Criteria for Indiana Medicaid
Hepatitis C Agents

Prepared for State of Indiana by OptumRx

EXECUTIVE SUMMARY

Purpose: Promote prudent prescribing of Hepatitis C Agents

Setting & Population: All members

Type of Criteria: ☒ **Increased Risk of ADE** ☒ **Non-Preferred Agent** ☒ **Appropriate Indications** ☒ **Other:**

Data Sources: ☒ **Only administrative databases** ☐ **Databases + Prescriber-supplied**

TARGETED PRODUCTS

Drug Name
EPCLUSA (SOFOSBUVIR/VELPATASVIR)
HARVONI (LEDIPASVIR/SOFOSBUVIR)
MAVYRET (GLECAPREVIR/PIBRENTASVIR)
SOVALDI (SOFOSBUVIR)
VOSEVI (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR)

APPROVAL CRITERIA

Prior authorization for the prescribed drug will be granted when the following approval criteria has been met:

PA Requirements for initial treatment:

If request is for EPCLUSA:
- Must be ≥ 3 years of age
- Must provide member specific justification for use of brand name Epclusa over authorized generic sofosbuvir/velpatasvir (400 mg-100 mg strength only)
- Dosage approved will be one of the following:
  - 400 mg-100 mg daily (one 400 mg-100 mg tablet or two 200 mg-50 mg packets) for adults and members weighing at least 30 kg
  - 200 mg-50 mg daily (one 200 mg-50 mg tablet/packet) for members weighing 17 kg to less than 30 kg
  - 150 mg-37.5 mg daily (one 150 mg-37.5 mg packet) for members weighing less than 17 kg

If request is for SOFOSBUVIR/VELPATASVIR:
- Must be ≥ 3 years of age
- Dosage approved will be one of the following:

- 400 mg-100 mg daily (one 400 mg-100 mg tablet) for adults and members weighing at least 30 kg

Note: Treatment naïve members (defined as: members without previous DAA therapy) 18 years of age and older do not require prior authorization for use within the established dose limits

If request is for HARVONI or LEDIPASVIR/SOFOSBUVIR:
- Must be ≥ 3 years of age
- Must provide member specific justification for use over preferred agents
- Dosage approved will be one of the following:
  - 90 mg-400 mg daily (one 90 mg-400 mg tablet or two 45 mg-200 mg tablets/packets) for members weighing at least 35 kg
  - 45 mg-200 mg daily (one 45 mg-200 mg tablet/packet) for members weighing 17 kg to less than 35 kg
  - 33.75 mg-150 mg daily (one 33.75 mg-150 mg packet) for members weighing less than 17 kg

If request is for MAVYRET:
- Must be ≥ 3 years of age
- Dosage approved will be one of the following:
  - 300 mg-120 mg daily (three 100 mg-40 mg tablets or six 50 mg-20 mg packets) for members ≥ 12 years of age or ≥ 3 years of age and weighing at least 45 kg
  - 250 mg-100 mg daily (five 50 mg-20 mg packets) for members between 3 and 11 years of age and weighing 30 kg to less than 45 kg
  - 200 mg-80 mg daily (four 50 mg-20 mg packets) for members between 3 and 11 year of age and weighing 20 kg to less than 30 kg
  - 150 mg-60 mg daily (three 50 mg-20 mg packets) for members between 3 and 11 years of age and weighing less than 20 kg

Note: Treatment naïve members (defined as: members without previous DAA therapy) 12 years of age and older do not require prior authorization for use of 100mg-40mg tablet within the established dose limits

If request is for SOVALDI:
- Must be ≥ 3 years of age
- Must provide member specific justification for use over preferred agents
- Dosage approved will be one of the following:
  - 400 mg daily (one 400 mg tablet or two 200 mg tablets/packets) for members weighing at least 35 kg
  - 200 mg daily (one 200 mg tablet/packet) for members weighing 17 kg to less than 35 kg
  - 150 mg daily (one 150 mg packet) for members weighing less than 17 kg

If request is for VOSEVI:
- Must be ≥ 18 years of age
- One of the following:
  - Must have hepatitis C genotype 3 with prior treatment failure of a regimen containing NS5B inhibitor (sofosbuvir) OR NS5A inhibitor (elbasvir, pibrentasvir)

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- Must have hepatitis C genotype 1, 2, 3, 4, 5, or 6 with prior treatment failure with an NS5A inhibitor plus NS3/4 PI regimen (e.g., elbasvir/grazoprevir or ombitasvir/paritaprevir/ritonavir/dasabuvir)
- Both of the following:
  - Must have hepatitis C genotype 1, 2, 4, 5, or 6 with prior treatment failure of a regimen containing NS5B inhibitor (sofosbuvir) OR NS5A inhibitor (elbasvir, pibrentasvir)
  - Prescriber has submitted member-specific justification as to why Mavyret (glecaprevir/pibrentasvir) therapy is inappropriate

- Must not have decompensated cirrhosis (Child-Pugh Class B or C)
- Dosage approved will be one 400 mg-100 mg-100 mg tablet daily
- Must meet treatment failure/re-infection criteria

PA Requirements for Treatment Failure or Re-infection or History of Paid Claims:

- Must meet PA requirements for initial treatment AND
- Must provide HCV RNA quantitative and qualitative labs within the past 6 months AND
- Must provide genotype of both current and previous infections AND
- Must confirm the level of member compliance with previous regimen
  - Non-compliance due to intolerance of drug therapy will be considered if new regimen does not contain therapy that produced intolerance
  - Non-compliance for other reasons will require an administrative review
    - Must provide documentation regarding rationale and methodology to ensure the member will be able to comply with therapy

- <u>If request for retreatment is due to treatment failure (member was not previously cured by or was intolerant of previous therapy)</u>
  - Must confirm that therapy requested is different than initial therapy
  - Must submit completed MedWatch form to FDA documenting treatment failure (and provide copy of form with PA submission)

- <u>If request for retreatment is due to re-infection (member was previously cured and virus was re-introduced):</u>
  - Re-infection through organ transplant or blood transfusion
    - Must provide documentation of transplant/transfusion
  - Re-infection for other reasons will require an administrative review
    - Must provide documentation demonstrating actions taken to prevent reinfection in the future

☐ Existing Criteria
☒ Revision of Existing Criteria
☐ New Criteria