Drugs Therapy Guidelines

Olysio™ (simeprevir)

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<thead>
<tr>
<th>Medical Benefit</th>
<th>Applicable</th>
<th>Effective: 11/15/19</th>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 9/20</td>
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<tr>
<td>Pharmacy- Formulary 2</td>
<td>x</td>
<td>Date of Origin: 3/14</td>
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<tr>
<td>Pharmacy- Formulary 3/Exclusive</td>
<td>x</td>
<td>Review Dates: 12/13, 10/14, 12/14, 1/15, 9/15, 9/16, 9/17, 9/18, 9/19</td>
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<td>Pharmacy- Formulary 4/AON</td>
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I. Medication Description

Simeprevir is a direct-acting antiviral (DAA) agent against the hepatitis C virus. It inhibits the HCV NS3/4A protease which is essential for viral replication. It is to be used as a component of a combination antiviral treatment regimen.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Olysio can be granted if the following criteria are met:

- The member is at least 18 years of age **AND**
- Medication is prescribed by or in partnership (defined as consultation, preceptorship, or via telemedicine) with a hepatologist, gastroenterologist, infectious disease specialist, transplant physician, healthcare practitioner under the direct supervision of one of the preceding listed specialists, or a healthcare practitioner experienced and trained in the treatment of HCV infection prescriber working in collaboration with one of these specialists, or a prescriber who has clinical experience with the management and treatment of HCV infection (defined as the management **AND** treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months) **AND**
- A diagnosis of chronic hepatitis C has been established and baseline viral load reported **AND**
- Genotype and subgenotype (if available) is confirmed and documented **AND**
- When requesting coverage of a brand medication for which a plan-preferred A/B rated generic is available, coverage will be provided when there is sufficient evidence that the use of the plan-preferred A/B rated generic equivalent has resulted in inadequate results **AND**
- Coverage will be provided when the member has a documented contraindication to the use of a disease-appropriate plan-preferred medication (Harvoni, Epclusa, Mavyret) that does not apply to the requested medication **OR** when at least ONE of the following criteria have been met:
  - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
o The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

o The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).

o The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities AND
  • Usage (medication combination, dose and duration) is in accordance with current AASLD/IDSA treatment guidelines for chronic hepatitis C (http://www.hcvguidelines.org).

IV. Quantity Limitations

150mg capsules are covered at a quantity of 28 per 28 days to allow for FDA-approved dosing.

V. Coverage Duration

Coverage duration will be determined in accordance with medication prescribing information and recommendations from current AASLD/IDSA treatment guidelines for chronic hepatitis C (http://www.hcvguidelines.org).

VI. Coverage Renewal Criteria

n/a

VII. Billing/Coding Information

Available as 150mg oral capsules- 28 count bottles.

VIII. Summary of Policy Changes

• 3/15/14: new policy
• 4/16/14: updated to reflect AASLD/IDSA treatment guideline changes
• 12/1/14: prioritization of patients based on disease severity added
• 12/23/14: updated to reflect changes in AASLD/IDSA guidelines
• 3/1/15: ViekiraPak is preferred agent for the treatment of genotype 1 disease
• 3/15/15: no policy changes
• 4/15/15: guideline updated to reflect changes in recommendations for the use of ViekiraPak outside of genotype 1 disease
• 7/1/15: formulary distinctions made
• 8/1/15: preferred status of ViekiraPak removed; preferred status of Harvoni/Sovaldi added
• 9/1/15: Coverage criteria opened to treat less urgent-need patients
• 12/15/15: no policy changes
• 4/22/16: Coverage criteria opened to allow consideration despite disease severity; specialist qualifications clarified
• 9/15/16: no policy changes
• 10/19/17: preferred status of Mavyret/Epclusa added
• 11/1/18: no policy changes
• 11/15/19: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.