

HEPATITIS C DIRECT ACTING ANTIVIRALS PRIOR AUTHORIZATION REQUEST PRESCRIBER FAX FORM

Only the prescriber may complete this form. This form is for prospective, concurrent, and retrospective reviews.

The following documentation is **REQUIRED**. Incomplete forms will be returned for additional information. For formulary information please visit www.myprime.com. Start saving time today by filling out this form electronically. Visit covermymeds.com to begin using this free service.

What is the priority level of this request?

- Standard review
- Expedited/Urgent review – prescriber certifies that waiting for a standard review could seriously harm the patient's life, health or ability to regain maximum function

Today's Date: _____

PATIENT AND INSURANCE INFORMATION

Date of Service (if differs from Today's Date): _____

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
Patient Address:	City, State, Zip:	Patient Telephone:	
Member ID Number:	Group Number:		

PRESCRIBER/CLINIC INFORMATION

Prescriber Name:	Prescriber NPI#:	Specialty:	Contact Name:
Clinic Name:	Clinic Address:		
City, State, Zip:	Phone #:	Secure Fax #:	

PLEASE ATTACH ANY ADDITIONAL INFORMATION THAT SHOULD BE CONSIDERED WITH THIS REQUEST

Patient's Diagnosis:

Hepatitis C genotype 1 Hepatitis C genotype 2 Hepatitis C genotype 3
 Hepatitis C genotype 4 Hepatitis C genotype 5 Hepatitis C genotype 6
 Hepatocellular carcinoma secondary to chronic hepatitis C genotype 2 or 3
 Hepatocellular carcinoma secondary to chronic hepatitis C genotype 1 or 4
 Other (ICD code plus description): _____

Medication(s) Requested:

_____	Strength: _____	Dosing Schedule: _____
_____	Strength: _____	Dosing Schedule: _____
_____	Strength: _____	Dosing Schedule: _____
_____	Strength: _____	Dosing Schedule: _____

Length of therapy: _____ weeks

For all requests:

- What is the patient's weight? _____ (kg)
- Is the patient currently being treated with the requested agent? Yes No
 If yes, is the patient currently stable on the requested agent? **Please note, chart notes are required**..... Yes No
- Has the patient been previously treated with the requested agent?..... Yes No
- Does the patient have any FDA labeled contraindications to the requested agent?..... Yes No
 If yes, please specify FDA labeled contraindications: _____
- Has the prescriber screened the patient for current or prior hepatitis B viral (HBV) infection?..... Yes No
 If yes, was the screening for HBV positive for current or prior HBV infection?..... Yes No
 If yes, will the prescriber monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent? Yes No
- Is the patient's age within FDA labeling for the requested indication for the requested agent? Yes No
 If no, please provide support for using the requested agent for the patient's age for the requested indication: _____

Please continue to the next page.

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For all requests continued:

7. Please list all reasons for selecting the requested agent for the indicated diagnosis, strength, dosing schedule, and quantity over alternatives (e.g., compendia support, journal articles, contraindications, allergies, history of adverse drug reactions to alternatives, lower dose has been tried, information supporting dose over FDA max). **Please note, documentation may be required:** _____

8. Is the prescriber a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, infectious disease), or has the prescriber consulted with a specialist in the area of the patient's diagnosis? Yes No
 If no, is the requested agent supported in AASLD guidelines for simplified treatment? Yes No
 If yes, does the patient meet any of the following? Please check all that apply.
 Hepatitis B surface antigen (HBsAg positive)
 Is currently pregnant
 Known or suspected hepatocellular carcinoma
 Prior liver transplantation
 Current or prior episode of decompensated cirrhosis, defined as Child-Pugh (CP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7)
 End-stage renal disease (i.e., eGFR less than 30 mL/min/m²)
9. Is the patient treatment naïve? Yes No
 If no, was the patient previously treated (i.e. treatment experienced) with ONLY peg-interferon and ribavirin with an HCV protease inhibitor? Yes No
 If no, was the patient previously treated (i.e. treatment experienced) with ONLY peg-interferon and ribavirin without an HCV protease inhibitor? Yes No
10. What is the status of the patient's liver?
 Compensated (Child-Pugh A) cirrhosis Decompensated (Child-Pugh B or C) cirrhosis
 No cirrhosis
11. Does the patient have hepatocellular carcinoma? Yes No
12. If genotype 1, what is the patient's subtype? _____
13. Is the patient a liver transplant recipient? Yes No
14. Is the patient a kidney transplant recipient? Yes No
15. Is the patient awaiting liver transplantation? Yes No
16. Is the patient ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)? Yes No

For Epclusa or Sofosbuvir/Velpatasvir requests:

17. Is the patient's age within FDA labeling for the requested indication for the requested agent? Yes No
 If no, is there support for the use of the requested agent for the patients age for the requested indication?
Please note, medical records are required Yes No
18. Did prior sofosbuvir- or NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) -based treatment fail? Yes No
19. Is the request for 2 or more Epclusa 200 mg/50 mg tablets per day? Yes No
 If yes, please provide support for why the patient cannot take 1 tablet of the 400 mg/100mg tablet: _____
20. Is the request for 2 or more Epclusa 200 mg/50 mg packets per day? Yes No
 If yes, please provide support for why the patient cannot take 1 tablet of the 400 mg/100mg tablet: _____

For Harvoni or Ledipasvir/Sofosbuvir requests:

21. If genotype 1, what is the patient's baseline HCV RNA level? _____
22. Is the request for 2 or more per day of Harvoni 45 mg/200 mg tablets? Yes No
 If yes, please explain why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength: _____
23. Is the request for 2 or more packets daily of Harvoni 45 mg/200 mg oral pellets? Yes No
 If yes, provide support for why the patient cannot take 1 tablet of Harvoni 90 mg/400 mg strength: _____
24. Does the patient have an initial viral load of less than 6 M IU/mL? Yes No
25. Is the patient treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir])? Yes No

Please continue to the next page.

