

# KAISER PERMANENTE PORTLAND

## MEDICATION REQUEST GUIDELINES



**KAISER PERMANENTE - PORTLAND  
MEDICATION REQUEST GUIDELINES**

**SIMEPREVIR**

Generic	Brand	HICL	GCN	Exception/Other
SIMEPREVIR	OLYSIO	40771	35648	

**PA DEPARTMENT: \*\*IMPORTANT: All decisions to approve or deny requests for simeprevir must be reviewed by the plan.\*\***

- Please collect all data necessary for the PA review, go through the decision making process using the guidelines listed below and then forward the decision to KP007 before approving or denying.
- If sofosbuvir is requested along with simeprevir, both MRFs should be forwarded to the plan for review.
- All requests must be forwarded to Clinical to ensure all necessary information is provided by the prescriber before forwarding the request to the plan for review.
- When forwarding the request to the plan, the request should include the following:
  - The MRF
  - All supporting documentation
  - The leading sentence in the MedResponse notes/comments section must indicate whether approval or denial is recommended based on the plan guidelines.
- Requests should be sent to the following recipients:
  - [Paul.E.Chamliès-Jr@kp.org](mailto:Paul.E.Chamliès-Jr@kp.org)
  - [Tony.J.Carnevale@kp.org](mailto:Tony.J.Carnevale@kp.org)
  - [Terrence.J.Olson@kp.org](mailto:Terrence.J.Olson@kp.org)

**GUIDELINES FOR USE**

Simeprevir (Olysio®) will be covered on the prescription drug benefit when the following criteria are met:

1. Is the prescriber a provider of a Hepatology Clinic (i.e. Hepatologist, Infectious Disease Specialist, etc.)?

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** Prescriber restriction. May only be prescribed by a provider of a Hepatology Clinic (i.e. Hepatologist, Infectious Disease Specialist, etc.).

2. Is the medication being used with sofosbuvir?

If yes, continue to #3.

If no, do not approve.

**DENIAL TEXT:** Sofosbuvir-containing regimens are preferred over simeprevir-containing regimens.

3. Is the patient treatment-naïve?

If yes, continue to #4.

If no, continue to #5.

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MEDICATION REQUEST GUIDELINES**

**SIMEPREVIR**

**GUIDELINES FOR USE (CONTINUED)**

4. Does the patient have any of the following contraindications to interferon?
- a. concurrent diagnosis of autoimmune hepatitis or other autoimmune disorder
  - b. a known hypersensitivity reaction to interferon
  - c. documented poorly controlled psychiatric illness
  - d. decompensated hepatic disease
  - e. baseline neutrophil count <1,500 per microliter
  - f. baseline platelet count <50,000
  - g. baseline hemoglobin <10g/dL that has not responded to treatment

If yes, continue to #5.

If no, do not approve.

**DENIAL TEXT:** Approval requires contraindication to interferon.

5. Has the patient failed treatment with a protease inhibitor, such as boceprevir or telaprevir?

If yes, do not approve.

**DENIAL TEXT:** Approval requires no prior treatment with a hepatitis C protease inhibitor.

If no, **approve simeprevir treatment for 12 weeks.**

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**RATIONALE**

Ensure the appropriate use of simeprevir.

**FDA APPROVED INDICATIONS**

Simeprevir is indicated for treatment of chronic hepatitis C (CHC) as a component of a combination antiviral treatment regimen for adults ages ≥ 18 years old.

- Simeprevir efficacy has been established in subjects with CHC genotype 1 only.

**EXCLUSION CRITERIA**

Simeprevir may not be used as monotherapy.

**REFERENCES**

1. Olysio [package insert]. Titusville, NJ: Janssen Therapeutics; November 2013.

Created: 07/14

Effective: 07/22/14

Client Approval: 07/21/14

P&T Approval: N/A

**KAISER PERMANENTE - PORTLAND  
MEDICATION REQUEST GUIDELINES**

**SOFOSBUVIR (SOVALDI)**

Generic	Brand	HICL	GCN	Exception/Other
SOFOSBUVIR	SOVALDI	40795	35708	

**PA DEPARTMENT: \*\*IMPORTANT: All decisions to approve or deny requests for sofosbuvir must be reviewed by the plan.\*\***

- Please collect all data necessary for the PA review, go through the decision making process using the guidelines listed below and then forward the decision to KP007 before approving or denying.
- If simeprevir is requested along with sofosbuvir, both MRFs should be forwarded to the plan for review.
- All requests must be forwarded to Clinical to ensure all necessary information is provided by the prescriber before forwarding the request to the plan for review.
- When forwarding the request to the plan, the request should include the following:
  - The MRF
  - All supporting documentation
  - The leading sentence in the MedResponse notes/comments section must indicate whether approval or denial is recommended based on the plan guidelines.
- Requests should be sent to the following recipients:
  - [Paul.E.Chamliès-Jr@kp.org](mailto:Paul.E.Chamliès-Jr@kp.org)
  - [Tony.J.Carnevale@kp.org](mailto:Tony.J.Carnevale@kp.org)
  - [Terrence.J.Olson@kp.org](mailto:Terrence.J.Olson@kp.org)

