Drug Therapy Guidelines

Poteligeo® (mogamulizumab-kpc)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Applicable*</th>
<th>Effective: 3/7/22</th>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 12/22</td>
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<td>Pharmacy- Formulary 2</td>
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<td>Date of Origin: 9/18</td>
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<td>Pharmacy- Formulary 3/Exclusive</td>
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<td>Review Dates: 9/18, 12/18, 12/19, 12/20, 12/21</td>
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<td>Pharmacy- Formulary 4/AON</td>
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I. Medication Description

Poteligeo (mogamulizumab-kpc) is a defucosylated, humanized IgG1 kappa monoclonal antibody that binds to CCR4, a G protein-coupled receptor for CC chemokines that is involved in the trafficking of lymphocytes to various organs. Non-clinical in vitro studies demonstrate mogamulizumab-kpc binding targets a cell for antibody-dependent cell cytotoxicity (ADCC) resulting in depletion of the target cells. CCR4 is expressed on the surface of some Tcell malignancies and is expressed on regulatory T-cells (Treg) and a subset of Th2 T-cells.

II. Position Statement

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

III. Policy

Coverage of Poteligeo is provided when the following criteria are met:
- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Quantity sufficient to allow the following:
- First 28-day cycle: 1mg/kg on days 1,8,15 and 22
- Subsequent 28-day cycles: 1mg/kg on days 1 and 15

V. Coverage Duration

Coverage is available for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage may be renewed based upon the following criteria:
• Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

• J9204: 1 billable unit = 1 mg
• Pertinent indications:
  o Adult T-Cell Leukemia/Lymphoma: C91.50, C91.52
  o Mycosis Fungoides/Sézary Syndrome: C84.00-C84.09, C84.10-C84.19
• Available as Injection: 20mg/5mL (4mg/mL) solution in a single-dose vial for dilution

VIII. Summary of Policy Changes

• 11/1/18: new policy
• 2/15/19: updated billing/coding information
• 1/30/20: no policy changes
• 2/26/21: update billing/coding information
• 3/7/22: no policy changes

IX. References

5. Facts and Comparisons Online, accessed September 2021

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

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