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For Mavyret requests:

26. Is the requested agent being used for acute HCV treatment or chronic HCV treatment?
 acute HCV treatment chronic HCV treatment
27. Is the patient's age within FDA labeling for the requested indication for the requested agent? Yes No
 If no, is there support for the use of the requested agent for the patients age for the requested indication?
Please note, medical records are required Yes No
28. Is the patient treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)? Yes No
29. Is the patient treatment experienced with an NS3/4A protease inhibitor but without prior treatment with an NS5A inhibitor? Yes No
30. Is the patient treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)? Yes No
31. Is the request for 7 or more Mavyret 50 mg/20 mg packets per day? Yes No
 If yes, provide support for why the patient cannot take 3 tablets of the Mavyret 100 mg/40 mg tablet: _____

For Sovaldi requests:

32. Is the patient an adult? Yes No
33. Is the patient a pediatric patient? Yes No
 If yes, please answer the following:
- a. Does the patient have an intolerance or hypersensitivity to BOTH Epclusa and Mavyret? **Please note, chart notes are required.** Yes No
- b. Does the patient have an FDA labeled contraindication to BOTH Epclusa and Mavyret? **Please note, chart notes are required.** Yes No
- c. Are BOTH Epclusa and Mavyret expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm? **Please note, chart notes are required.** Yes No
- d. Are BOTH Epclusa and Mavyret not in the best interest of the patient based on medical necessity? **Please note, chart notes are required.** Yes No
- e. Is there support for the use of the requested agent over BOTH Epclusa and Mavyret (e.g., the patient is currently taking the requested agent)? Yes No
 If yes, please provide supporting information: _____

34. Is the patient interferon ineligible defined as one or more of the following: Intolerance to interferon, Autoimmune hepatitis and other autoimmune disorders, Hypersensitivity to PEG interferon or any of its components, Decompensated hepatic disease, Major uncontrolled depressive illness, A baseline neutrophil count below 1500/L, A baseline platelet count below 90,000/L, A baseline hemoglobin below 10 g/dL, A history of preexisting cardiac disease)? Yes No
35. Has the patient failed an interferon based regimen with or without ribavirin? Yes No
36. Is the request for 2 or more packets daily of Sovaldi 200 mg oral pellets? Yes No
 If yes, provide support for why the patient cannot take 1 tablet of Sovaldi 400 mg strength: _____

37. Is the request for 2 tablets or more daily of Sovaldi 200 mg tablets? Yes No
 If yes, please explain why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength: _____

For Vosevi requests:

38. Was the patient previously treated with an HCV regimen containing NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir)? Yes No
39. Was the patient previously treated with an HCV regimen containing sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (simeprevir)? Yes No

For Zepatier requests:

40. Does the patient have hepatitis C genotype 1a? Yes No
If yes, has the prescriber tested the patient for NS5A polymorphisms? Yes No
If yes, does the patient have baseline NS5A polymorphism at amino acid positions 28, 30, 31, or 93? Yes No

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Genotype	Preferred Agents	Non-Preferred Agents
1	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Mavyret (glecaprevir/pibrentasvir) Sofosbuvir/Velpatasvir Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
2 or 3	Epclusa (sofosbuvir/velpatasvir) Mavyret (glecaprevir/pibrentasvir) Sofosbuvir/Velpatasvir Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Sovaldi (sofosbuvir)
4	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Mavyret (glecaprevir/pibrentasvir) Sofosbuvir/Velpatasvir Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
5 or 6	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Mavyret (glecaprevir/pibrentasvir) Sofosbuvir/Velpatasvir Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	

For Non-Preferred Agent requests, please submit chart notes to support the answers to the following questions:

41. Has the patient been treated with the requested non-preferred agent in the past 30 days? Yes No
42. Has the patient tried and had an inadequate response to ALL of the preferred agents for the patient's specific factors? Yes No
43. Were ALL of the preferred agents for the patient's specific factors discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? Yes No
44. Does the patient have an intolerance or hypersensitivity to ALL of the preferred agents for the patient's specific factors? Yes No
45. Does the patient have an FDA labeled contraindication to ALL of the preferred agents for the patient's specific factors? Yes No
46. Are ALL of the preferred agents for the patient's specific factors expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm? Yes No
47. Are ALL of the preferred agents for the patient's specific factors not in the best interest of the patient based on medical necessity? Yes No
48. Has the patient tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agents for the patient's specific factors and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? Yes No
49. Is there support for the use of the requested non-preferred agent over the preferred agents? Yes No
 If yes, please provide supporting information: _____

Please fax or mail this form to:
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 Eagan, MN 55121

TOLL FREE

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