**GUIDELINES FOR USE**

Sofosbuvir (Sovaldi®) will be covered on the prescription drug benefit when the following criteria are met:

1. Is the prescriber a provider of a Hepatology Clinic (i.e. Hepatologist, Infectious Disease Specialist, etc.)?

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** Prescriber restriction. May only be prescribed by a provider of a Hepatology Clinic (i.e. Hepatologist, Infectious Disease Specialist, etc.).

2. Does the patient have end stage renal disease or require dialysis?

If yes, do not approve.

**DENIAL TEXT:** Approval requires CrCl>30ml/min and no dialysis dependency.

If no, continue to #3.

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MEDICATION REQUEST GUIDELINES**

**SOFOSBUVIR (SOVALDI)**

**GUIDELINES FOR USE (CONTINUED)**

3. Does the patient have at least **one** of the following:
- a. A biopsy or other non-invasive technology (FibroScan), including serum tests (FibroSure, FibroTest) to indicate advanced fibrosis (stage 3) or cirrhosis (stage 4) or radiologic, laboratory, or clinical evidence of cirrhosis without decompensation.
  - b. A biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate advanced fibrosis (stage 3) **AND** at least one of the following:
    - i. HIV co-infection
    - ii. Post-liver transplant
    - iii. Genotype 2 virus
  - c. Proven CHC-associated extrahepatic manifestations (vasculitis, glomerulonephritis, lymphoma) that requires urgent CHC-treatment.
  - d. Acute HCV, if poor prognostic criteria for spontaneous cure
  - e. Pre-liver transplant if listed with intent to clear virus >30 days before transplantation or achieve cure
  - f. History of hepatoma
  - g. Fibrosing cholestatic hepatitis due to CHC in post-liver transplant

If yes, continue to #4.

If no, do not approve.

**DENIAL TEXT:** Approval requires at least one of the following: (a) A biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate cirrhosis (stage 4) or radiologic, laboratory, or clinical evidence of cirrhosis without decompensation. (b) A biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate advanced fibrosis (stage 3) **AND** at least one of the following: HIV co-infection, Post-liver transplant or Genotype 2 virus (c) Proven CHC-associated extrahepatic manifestations (vasculitis, glomerulonephritis, lymphoma) that requires urgent CHC-treatment (d) Acute HCV, if poor prognostic criteria for spontaneous cure (e) Pre-liver transplant if listed with intent to clear virus >30 days before transplantation or achieve cure (f) History of hepatoma (g) Fibrosing cholestatic hepatitis due to CHC in post-liver transplant.

4. Does the patient have HIV coinfection?

If yes, continue to #5.

If no, continue to #6.

5. Is the patient under the supervision of an HIV specialist?

If yes, continue to #6.

If no, do not approve.

**DENIAL TEXT:** Approval requires supervision of an HIV specialist for treatment of patients who are coinfecting with HIV.

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**SOFOSBUVIR (SOVALDI)**

**GUIDELINES FOR USE (CONTINUED)**

6. If applicable, has the patient been abstinent from IV drug use or alcohol for  $\geq 6$  months?

If yes, continue to #7.

If no, do not approve.

**DENIAL TEXT:** Approval requires abstinence from IV drug use and alcohol for at least 6 months.

7. Does the patient have severe non-liver related comorbidity causing diminished life expectancy to < 5 years?

If yes, do not approve.

**DENIAL TEXT:** Approval requires no severe non-liver related comorbidity causing diminished life expectancy to < 5 years

If no, continue to #8.

8. Does the patient have a diagnosis of CHC with HCC and is listed for liver transplant?

If yes, continue to #9.

If no, continue to #10.

9. Is the medication being used as combination therapy with ribavirin?

If yes, **approve for up to 48 weeks.**

If no, do not approve.

**DENIAL TEXT:** Approval for use in patients with a diagnosis of CHC with HCC and is listed for liver transplant requires combination therapy with ribavirin.

10. Has the patient undergone a liver transplant?

If yes, consider treatment duration of 24 weeks regardless of the treatment regimen (to be determined by the clinician). Continue to #11.

If no, continue to #11.

11. Does the patient have genotype 1 CHC?

If yes, continue to #12.

If no, continue to #18.

12. Is the patient treatment-naïve?

If yes, continue to #13.

If no, continue to #16.

