Drug/Drug Class

Agents for the Treatment of Hepatitis C

Clinical Edit Information Included in this Document

Agents for the Treatment of Hepatitis C

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical edit
- **Prior authorization criteria logic**: a description of how the prior authorization request will be evaluated against the clinical edit criteria rules
- **Logic diagram**: a visual depiction of the clinical edit criteria logic
- **Supporting tables**: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References**: clinical publications and sources relevant to this clinical edit

**Note**: Click the hyperlink to navigate directly to that section.

Revision Notes

- N/A, initial publication
Agents for the Treatment of Hepatitis C

Drugs Requiring Prior Authorization

<table>
<thead>
<tr>
<th>Label Name</th>
<th>GCN</th>
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<tbody>
<tr>
<td>INCIVEK 375MG TABLET</td>
<td>29964</td>
</tr>
<tr>
<td>OLYSIO 150MG CAPSULE</td>
<td>35648</td>
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<tr>
<td>SOVALDI 400MG TABLET</td>
<td>35708</td>
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<tr>
<td>VICTRELIIS 200MG CAPSULE</td>
<td>29941</td>
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</tbody>
</table>
Agents for the Treatment of Hepatitis C

Clinical Edit Criteria Logic

Initial Request:

1. Does the client have a diagnosis of hepatitis C in the last 730 days?
   - [] Yes – Go to #2
   - [] No – Deny

2. Does the client have any listed contraindication to treatment with these agents?
   - [] Yes - Deny
   - [] No – Go to #3

3. Does the client have a co-infection with HIV?
   - [] If yes and IFN-eligible - Deny (IFN/RBV can be used – does not require a prior authorization)
   - [] If yes and IFN-ineligible - Approve Sofosbuvir/RBV for 24 weeks
   - [] No – Go to #4

4. Has the client been treated for hepatitis C previously?
   - [] Yes – Go to #8
   - [] No – Go to #5

5. Does the client have documented liver disease (fibrosis score 3/4 or CTP class B/C*)
   - [] Yes – Go to #6
   - [] No – Deny

6. Does the client have hepatocellular carcinoma?
   - [] Yes – Approve Sofosbuvir/RBV for up to 48 weeks
   - [] No – Go to #7

7. Does the client have documented intolerance to IFN?
   - [] If yes and genotype 1 – Approve Sofosbuvir/RBV for 24 weeks
   - [] If yes and genotype 2 – Approve Sofosbuvir/RBV for 12 weeks
   - [] If yes and genotype 3/4/5/6 – Approve Sofosbuvir/RBV for 24 weeks
   - [] If no and genotype 1 – Approve IFN/RBV/PI for 24 weeks
     OR IFN/RBV/Sofosbuvir for 12 weeks
   - [] If no and genotype 2/3/4/5/6 – Deny (IFN/RBV can be used – does not require a prior authorization)

8. Is the client a candidate for retreatment?
   - [] Yes – Go to #9
   - [] No – Deny

9. Has the client been previously treated with a protease inhibitor?
   - [] Yes – Go to #10
   - [] No – Go to #11
Agents for the Treatment of Hepatitis C

Clinical Edit Criteria Logic

10. Was the client responsive to treatment with a protease inhibitor?
   [ ] Yes – Go to #11
   [ ] No – Approve Sofosbuvir/RBV for 24 weeks

11. Does the client have documented liver disease (fibrosis score 3/4 or CTP class B/C*)?
   [ ] Yes – Go to #12
   [ ] No – Deny

12. Does the client have hepatocellular carcinoma?
   [ ] Yes – Approve Sofosbuvir/RBV for up to 48 weeks
   [ ] No – Go to #13

13. Does the client have documented intolerance to IFN?
   [ ] If yes and genotype 1 – Approve Sofosbuvir/RBV for 24 weeks
   [ ] If yes and genotype 2 – Approve Sofosbuvir/RBV for 12 weeks
   [ ] If yes and genotype 3/4/5/6 – Approve Sofosbuvir/RBV for 24 weeks
   [ ] If no and genotype 1 – Approve IFN/RBV/BOC for 36 weeks
   OR IFN/RBV/TVR for 12 weeks OR Sofosbuvir/RBV/IFN for 12-24 weeks
   OR Simeprevir**/RBV/IFN for 12 weeks
   [ ] If no and genotype 2 – Approve Sofosbuvir/RBV for 12 weeks
   [ ] If no and genotype 3/4/5/6 – Approve Sofosbuvir/RBV/IFN for 12 weeks

*CTP score of 7-9 is Grade B and 10-15 is Grade C

**Use of Simeprevir requires documentation of testing for Q80K polymorphism
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Clinical Edit Criteria Logic

Renewal Request:

1. Is the client taking hepatitis C therapy as prescribed (not more than 7 days elapsed between refills)?
   [] Yes – Go to #3
   [] No – Go to #2

2. Did the provider include documentation of hospitalization or other reason for non-compliance?
   [] Yes – Go to #3
   [] No – Deny

3. Is the client showing signs of high risk behavior?
   [] Yes – Deny
   [] No – Go to #4

4. Were HCV RNA levels supplied? (Week 4 levels should be sent at the end of week 8, week 8 levels at the end of week 12, etc.)
   [] Yes - Go to #5
   [] No – Deny

5. Has the client completed their scheduled duration of therapy?
   [] Yes – Deny
   [] No – Approve (28 days)
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Clinical Edit Criteria Logic Diagram

Step 1
Does the client have a diagnosis of hepatitis C in the last 730 days?

Yes → Step 2

No → Deny Request

Step 2
Does the client have a contraindication to treatment with any of these agents?

Yes → Deny Request

No → Step 3

Step 3
Does the client have co-infection with HIV?

Yes → Deny Request

No → Step 4

Step 4
Has the client been treated for hepatitis C previously?

Yes → Deny Request

No → Step 5

Step 5
Does the client have documented liver disease?

Yes → Step 6

No (genotype 1) → No (genotype 2/3/4/5/6) → Approve Request

Step 6
Does the client have hepatocellular carcinoma?

Yes → Approve Request

No → Step 7

Step 7
Does the client have documented intolerance to IFN?

Yes → Approve Request

No → Approve Request

Step 8
Is the client a candidate for retreatment?

Yes → Approve Request

No → Step 9

Step 9
Does the client have hepatocellular carcinoma?

Yes → Deny Request

No → Step 10

Step 10
Was the client responsive to treatment with a protease inhibitor?

Yes → Approve Request

No → Step 11

Step 11
Does the client have documented liver disease?

Yes → Deny Request

No → Approve Request

Step 12
Does the client have documented intolerance to IFN?

Yes → Approve Request

No → Approve Request

Approve Request
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Clinical Edit Criteria References


Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the most current revision are also provided in the Revision Notes on the first page of this document.

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