

Clinical Pharmacy Program Guidelines for Hepatitis C Agents – ARIZONA

Program	Prior Authorization
Medication	<p>Hepatitis C Agents</p> <p>Preferred Agents: Mavyret™ (glecaprevir/pibrentasvir)</p> <p>Non-preferred Agents: Daklinza® (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni™ (ledipasvir/sofosbuvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir tablets), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), Viekira XR™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release tablets), Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir), Zepatier™ (elbasvir/grazoprevir)</p>

1. State Mandated Criteria - LOD



320-N-Hepatitis-C-H
CV-Prior-Authorizatio

2. Amount, Duration and Scope:

<p>In order to obtain prior authorization approval of hepatitis C direct acting antiviral medications, members must meet all of the following requirements:</p> <ol style="list-style-type: none"> 1. Diagnosis of chronic hepatitis C infection status which has been confirmed by detectable serum HCV RNA by quantitative assay completed within the past 90 days from the date of the prior authorization request that includes the HCV genotype, viral resistance status (when applicable), hepatic status (Child Pugh Score) and HCV viral load; AND 2. Adult age ≥ 18 years or adolescent age between 12 and 18 years old¹; and 3. Are prescribed HCV medications by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician, and 4. Patient readiness has been assessed and patient attestation of compliance is submitted and on file in the member's medical record (prescribers shall use the CSPMP as a tool to aid in the review of compliance);² and 5. The member agrees to complete the regimen and understands the risks of

- reinfection and other contributors to liver disease and/or damage, through a signed attestation; and
6. The prescribing clinician agrees to maintain HCV RNA levels obtained at 12 & 24-weeks post therapy completion to demonstrate the Sustained Virilologic Response (SVR);³ and
 7. Member has been screened for Hepatitis A and B and must have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity;⁴ and
 8. The member must be in remission for the past three months from the request date for treatment and must be engaged in a substance use disorder treatment program at the time of the prior authorization and over the course of the treatment if the member has/had a substance use disorder in the past 12 months.⁵

If the request is for a non-preferred medication, the patient has a history of failure, contraindication, or intolerance to all preferred AHCCCS Hepatitis C agents.

A. TREATMENT MONITORING REQUIREMENTS

1. Members prescribed HCV treatment must participate in a treatment adherence program.
2. Providers are required to monitor hemoglobin levels periodically when a member is prescribed ribavirin.

B. HEPATITIS C RETREATMENT REQUIREMENTS⁶

For members who have HCV and a history of treatment with a DAA, the following criteria must be met for DAA retreatment approval:

1. The member was adherent to previous DAA therapy as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record must be provided which documents these adverse effects and recommendation of discontinuation by treatment provider; and
2. If a member has a substance use disorder in the past 12 months from the request date for treatment, the member must be in remission for the past three months from the request date for treatment and must be engaged in a substance use disorder treatment program at the time of the prior authorization request and over the course of treatment if the DAA medications are approved.
3. Member commits to the documented planned course of treatment including

anticipated laboratory, imaging tests, and prescribing provider visits.

4. Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when⁷:
 1. Required for regimens whereby the FDA requires such testing prior to treatment to ensure clinical appropriateness; and
 2. Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen

Hepatitis C Retreatment shall not be approved when:

1. The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy.
2. A member was non-adherent to the initial DAA treatment regimen as evidenced by medical records and/or pharmacy prescription claims.
3. Is considered an experimental service as defined in R9-22-203. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA.

C. LIMITATIONS

Direct Acting Antiviral HCV treatment coverage is not provided for the following:

1. Monotherapy of:
 - a. Daclatasvir (Daklinza),
 - b. Simeprevir (Olysio),
 - c. Sofosbuvir (Sovaldi).
2. Direct Acting Antiviral Dosages greater than the FDA approved maximum dosage.
3. Ombitasvir, Paritaprevir and Ritonavir (Technivie) or Ombitasvir, Paritaprevir and Ritonavir; Dasabuvir tablets (Viekira Pak) shall not be approved for members whose Child Pugh score is B or C.
4. Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request.
5. Members when there is documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures.
6. Members declining to participate in a treatment adherence program.
7. Members declining to participate in a substance abuse disorder treatment

program.

8. Members whose comorbidities are such that their life expectancy is one year or less.
9. Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.).
10. Greater than one Direct Acting Antiviral drug regimen used for retreatment.⁸⁹.
11. Lost or stolen medication absent of good cause.
12. Fraudulent use of HCV medications.

D. REQUIRED DOCUMENTATION FOR SUBMISSION OF HCV PRIOR AUTHORIZATION REQUESTS

In order for a prior authorization request for HCV medications to be considered, the following minimum information must be submitted for the member:

1. HCV treatment history and responses.
2. Evidence of Hepatitis A & B vaccinations or laboratory evidence of immunity.
3. Current medication list.
4. Laboratory results for all of the following:

HCV screen, genotype and current baseline viral load, total bilirubin, albumin, INR, CrCl or GFR, LFTs, CBC and drug/alcohol screen completed within the past 90 days.

