Drug Therapy Guidelines

Otezla® (apremilast)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Applicable</th>
<th>Effective: 1/1/18</th>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 12/18</td>
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<tr>
<td>Pharmacy- Formulary 2</td>
<td>x</td>
<td>Date of Origin: 9/15/14</td>
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<tr>
<td>Pharmacy- Formulary 3/Exclusive</td>
<td>x</td>
<td>Review Dates: 6/14, 12/14, 12/15, 12/16, 12/17</td>
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<td>Pharmacy- Formulary 4/AON</td>
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I. Medication Description

Otezla, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for treatment of adult patients with psoriatic arthritis (PsA). Otezla is an oral small-molecule inhibitor of PDE4 specific for cyclic adenosine monophosphate (cAMP). Inhibition of PDE4 results in increased intracellular cAMP levels. The specific mechanism by which Otezla exerts its effect in PsA is not well defined.

II. Position Statement

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

III. Policy

Coverage of Otezla is provided for adult members for the following conditions when the listed criteria are met:

- Plaque psoriasis (moderate to severe disease):
  - Prescribed by a rheumatologist or dermatologist AND
  - At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement AND
  - Member has had an inadequate response to PUVA or UVB therapy unless contraindicated AND
  - Member has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated

- Psoriatic arthritis (active disease):
  - Prescribed by a rheumatologist or dermatologist AND
  - One of the following:
    - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) OR
    - If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated) AND
  - The member has tried therapy with at least one of the following plan-preferred medications first: Cosentyx, Enbrel, Humira, or Stelara OR the following criteria have been met:
    - When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
• At least one of the following is 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.
  • 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.
  • 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 due to the availability of a drug sample or a coupon card).
  • 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.

IV. Quantity Limitations

• 1 titration pack is covered in the first month to accommodate induction dosing
• Up to 60 tablets per 30 days are covered to accommodate maintenance dosing

V. Coverage Duration

Coverage is available for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
  • Clinical response or remission of disease is maintained with continued use AND
  • Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as:
• 30mg tablets
• Two-week starter pack including
  o 4 x 10mg tablets
  o 4 x 20mg tablets
  o 5 x 30mg tablets (with an additional 14 x 30mg tablets)
• Twenty eight-day starter pack including
  o 4 x 10mg tablets
  o 4 x 20mg tablets
  o 47 x 30mg tablets

VIII. Summary of Policy Changes

• 9/15/14: new policy
• 10/6/14: included new indication for psoriasis
• 3/15/15: addition of coverage criteria for new indication of psoriasis
• 7/1/15: formulary distinctions made
• 3/15/16: no policy changes
• 1/1/17: step therapy rules updated on the pharmacy benefit
• 5/1/17: step therapy criteria added
• 1/1/18: no policy changes

IX. References

involvement (PALACE 3) [abstract 311]. Presented at: the American College of Rheumatology (ACR) Annual Meeting; San Diego, CA; October 26-30, 2013.


*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.*