Texas Prior Authorization Program
Clinical Edit Criteria

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

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Drugs Requiring Prior Authorization

Agents for the Treatment of Hepatitis C	
Label Name	**GCN**
INCIVEK 375MG TABLET	29964
OLYSIO 150MG CAPSULE	35648
SOVALDI 400MG TABLET	35708
VICTRELIS 200MG CAPSULE	29941

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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

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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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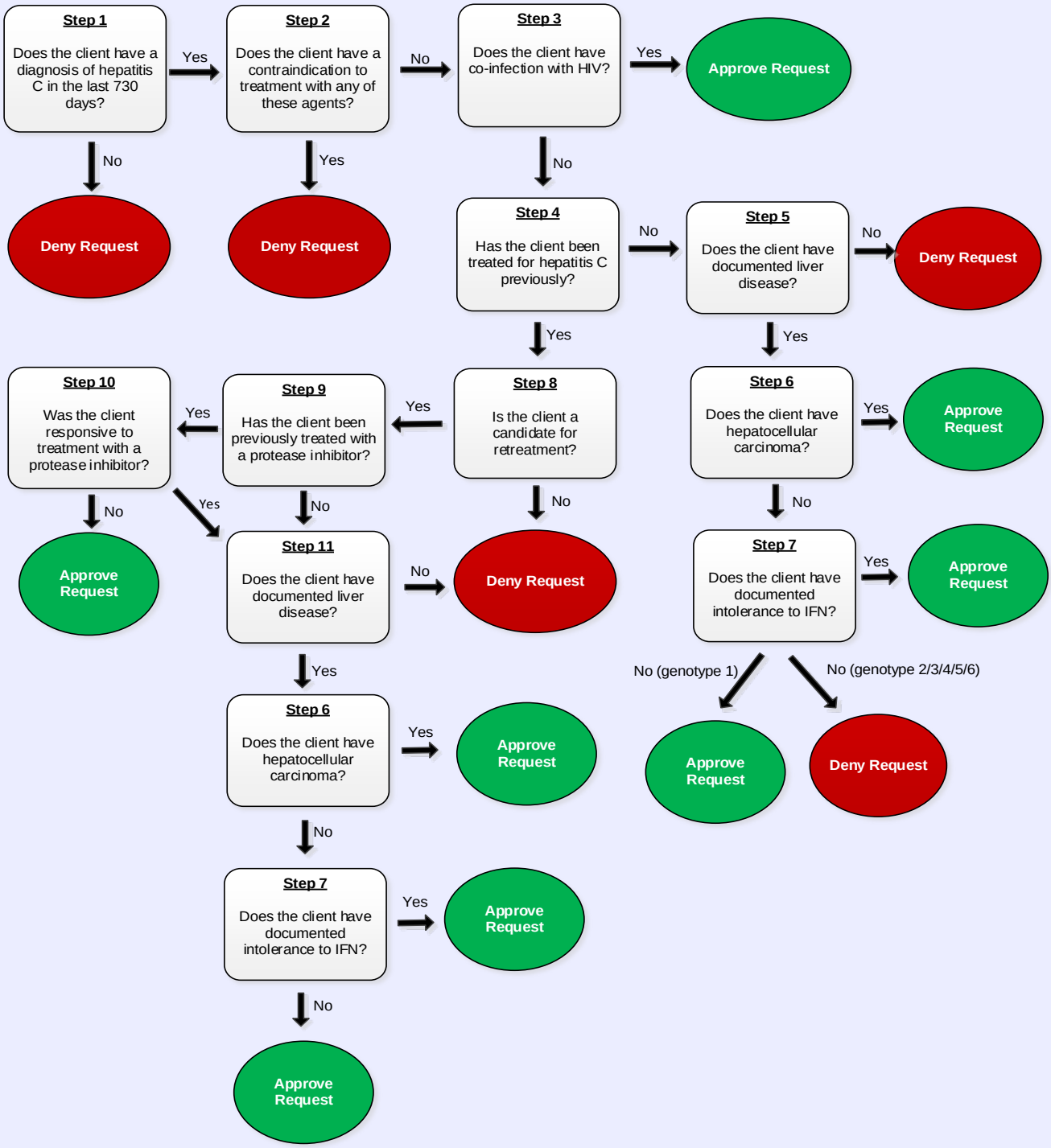
Clinical Edit Criteria Logic Diagram



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Clinical Edit Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2014. Available at http://www.clinicalpharmacology.com. Accessed on March 26, 2014.

2. Incivek Prescribing Information. Vertex Pharmaceuticals Incorporated. Cambridge, MA. October 2013.

3. Olysio Prescribing Information. Janssen Therapeutics. Titusville, NJ. November 2013.

4. Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. December 2013.

5. Victrelis Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. February 2014.

6. American Association for the Study of Liver Diseases (AASLD) – Infectious Diseases Society of America (IDSA). Recommendations for Testing, Managing, and Treating Hepatitis C. Available at **www.hcvguidelines.org**. Revised March 21, 2014.

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.

Publication Date	Notes