E. Pegasys and PegIntron

1. Pegasys or PegIntron as part of a combination antiviral treatment regimen

- a. **Pegasys or PegIntron** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic hepatitis C infection

-AND-

(2) Patient without decompensated liver disease (defined as Child-Pugh Class B or C)

⁸ POST TCN/PC Change Limiting retreatment to one regimen based on our conversation with Dr. Manch

⁹ POST TCN/PC Change Removing and replacing with retreatment guidelines in the policy.

-AND-

(3) Will be used as part of a combination antiviral treatment regimen

Authorization will be issued for 48 weeks

F. Ribavirin Tablets and Capsules

1. Ribavirin tablets and capsules as part of a combination antiviral treatment regimen

a. **Ribavirin tablets or capsules** will be approved based on **both** of the following criteria:

(1) Diagnosis of chronic hepatitis C infection

-AND-

(2) Used in combination with a direct-acting agent

Authorization will be issued for 12 months

4. References

1. A new scoring system for prediction of fibrosis in chronic hepatitis C; Simona Bota, Roxana Sirli, Ioan Sporea, Mircea Focsa, Alina Popescu, Mirela Danila, Mihnea Strain, Madalina Sendroiu, Alexandra Deleanu, and Isabel Dan; July 1, 2011.
2. 42; Cryoglobulinemia and Hepatitis C Virus; Clodoveo Ferri, Marco Sebastiani, David Saadoun and Patrice Cacoub; March 9, 2012.
3. OlysioTM (package insert). Titusville, NJ: Janssen Products, LP; November 2013.
4. SovaldiTM (package insert). Foster City, CA: Gilead Sciences, Inc. December 2013.
5. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America: Recommendations for Testing, Managing, and Treating Hepatitis C. January 2014.
6. Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health; March 2014.
7. The Comparative Clinical Effectiveness and Value of Simeprevir and



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Sofosbuvir in the Treatment of Chronic Hepatitis C Infection; California Technology Assessment Forum; March 2014.

8. Sofosbuvir for the Treatment of Hepatitis C and Evaluation of the 2014 American Association for the Study of Liver Diseases Treatment Guideline; Oregon Health & Science University Center for Evidence-based Policy; May 2014.
9. Transient elastography: a meta-analysis of diagnostic accuracy in evaluation of portal hypertension in chronic liver disease; Shi KQ, Fan YC, Pan ZZ, Lin XF, Liu WY, Chen YP, Zheng MH; Liver Int. 2013 Jan;33(1):62-71; Epub 2012 Sep 2014.
10. HarvoniTM (package insert); Foster City, CA: Gilead Sciences, Inc. October 2014.
11. ViekiraTM (package insert). North Chicago, IL: Abbvie; December 2014.
12. Hepatitis C virus syndrome: A constellation of organ- and non-organ specific autoimmune disorders, B-cell non- Hodgkin lymphoma and cancer; ; Clodoveo Ferri, Marco Sebastiani, Dilia Giuggioli, Michele Colaci, Poupak Fallahi, Alessia Piluso, Alessandro Antonelli, and Anna Linda Zignego; World Journal Hematology; 2015 March 27; 7(3): 327-343.
13. TechnivieTM (package insert). North Chicago, IL: ABBVIE; July 2015.
14. DaklinzaTM (package insert). Princeton, NJ: Bristol Myers Squibb; July 2015.
15. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America: Recommendations for Testing, Managing, and Treating Hepatitis C. January 2016.
16. ZepatierTM (package insert). Kenilworth, NJ; Merck; January 2016.
17. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America: Recommendations for Testing, Managing, and Treating Hepatitis C. February 24, 2016.
18. EpclusaTM (package insert). Foster City, CA: Gilead Sciences, Inc. June 2016.
19. Calculator: Aspartate aminotransferase (AST) to platelet ratio index (APRI); UpToDate: Wolters Kluwer Health. St Louis, MO Updated daily; July 5, 2016.
20. Drug Facts and Comparisons on-line (www.drugfacts.com); Wolters Kluwer Health; St Louis, MO Updated daily.



Community Plan

Program	Prior Authorization – Hepatitis C Agents
Change Control	
Date	Change
11/2016	Arizona-specific policy created
6/2017	Added ribavirin, Pegasys, and PegIntron review criteria
1/2018	Updated background to include Mavyret as only preferred product as of 1/1/18. Removed fibrosis requirement as of 1/1/18.
1/2018	Removed description section. Added preferred and non-preferred agents to medications section. Replaced criteria with updated state mandated criteria.