CVS caremark™ {{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.

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: {{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.

❑ 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
   ❑ 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 F.*
   ❑ Systemic mastocytosis, *skip to Section F.*
   ❑ Adult T-cell leukemia/lymphoma, *skip to Section F.*
   ❑ Mycosis fungoides/Sezary syndrome, *skip to Section F.*
   ❑ Primary cutaneous CD30+ T-cell lymphoproliferative disorders, *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 State Step Therapy section.*

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 Hepatitis C State Step, VF, ACSF SGM - 2/2021.

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. *List continues on following page.*
    Indicate ALL that apply or mark "None of the above."
    ❑ HIV co-infection
    ❑ Known or suspected hepatocellular carcinoma
    ❑ Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)
    ❑ Moderate or severe hepatic impairment (CTP class B or C)
    ❑ Received organ transplanted from HCV-RNA-positive donor
    ❑ Recurrent HCV infection post liver transplantation
    ❑ End-stage renal disease (eGFR < 30 mL/min/m^2)
    ❑ Awaiting liver transplantation
    ❑ Compensated cirrhosis
    ❑ Kidney transplant recipient
    ❑ HIV or HBsAG positive
    ❑ Current pregnancy
    ❑ Prior liver transplantation

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- ❑ 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 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, 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 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, Systemic Mastocytosis, Adult T-Cell Leukemia/Lymphoma, Mycosis Fungoides/Sezary Syndrome, Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders

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/leukocytosis, 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

31. *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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