STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR	SOVALDI	40795		GPI-10 (1235308000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C and meet **ONE** of the following criteria?
   - The patient is 18 years of age or older with genotype 1 or 3
   - The patient is 3 to 17 years old with genotype 2 or 3

   If yes, continue to #2.
   If no, continue to #22.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient has severe renal impairment (estimated glomerular filtration rate (GFR) less than 30 mL/min/1.73m2), end stage renal disease, or requires dialysis
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - The patient is concurrently taking any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), Aptivus (tipranavir)/ritonavir, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
   - The patient is using the requested medication with a direct acting antiviral (e.g., Olysio [simeprevir] or Daklinza [daclatasvir]) AND is concurrently taking amiodarone

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient younger than 18 years of age?

   If yes, continue to #18.
   If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following?
   - The patient is treatment naïve OR treatment experienced (prior treatment with peginterferon/ribavirin)
   - The patient is without cirrhosis OR has decompensated cirrhosis OR is post-liver transplant (with or without cirrhosis)

   If yes, continue to #6.
   If no, continue to #22.

6. Does the patient have a trial of or contraindication to the preferred formulary agent based on their genotype?
   - For genotype 1 HCV infection: a short trial of Epclusa (velpatasvir/sofosbuvir) or Harvoni (ledipasvir/sofosbuvir) or contraindication to BOTH agents
   - For genotype 3 HCV infection: a short trial of or contraindication to Epclusa (velpatasvir/sofosbuvir)
     (**NOTE:** An individual who has completed a full course of therapy with the preferred agent that did not achieve a sustained virologic response (SVR will not be approved)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have decompensated cirrhosis?

   If yes, continue to #13.
   If no, continue to #8.

8. Is the requested medication being used with ribavirin **OR** peginterferon alfa and ribavirin?

   If yes, continue to #22.
   If no, continue to #9.

9. Is the requested medication being used in combination with Daklinza (daclatasvir)?
   CLINICAL PHARMACISTS: The patient must also meet all criteria in Daklinza (daclatasvir) guideline to be approvable for both agents. Review the hepatitis C MRF and Daklinza request to ensure that the patient meets criteria for both agents.

   If yes, continue to #14.
   If no, continue to #10.

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GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a genotype 1 hepatitis C infection **AND** meet the following criterion?
    - The requested medication is being used in combination with Olysio (simeprevir)

    If yes, continue to #11.
    If no, continue to #22.

11. Does the patient meet **ONE** of the following?
    - The patient has cirrhosis
    - The patient completed a full course of therapy with ONE of the following:
      - Any HCV protease inhibitor [for example, Incivek (telaprevir), Olysio (simeprevir), or Victrelis (boceprevir)] and has not achieved a sustained virologic response (SVR)
      - A regimen containing NS5A inhibitor [e.g., Harvoni (ledipasvir/sofosbuvir), Epclusa (velpatasvir/sofosbuvir), Technivie (ombitasvir-paritaprevir-ritonavir), Viekira Pak or Viekira XR (ombitasvir-paritaprevir-ritonavir), Zepatier (grazoprevir), or Daklinza (daclatasvir)-containing regimen]

    If yes, continue to #22.
    If no, continue to #12.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

12. Is the patient concurrently using the requested medication and Olysio (simeprevir) with ANY of the following medications?
    - Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (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)
    - An HIV medication: delavirdine, etravirine, nevirapine, or efavirenz
    - A Cobicistat-containing medication [e.g., Stribild or Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir), Evotaz (atazanavir/cobicistat), Prezcobix (darunavir/cobicistat), Tybost (cobicistat)]
    - An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, Aptivus [tipranavir], ritonavir, darunavir/ritonavir)

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

    If no, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **400mg tablets: #1 per day.**
    - **200mg pellets: #2 per day.**

    (NOTE: Regimen approved for genotype 1 patient without cirrhosis: Olysio (simeprevir) and Sovaldi for 12 weeks)
    CLINICAL PHARMACISTS: The patient must also meet all of the criteria in the Olysio (simeprevir) guideline to be approved for both agents. Review the hepatitis C MRF and Olysio (simeprevir) request to ensure that the patient meets criteria for both agents.

13. Is the requested medication being used in combination with Daklinza (daclatasvir)?
    CLINICAL PHARMACISTS: The patient must also meet all criteria in the Daklinza (daclatasvir) guideline to be approved for both agents. Review the hepatitis C MRF and Daklinza (daclatasvir) request to ensure the patient meets criteria for both agents.

    If yes, continue to #14.
    If no, continue to #22.

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GUIDELINES FOR USE (CONTINUED)

14. Is the patient concurrently using the requested medication and Daklinza (daclatasvir) with ANY of the following medications: amiodarone, carbamazepine, phenytoin, rifampin, or Priftin (rifapentine)?

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

    If no, continue to #15.

15. Does the patient have compensated cirrhosis?

    If yes, continue to #22.
    If no, continue to #16.

16. Does the patient have decompensated cirrhosis or is post-liver transplant?

    If yes, continue to #17.
    If no, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows: (Sovaldi in combination with Daklinza)**
    - **400mg tablets: #1 per day.**
    - **200mg pellets: #2 per day.**

    CLINICAL PHARMACISTS: The patient must also meet all criteria in the Daklinza (daclatasvir) guideline to be approved for both agents. Review the hepatitis C MRF and Daklinza (daclatasvir) request to ensure the patient meets criteria for both agents.

