



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIMEPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIMEPREVIR	OLYSIO	40771		GPI-10 (1235307710)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1 and meet **ALL** of the following?
 - The patient is 18 years of age or older
 - The patient has a recent HCV infection documented by one detectable HCV RNA level within the past 6 months

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient completed a prior full course of therapy with 1) any HCV protease inhibitor [for example, telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis)] OR 2) regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen) and has not achieved a sustained virologic response (SVR)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?

- The patient has decompensated or compensated cirrhosis
- The patient has limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- The requested medication is being used with ribavirin AND peginterferon alfa
- The patient is taking any of the following medications that are not recommended for concurrent use with Olysio:
 - Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
 - Any of the following HIV medications:
 - A cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcofix, Tybost)
 - An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, darunavir/ritonavir)
 - Delavirdine, etravirine, nevirapine, or efavirenz

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

4. Is the request for a combination regimen with Sovaldi plus Olysio for 12 weeks?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following?

- The patient has contraindications to Epclusa, Harvoni and Mavyret
- The patient has previously failed a short trial with Epclusa, Harvoni or Mavyret (e.g., inability to tolerate, adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa, Harvoni or Mavyret that did not achieve SVR will not be approved]

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following?

- The patient is treatment naïve
- The patient is treatment experienced with prior treatment with peginterferon/ribavirin

If yes, **approve for the requested strengths for 12 weeks by HICL or GPI-10 for #1 per day.**

CLINICAL PHARMACISTS: Please review Sovaldi prior authorization guideline, member history, and hepatitis C MRF if available to ensure appropriate length of approval.

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **SIMEPREVIR (Olysio)** requires the following rule(s) be met for approval:

- A. You have chronic hepatitis C, genotype 1 (type of liver inflammation)
- B. You are 18 years of age or older
- C. You must have documentation of a recent hepatitis c virus infection by at least one detectable HCV RNA level (amount of virus in your blood) within the past 6 months
- D. You will be using Olysio with Sovaldi taken at the same time
- E. You have previously failed a short trial of Harvoni, Mavyret or Epclusa and stopped due to reasons such as adverse effect or intolerance early in therapy, unless there is a medical reason why you cannot (contraindication) take all 3 agents. The medication will not be approved for an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response)
- F. You are treatment naïve (never previously treated) or treatment-experienced with prior treatment with peginterferon/ribavirin

Olysio will not be approved for the following patients:

- A. You have failed a full course of treatment with 1) any HCV protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek] or boceprevir [Victrelis]) OR 2) a regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
- B. You have compensated cirrhosis (no symptoms related to liver damage) or decompensated cirrhosis (you have symptoms related to liver damage)
- C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- D. You are using Olysio with ribavirin and peginterferon alfa
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GUIDELINES FOR USE (CONTINUED)

- E. You are taking any of the following medications that are not recommended for concurrent use with Olysio:
1. Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
 2. Any cobicistat-containing medication (such as Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcofix, Tybost)
 3. Delavirdine, etravirine, nevirapine, or efavirenz
 4. Any HIV protease inhibitor (such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, darunavir/ritonavir)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Olysio.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed November 3, 2022.
- Olysio [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals; November 2017.

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Yes	Yes	No

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