Clinical Pharmacy Program Guidelines for Zinbryta

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<tr>
<th>Program</th>
<th>Prior Authorization</th>
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<tr>
<td>Medication</td>
<td>Zinbryta™ (daclizumab)</td>
</tr>
<tr>
<td>Issue Date</td>
<td>4/2017</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>7/2017</td>
</tr>
<tr>
<td>Effective Date</td>
<td>9/2017</td>
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1. **Background:**

Zinbryta™ (daclizumab) is an interleukin-2 receptor blocking antibody indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Zinbryta should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Because of the risks of hepatic injury, including autoimmune hepatitis and other immune-mediated disorders, Zinbryta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zinbryta REMS Program.

2. **Coverage Criteria:**

A. **Multiple Sclerosis**

   1. **Initial Authorization**

      a. **Zinbryta** will be approved based **all** of the following criteria:

         (1) Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses)

         **-AND-**

         (2) History of failure, intolerance or contraindication to at least **two** of the following:

            (a) interferon β-1a (Avonex® or Rebif®)
            (b) interferon β-1b (Betaseron® or Extavia®)
            (c) glatiramer acetate (Copaxone® or Glatopa™)
            (d) dimethyl fumarate (Tecfidera®)
            (e) teriflunomide (Aubagio®)
            (f) fingolimod (Gilenya®)
            (g) peginterferon beta-1a (Plegridy™)
1. Patient is not receiving daclizumab in combination with another disease modifying agent for MS (e.g., interferon beta preparations, glatiramer acetate, dimethyl fumarate, fingolimod, teriflunomide, alemtuzumab, natalizumab, or ocrelizumab)

Authorization will be issued for 12 months.

2. Reauthorization
   a. Zinbryta will be approved based both of the following criteria:
      (1) Documentation of positive clinical response to Zinbryta therapy
      -AND-
      (2) Patient is not receiving daclizumab in combination with another disease modifying agent for MS (e.g., interferon beta preparations, glatiramer acetate, dimethyl fumarate, fingolimod, teriflunomide, alemtuzumab, natalizumab, or ocrelizumab)

Authorization will be issued for 12 months.

4. References:

<table>
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<th>Program</th>
<th>Prior Authorization/Notification - Zinbryta (daclizumab)</th>
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<tr>
<td></td>
<td><strong>Change Control</strong></td>
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<tr>
<td>4/2017</td>
<td>New program.</td>
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<tr>
<td>7/2017</td>
<td>Added Ocrevus (ocrelizumab) to qualifying and concomitant agents.</td>
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