
   ❑ Systemic mastocytosis, *skip to Section F.*
   ❑ Other _____

4. *If brand ribavirin is being prescribed (Moderiba or Ribasphere RibaPak),* generic ribavirin is the preferred product for your patient's health plan. Can the patient's treatment be switched to generic ribavirin?
   If Yes, skip to #8 ❑ Yes ❑ No - continue request for brand ribavirin
   ❑ Not applicable, regimen does not include brand ribavirin, *skip to #8*

5. Has the patient failed treatment with generic ribavirin due to an intolerable adverse event (eg, rash, nausea, vomiting)? ❑ Yes ❑ No *If No, complete this form in its entirety and Maryland State Step Therapy section.*

6. Was the intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and generic medication)?
   If Yes, complete this form in its entirety and Maryland State Step Therapy section. ❑ Yes ❑ No

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

7. Was this documented in the patient's chart? *Documentation is required for approval. Provide **SPECIFIC and DETAILED** chart documentation including description, date/time, and severity of the adverse event, dosage and duration of generic medication treatment, required intervention (if any), and relevant tests or laboratory data (if any) **OR** MedWatch form of this trial and failure including the adverse reaction.*
❑ Yes ❑ No *If No, complete this form in its entirety and Maryland State Step Therapy section.*

8. *If generic sofosbuvir/velpatasvir (generic Epclusa) or ledipasvir/sofosbuvir (generic Harvoni) 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 #10 ❑ 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 #10*

9. 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 *If No, complete this form in its entirety and Maryland State Step Therapy section.*

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

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

12. Indicate baseline viral load (HCV-RNA) and date of lab work:

BASELINE: _____ IU/mL Date: _____

13. Indicate patient's genotype. _____
If genotype 1, specify the subtype: ❑ 1a ❑ 1b ❑ Mixed ❑ Unknown

14. 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

15. Indicate <u>planned</u> duration of therapy: _____ weeks

16. 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

17. Do any of the following apply to the patient? ***Indicate ALL that apply or mark "None of the above."***
❑ HIV co-infection
❑ Compensated cirrhosis
❑ Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)
❑ Moderate or severe hepatic impairment (CTP class B or C)
❑ Recurrent HCV infection post liver transplantation
❑ Hepatocellular carcinoma
❑ Awaiting liver transplantation
❑ Kidney transplant recipient
❑ African American
❑ Documented anemia - *Indicate <u>baseline</u> hemoglobin level:* _____ g/dL
❑ Documented <u>interferon</u> ineligibility - *Indicate reason:* _____
❑ Ineligible/Intolerance to receive <u>ribavirin</u> - *Indicate reason:* _____
❑ None of the above

18. What was the patient's treatment status prior to the requested regimen? *Question continues on next page.*
❑ Treatment-naive ❑ Failed prior treatment(s) - *Please indicate regimen(s) and date(s) of treatment below.*

Regimen 1: _____

Dates of treatment: _____

Regimen 2: _____

Dates of treatment: _____

❑ Other _____

19. *If the requested regimen includes Mavyret, Viekira Pak, Viekira XR, 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
If No, complete this form in its entirety and Maryland State Step Therapy section.

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

Section A: Epclusa + Ribavirin **OR** Vosevi Monotherapy **OR** Daklinza + Sovaldi + Ribavirin

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

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

Section B: Olysio + Pegasys + Ribavirin **OR** Sovaldi + Olysio

22. *If patient has genotype 1a,* is the NS3 Q80K polymorphism present? ❑ Yes ❑ No ❑ Unknown

23. *If Olysio + Pegasys + ribavirin is being prescribed,* did the patient have HCV-RNA less than 25 IU/mL at week 4 of treatment? ❑ Yes ❑ No ❑ Not applicable/New start

Section C: Sovaldi + Ribavirin

24. 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 D: Viekira Pak/Viekira XR + Ribavirin

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

Section E: Zepatier +/- Ribavirin - Genotype 1

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

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

Section F: Myeloproliferative Neoplasm and Systemic Mastocytosis

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

29. *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/leucocytosis, etc.)? ❑ Yes ❑ No

30. *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

Maryland State Step Therapy

1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

2. Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

3. Is the preferred drug (Epclusa, Harvoni, Vosevi) FDA-approved for the medical condition being treated? ❑ Yes ❑ No *If No, please specify:* _____

4. Has the prescriber provided proof, documented in the patient's chart notes, indicating that the requested drug was ordered for the patient in the past 180 days? ❑ Yes ❑ No *If No, skip to #6.*

5. Has the prescriber provided proof, documented in the patient chart notes, that in their opinion the requested drug is effective for the patient's condition? ❑ Yes ❑ No *No further questions.*

6. Has the patient experienced an inadequate treatment response to the preferred drug (Epclusa, Harvoni, Vosevi)? ❑ Yes ❑ No *If Yes, please specify:* _____

7. Has the patient experienced an intolerance to the preferred drug (Epclusa, Harvoni, Vosevi)? ❑ Yes ❑ No *If Yes, please specify:* _____

8. Does the patient have a contraindication that would prohibit a trial of the preferred drug (Epclusa, Harvoni, Vosevi)? ❑ Yes ❑ No *If Yes, please specify:* _____

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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