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**SOFOSBUVIR (SOVALDI)**

**GUIDELINES FOR USE (CONTINUED)**

13. Is the medication being used as triple therapy with both ribavirin and peginterferon?

If yes, **approve for 12 weeks.**

If no, continue to #14.

14. Is the medication being used with simeprevir?

If yes, continue to #15.

If no, do not approve.

**DENIAL TEXT:** Deny for appropriateness.

15. Does the patient have any of the following contraindications to interferon?

- a. concurrent diagnosis of autoimmune hepatitis or other autoimmune disorder
- b. a known hypersensitivity reaction to interferon
- c. documented poorly controlled psychiatric illness
- d. decompensated hepatic disease
- e. baseline neutrophil count <1,500 per microliter
- f. baseline platelet count <50,000
- g. baseline hemoglobin <10g/dL that has not responded to treatment

If yes, continue to #17.

If no, do not approve.

**DENIAL TEXT:** Approval with simeprevir requires contraindication to interferon.

16. Is the medication being used with simeprevir?

If yes, continue to #17.

If no, do not approve.

**DENIAL TEXT:** Approval in treatment experienced patients with genotype 1 requires combination therapy with simeprevir.

17. Has the patient failed treatment with a protease inhibitor, such as boceprevir or telaprevir?

If yes, do not approve.

**DENIAL TEXT:** Approval with Simeprevir requires no prior treatment with a hepatitis C protease inhibitor.

If no, **approve sofosbuvir treatment for 12 weeks.**

18. Does the patient have genotype 2 CHC?

If yes, continue to #19.

If no, continue to #26.

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**SOFOSBUVIR**

**GUIDELINES FOR USE (CONTINUED)**

19. Is the patient treatment-naïve?

If yes, continue to #20.

If no, continue to #21.

20. Is the medication being used as combination therapy with ribavirin?

If yes, **approve for 12 weeks.**

If no, do not approve.

**DENIAL TEXT:** Approval for use in treatment naïve patients with genotype 2 requires combination therapy with ribavirin.

21. Does the patient have advanced fibrosis (stage 3 or 4) or evidence of cirrhosis?

If yes, continue to #23.

If no, continue to #22.

22. Is the medication being used as combination therapy with ribavirin?

If yes, **approve for 12 weeks.**

If no, do not approve.

**DENIAL TEXT:** Approval for use in patients with genotype 2 requires combination therapy with ribavirin.

23. Does the patient have a contraindication to interferon (refer to definition in #15)?

If yes, continue to #24.

If no, continue to #25.

24. Is the medication being used as combination therapy with ribavirin?

If yes, **approve for 16 weeks.**

If no, do not approve.

**DENIAL TEXT:** Approval for use in patients with genotype 2 requires combination therapy with ribavirin.

25. Is the medication being used as combination therapy with peginterferon and ribavirin?

If yes, **approve for 12 weeks.**

If no, do not approve.

**DENIAL TEXT:** Approval for use in patients with genotype 2 requires combination therapy with peginterferon and ribavirin.

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**KAISER PERMANENTE - PORTLAND  
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**SOFOSBUVIR (SOVALDI)**

**GUIDELINES FOR USE (CONTINUED)**

26. Does the patient have genotype 3, 4, 5, or 6 CHC?

If yes, continue to #27.

If no, do not approve.

**DENIAL TEXT:** Deny for appropriateness.

27. Does the patient have a contraindication to interferon (refer to definition in #15)?

If yes, continue to #28.

If no, continue to #29.

28. Is the medication being used as combination therapy with ribavirin?

If yes, **approve for 24 weeks.**

If no, do not approve.

**DENIAL TEXT:** Approval for use in patients with genotype 3, 4, 5, or 6 requires combination therapy with ribavirin.

29. Is the medication being used as combination therapy with peginterferon and ribavirin?

If yes, **approve for 12 weeks.**

If no, do not approve.

**DENIAL TEXT:** Approval for use in patients with genotype 3, 4, 5, or 6 requires combination therapy with peginterferon and ribavirin.

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**RATIONALE**

Ensure the appropriate use of sofosbuvir.

**FDA APPROVED INDICATIONS**

Sofosbuvir is indicated for treatment of chronic hepatitis C (CHC) as a component of a combination antiviral treatment regimen for adults ages  $\geq 18$  years old.

- Sofosbuvir efficacy has been established in subjects with CHC genotype 1, 2, 3, or 4 infection, including those with hepatocellular carcinoma (HCC) meeting Milan criteria (awaiting liver transplantation) and those with human immunodeficiency virus (HIV-1) and HCV co-infection.

**EXCLUSION CRITERIA**

Sofosbuvir may not be used as monotherapy.

**REFERENCES**

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences; December 2013.

Created: 07/14

Effective: 09/01/14

Client Approval: 08/25/14

P&T Approval: N/A