Louisiana Medicaid
Infectious Disorders – Hepatitis C Direct-Acting Antiviral (DAA) Agents

To request authorization for **non-preferred** DAA agents, the prescriber must submit the following documents which must be completed, dated and signed by the prescriber - signature stamps and proxy signatures are not acceptable:

- *Louisiana Uniform Prescription Drug Prior Authorization Form*; **AND**
- *Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV) Medication Therapy Worksheet for Louisiana Medicaid Recipients*; **AND**
- *Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV) Treatment Agreement for Louisiana Medicaid Recipients*. Each item on the Hepatitis C Therapy Treatment Agreement must be initialed by the recipient, and the agreement must be dated and signed by the recipient.
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To request clinical authorization for sofosbuvir/velpatasvir/voxilaprevir (Vosevi®), the prescriber must submit the request using the *Louisiana Uniform Prescription Drug Prior Authorization Form.*

Additional Point-of-Sale edits may apply.

The authorized generic (AG) of Epclusa® is preferred and does not require authorization. However, point-of-sale (POS) edits may apply (see POS document).

By submitting the authorization request, the prescriber attests to the conditions available HERE.
*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations; refer to individual prescribing information for details.*

ALL of the following are required when requestingApproval Criteria for Nnon-Ppreferred Aagents:

- The recipient has a diagnosis of chronic hepatitis C (B18.2) and appropriate genotype for agent requested (see Table 1); **AND**
- The recipient's age (or weight, as applicable – see Table 2) is appropriate for the requested medication (see POS document); **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc. (e.g., for requested non-preferred generic Epclusa® and brand Epclusa®, the preferred authorized generic for Epclusa® is the exact same chemical entity, formulation, strength, etc.); **AND**
- Previous use of a preferred products - **ONE** of the following is required and must be **stated on the request**: (Description of **ONE** of the following must be **stated on the request**)
    - The recipient *has had a treatment failure (defined as lackfailed to achieve of achieving a sustained virologic response* (SVR-12) 12 weeks or more after

completing one course of treatment ~~) with~~with ~~at least BOTH~~**EACH**~~one~~ preferred product~~s~~; **OR**

- The recipient has a condition that would prevent the use of the preferred products that are appropriate for the use of the indication being treated, and the condition is **stated on the request**; **OR**
- ~~The recipient has had an *intolerable side effect* to at least one preferred product; **OR**~~
- ~~The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**~~
- ~~There is *no preferred product that is appropriate* to use for the condition being treated; **OR**~~
- T~~he prescriber states that t~~he recipient is currently using the requested medication, and the request is to complete the patient-specific course of treatment recommended in the prescribing information (see POS document).~~; **AND**~~

- ~~By submitting the authorization request, the prescriber attests to the following:~~
  - ~~The prescribing information for the requested medication (and all other medications used in a combination hepatitis C virus treatment regimen) has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**~~
  - ~~All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended (including renal function, hepatic state and monitoring for reactivation of hepatitis B); **AND**~~
  - ~~The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.~~

Duration of authorization approval: Up to maximum duration of therapy depending upon patient-specific factors (see POS document).

Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)

Note: Vosevi® is the preferred agent for the re-treatment of chronic hepatitis C for persons who have experienced treatment failure with DAA therapy.

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of chronic hepatitis C (B18.2); **AND**
- The recipient *failed to achieve a sustained virologic response* [SVR-12 is preferred] with any direct-acting antiviral (DAA) agent indicated for the treatment of chronic hepatitis C. It is preferred that SVR be tested/determined 12 weeks or more after completing a course of DAA treatment; however, an earlier SVR determination indicating failure would be acceptable. The following information must be **stated on the request**:

- Name of previously used DAA agent; **AND**
- DAA agent treatment dates; **AND**
- Quantitative HCV RNA test date; **AND**
- Quantitative HCV RNA results definitively showing failure to achieve SVR.

Duration of authorization approval: 12 weeks

Table 1. Genotype Indications	
Treatment	Indicated for Genotype(s)
Elbasvir/Grazoprevir (Zepatier®)	1, 4
Glecaprevir/Pibrentasvir (Mavyret®)	1, 2, 3, 4, 5, 6
Ledipasvir/Sofosbuvir (Harvoni®; Authorized Generic)	1, 4, 5, 6
Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir (Viekira PAK®)	1
Sofosbuvir (Sovaldi®)	1, 2, 3, 4
Sofosbuvir/Velpatasvir (Epclusa®; Authorized Generic)	1, 2, 3, 4, 5, 6
~~Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)~~	~~1, 2, 3, 4, 5, 6~~

Table 2. Minimum Indicated Age	
Treatment	Minimum Age
Elbasvir/Grazoprevir (Zepatier®)	≥ 12 years*
Glecaprevir/Pibrentasvir (Mavyret®)	≥ 3 years
Ledipasvir/Sofosbuvir (Harvoni®; Authorized Generic)	≥ 3 years
Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir (Viekira PAK®)	≥ 18 years
Sofosbuvir (Sovaldi®)	~~—~~≥ 3 years**
Sofosbuvir/Velpatasvir (Epclusa®)	~~————~~≥ 3 years
~~Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)~~	~~≥ 18 years~~

** Recipients younger than 12 years of age must weigh at least 30kg.*

*** Recipients 3-17 years of age must have genotype 2 or 3 without cirrhosis or with compensated ~~– -~~cirrhosis.*

References

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Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Removed Fee-for-Service from title,added wording that AG Epclusa® does not require prior-authorization, moved genotype/age/quantity limit for each agent to tables, modified duration of therapy for Mavyret® per prescribing information, removed other drug-specific criteria wording, added Vosevi genotype/age/duration/quantity limit to tables / July 2019	July 2019
Moved all point-of-sale information except minimum age to the POS document / May 2020	July 2020
Removed Daklinza, updated references / June 2020	October 2020
Updated minimum ages for Epclusa® and AG Epclusa®, updated references / July 2020	October 2020
Formatting changes, updated references / May 2021	July 2021
Updated minimum ages for Epclusa® and Mavyret®, updated references / June 2021	October 2021
Updated minimum ages / weight for Zepatier®, updated references / December 2021	April 2022
Added clinical authorization requirement for Vosevi®, formatting changes, updated references / April 2024	July 2024