

Member Name: {{MEMFIRST}} {{MEMLAST}} DOB: {{MEMBERDOB}} PA Number: {{PANUMBER}}



{{PANUMCODE}}

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: {{MEMFIRST}} {{MEMLAST}} **Date:** {{TODAY}}
Patient's ID: {{MEMBERID}} **Patient's Date of Birth:** {{MEMBERDOB}}
Physician's Name: {{PHYFIRST}} {{PHYLAST}}
Specialty: _____, **NPI#:** _____
Physician Office Telephone: {{PHYSICIANPHONE}} **Physician Office Fax:** {{PHYSICIANFAX}}
Request Initiated For: {{DRUGNAME}}

1. What is the prescribed regimen for patient's course of treatment?

Indicate ALL drugs for this course of treatment.

- | | | | |
|---|---|--|-----------------------------------|
| <input type="checkbox"/> Epclusa | <input type="checkbox"/> Harvoni | <input type="checkbox"/> Mavyret | <input type="checkbox"/> Moderiba |
| <input type="checkbox"/> Pegasys | <input type="checkbox"/> Ribasphere RibaPak | <input type="checkbox"/> ribavirin | <input type="checkbox"/> Sovaldi |
| <input type="checkbox"/> Viekira Pak | <input type="checkbox"/> Vosevi | <input type="checkbox"/> Zepatier | |
| <input type="checkbox"/> sofosbuvir/velpatasvir (generic Epclusa) | | <input type="checkbox"/> ledipasvir/sofosbuvir (generic Harvoni) | |
| <input type="checkbox"/> Other _____ | | | |

2. What is the ICD-10 code? _____

3. What is the diagnosis?

- Chronic hepatitis C
 Acute hepatitis C
 Chronic hepatitis B, including HDV co-infection, *no further questions.*
 Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic low risk myelofibrosis), *skip to Section E*
 Systemic mastocytosis, *skip to Section E*
 Adult T-cell leukemia/lymphoma, *skip to Section E*
 Mycosis fungoides/Sezary syndrome, *skip to Section E*
 Primary cutaneous CD30+ T-cell lymphoproliferative disorders, *skip to Section E*
 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 State Step Therapy section.*

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

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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 State Step Therapy section. Yes No
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 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 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 or 6, specify the subtype: _____ 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 planned 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. Please indicate which, if any, of the following applies to the patient.
Indicate ALL that apply or mark "None of the above." *List continues on next page.*
- HIV co-infection
 - Awaiting liver transplantation
 - Known or suspected hepatocellular carcinoma
 - Compensated cirrhosis
 - Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)
 - Kidney transplant recipient
 - Moderate or severe hepatic impairment (CTP class B or C)
 - HIV or HBsAG positive

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- Current pregnancy
- Received liver or non-liver organ transplant from HCV-viremic donor
- Prior liver transplantation
- Recurrent HCV infection post liver transplantation
- Documented anemia - Indicate baseline hemoglobin level: _____ g/dL
- Documented interferon ineligibility - Indicate reason: _____
- Ineligible/Intolerance to receive ribavirin - Indicate reason: _____
- None of the above

18. What was the patient's treatment status prior to the requested regimen? **Indicate ALL that apply.**

- Treatment-naive
- Failed prior treatment with a direct-acting antiviral (DAA), *specify*: _____
- Failed regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni),
specify: _____
- Failed prior treatment with an NS3/4A protease inhibitor, *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 _____

19. *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/1.73m²)? 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

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: Sovaldi +/- Ribavirin

22. 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

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

Section D: Zepatier +/- Ribavirin - Genotype 1

24. Was the patient tested for baseline NS5A resistance-associated substitutions (RASs)/polymorphisms?

Yes No Unknown

25. 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

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

27. *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

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28. *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
29. *If patient's diagnosis is adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome or primary cutaneous CD30+ T-cell lymphoproliferative disorders*, has the patient experienced unacceptable toxicity or disease progression while on the current regimen? Yes No

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. Does the patient reside in Maryland? Yes No *If No, skip to #7*
4. Is the alternate drug (generic ribavirin, Epclusa, Harvoni, Vosevi) FDA-approved for the medical condition being treated? Yes No *If No, please specify: _____*
5. 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 #7*
6. 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*
7. Are any of the following conditions met for the alternate drug (generic ribavirin, Epclusa, Harvoni, Vosevi)?
 - The alternate drug is contraindicated
 - The alternate drug is likely to cause an adverse reaction, physical or mental harm
 - The alternate drug is expected to be ineffective
 - The alternate drug was previously tried or a drug in the same class or with the same action was previously tried and was stopped due to ineffectiveness or an adverse event
 - The alternate drug is not in the patient's best interest
 - The alternate drug was tried while covered by the current or the previous health benefit plan
 - None of the above*If Yes, please specify: _____*
8. Is the patient stable or currently receiving a positive therapeutic outcome with the requested drug and a change in the prescription drug is expected to be ineffective or cause harm to the patient? 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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