



Rhode Island AIDS Drug Assistance Program (ADAP)

Executive Office of Health & Human Services

Medications for Treatment of Hepatitis C Prior Authorization Guidelines

Effective Date: September 25, 2017

Introduction:

Hepatitis C has been identified as a significant etiology of chronic liver disease, associated co-morbidities, need for liver transplant and death. This prior authorization process is specific for the use of medications on the Rhode Island AIDS Drug Assistance Program (ADAP) formulary. Additional medications or drug classes subsequently receiving FDA approval will require separate review. On October 4, 2016 the U.S. Food and Drug Administration (FDA) began requiring a *Boxed Warning* about the risk of Hepatitis B Virus (HBV) reactivation to be added to the labels of direct acting antiviral (DAA) agents. Detailed information is available at <http://www.fda.gov/Drugs/DrugSafety/ucm522932.htm>.

General Approval Criteria:

1. Prescribers

- a. Requesting physician must be a gastroenterologist, hepatologist or infectious disease (ID) specialist. Consideration will also be given to physicians with clinical expertise and care management of patients with Hepatitis C. Interested physicians must submit the Preferred Provider Application available on the EOHHS website on the pharmacy page under ADAP, and await approval before submitting medication pre-authorization requests.
- b. Physician Assistants and Nurse Practitioners employed by and co-located with a Physician on the Preferred Provider List may request preferred Provider status. Interested mid-levels must submit the Preferred Provider Application available on the EOHHS website on the pharmacy page under ADAP, and await approval before submitting medication pre-authorization requests.
- c. Link to EOHHS Preferred Provider Application
<http://www.eohhs.ri.gov/Portals/0/Uploads/Documents/PA22-PP.pdf>

2. Documentation

- a. Pre-authorization (PA) request must be completed in its' entirety. **Further information is unnecessary.**
- b. The PA form is located on the EOHHS website on the pharmacy page under ADAP.
- c. The quantitative viral load must be within 90 days of the PA request.

3. Monitoring Program

For patients with current or past significant alcohol or intravenous drug abuse, patient must be actively participating in a clinician monitored treatment program or abuse free for a minimum of 6 months. Treatment and monitoring may be maintained in the treating clinician's office and may be documented by attestation. The "Patient Contract" is related to the patient's history of alcohol and intravenous drug use. It is intended to be an assessment for quantifying patients with these conditions, and not an eligibility screen for denying HCV drugs.

4. Patient Responsibility

- a. Patient must indicate a willingness to comply with treatment and monitoring plans as documented by having a signed “Patient Contract” (sample is available on EOHHS website on the pharmacy page under ADAP).
- b. Contract does not have to be submitted with pre-authorization request but must be maintained as part of the provider’s clinical documentation.

5. Approval

- a. Formulary medications:

<i>DAA & PI's</i>		
<i>Brand</i>	<i>(generic)</i>	<i>Strength</i>
Olysio®	(simeprevir)	150mg
Sovaldi®	(sofosbuvir)	400mg
Harvoni®	(ledispavir & sofosbuvir)	90mg-400mg
Viekira Pak™	(ombitasvir, paritaprevir, ritonavir & dasabuvir)	12.5-75-50 & 250mg
Viekira XR™	(dasabuvir, ombitasvir, paritaprevir & ritonavir)	200, 8.33, 50 & 33.33 mg
Daklinza™	(daclatasvir)	30mg, 60mg, 90mg
Technivie™	(ombitasvir, paritaprevir & ritonavir)	12.5-75 & 50 mg
Zepatier™	(elbasvir & grazoprevir)	50mg-100mg
Epclusa®	(sofosbuvir & velpatasvir)	400-100mg
Vosevi™	(sofosbuvir, velpatasvir & voxilaprevir)	400-100mg-100mg
Mayvret™	(glecaprevir & pibrentasvir)	300mg -120mg

- b. Medication approval will be for a full course of treatment with medication being dispensed in 28 day increments.
- c. Approval will be for FDA approved indications and regimens.
- d. EOHHS will periodically review randomly selected, de-identified prior authorizations to ensure consistent application of this policy for all ADAP beneficiaries.
- e. Evidence of non-compliance may be communicated to the prescriber.
- f. EOHHS/ADAP may request patient specific clinical information post treatment regimen.

6. Continuity of Treatment

When transitioning between publicly funded delivery systems (e.g. between Fee for Service Medicaid, Managed Care Medicaid, RI AIDS Drug Assistance Program or the Department of Corrections) any authorization granted by the prior delivery system will be honored for the portion of the treatment that remains after the transition.