17. Is the patient using a regimen of Daklinza and Sovaldi (sofosbuvir) **WITH** ribavirin?

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows: (Sovaldi in combination with Daklinza and ribavirin)**
    - **400mg tablets: #1 per day.**
    - **200mg pellets: #2 per day.**

    CLINICAL PHARMACISTS: The patient must also meet all criteria in Daklinza guideline to be approvable for both agents. Review hepatitis C MRF and Daklinza request to ensure patient meets criteria for both agents.

    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)

18. Does the patient have genotype 2 infection **AND** compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

    If yes, continue to #19.
    If no, continue to #20.

19. Is the requested medication being used with ribavirin?

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **400mg tablets: #1 per day.**
    - **200mg tablets: #1 per day.**
    - **200mg pellets: #2 per day.**
    - **150mg pellets: #1 per day.**

    If no, continue to #22.

20. Does the patient have genotype 3 infection **AND** compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

    If yes, continue to #21.
    If no, continue to #22.

21. Is the requested medication being used with ribavirin?

    If yes, **approve for 24 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **400mg tablets: #1 per day.**
    - **200mg tablets: #1 per day.**
    - **200mg pellets: #2 per day.**
    - **150mg pellets: #1 per day.**

    If no, continue to #22.

22. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

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 **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
B. You have chronic hepatitis C (type of liver inflammation)
C. You are 18 years of age or older with genotype 1 or 3, OR you are 3 to 17 years old with genotype 2 or 3
D. You have an HCV RNA level (amount of virus in your blood) within the past 6 months
E. **If you are an adult patient (18 years of age or older), approval also requires:**
    1. You are treatment naive (never previously treated) or treatment experienced (prior treatment with peginterferon/ribavirin)
    2. You will be using Sovaldi with Olysio (simeprevir) (genotype 1 only) or Daklinza (daclatasvir) (genotype 1 or 3 only)
    3. You had a short trial of therapy with the following preferred formulary medication(s).If you completed a full course of therapy but did not achieve a sustained virologic response (SVR), you will not be approved to receive the requested medication.
        a. If you have genotype 1 infection, you had a short trial of Epclusa (velpatasvir/sofosbuvir) or Harvoni (ledipasvir/sofosbuvir) or you have a contraindication (harmful for) to BOTH agents
        b. If you have genotype 3 infection, you had a short trial of Epclusa (velpatasvir/sofosbuvir) or you have a contraindication (harmful for) to this agent
F. **If you are a pediatric patient (under 18 years of age), approval also requires:**
    1. The request must meet the Food and Drug Administration (FDA)-approved indication [treatment naive (never previously treated) or treatment experienced patient with compensated cirrhosis (no symptoms related to liver damage) (Child-Pugh A) or without cirrhosis (liver scarring)]
    2. You will be using Sovaldi together with ribavirin (genotypes 2 and 3)

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GUIDELINES FOR USE (CONTINUED)

G. **Sovaldi will not be approved if you meet any of the following:**
   1. You have severe renal (kidney) impairment (glomerular filtration rate less than 30 mL/min/1.73m2), end stage renal disease and/or those requiring dialysis
   2. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
   3. You are an adult with compensated cirrhosis (type of liver condition)
   4. You are using any of the following medications at the same time while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), Aptivus (tipranavir)/ritonavir, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
   5. You are using Sovaldi with another direct acting antiviral (such as Olysio [simeprevir] or Daklinza [daclatasvir]) AND are on concurrent amiodarone
   6. You are 18 years of age or older and are taking Sovaldi with ribavirin OR peginterferon alfa and ribavirin

H. **If the request is for Sovaldi and Olysio (simeprevir), approval also requires:**
   1. You are 18 years of age or older
   2. You have genotype 1 hepatitis C (type of liver inflammation)
   3. You do not have cirrhosis (liver scarring)
   4. You have not previously failed a full course of therapy with ONE of the following:
      a. Any hepatitis C virus protease inhibitor (type of hepatitis C drug such as Incivek [telaprevir], Olysio [simeprevir], or Victrelis [boceprevir)
      b. A regimen containing NS5A inhibitor (type of hepatitis medication such as Harvoni (ledipasvir/sofosbuvir), Epclusa (velpatasvir/sofosbuvir), Technivie (ombitasvir-paritaprevir-ritonavir), Viekira Pak or Viekira XR (ombitasvir-paritaprevir-ritonavir), Zepatier (grazoprevir), or Daklinza (daclatasvir)-containing regimen)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

I. **You will not use the requested medication together with any of the following medications as they are contraindicated (harmful for) or not recommended by the manufacturer:**
   1. Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (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)
   2. Any of the following human immunodeficiency virus (HIV) medications: delavirdine, etravirine, nevirapine, or efavirenz
   3. A cobicistat-containing medication such as Stribild or Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir), Evotaz (atazanavir/cobicistat), Prezcobix (darunavir/cobicistat), or Tybost (cobicistat)
   4. A human immunodeficiency virus (HIV) protease inhibitor such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, Aptivus (tipranavir), ritonavir, or darunavir/ritonavir

J. **If the request is for Sovaldi with Daklinza (daclatasvir), approval also requires:**
   1. You are 18 years of age or older
   2. You have genotype 1 or 3 hepatitis C (type of liver inflammation)
   3. You will not be using the requested medication together with any of the following medications because they are contraindicated (medical reason why you cannot use a drug) or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or Priftin (rifapentine)
   4. You will be taking ribavirin together with Sovaldi and Daklinza if you have decompensated cirrhosis (type of liver condition) or you are post-liver transplant

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.

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SOFOSBUVIR

RATIONALE

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

REFERENCES

- Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, and Managing. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 3, 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
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Client Approval: 08/23
P&T Approval: 04/22