Clinical Policy: Teriflunomide (Aubagio)
Reference Number: ERX.SPA.114
Effective Date: 10.01.16
Last Review Date: 05.18

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Teriflunomide (Aubagio®) is a pyrimidine synthesis inhibitor.

FDA Approved Indication(s)
Aubagio is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Aubagio is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Multiple Sclerosis (must meet all):
      1. Diagnosis of relapsing-remitting MS;
      2. Prescribed by or in consultation with a neurologist;
      3. Age ≥ 18 years;
      4. Aubagio is not prescribed concurrently with other disease modifying therapies for MS (see Appendix C);
      5. At the time of request, member has none of the following contraindications:
         a. Pregnancy;
         b. Current leflunomide treatment;
      6. Dose does not exceed 14 mg/day (1 tablet/day).
   Approval duration: 6 months

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Multiple Sclerosis (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. Aubagio is not prescribed concurrently with other disease modifying therapies for MS (see Appendix C);
      4. If request is for a dose increase, new dose does not exceed 14 mg/day (1 tablet/day).
   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
      Approval duration: Duration of request or 6 months (whichever is less); or
      2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Primary progressive MS.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MS: multiple sclerosis

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: General Information
- Disease-modifying therapies for MS are: daclizumab (Zinbryta®), glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocreliuzumab (Ocrevus™).

V. Dosage and Administration

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<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tr>
<td>Relapsing MS</td>
<td>7 or 14 mg PO QD with or without food</td>
<td>14 mg/day</td>
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VI. Product Availability
Tablets: 7 mg, 14 mg

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy split from USS.SPMN.36 Multiple Sclerosis (MS) Treatments and converted to new template. Removed all safety criteria, added max dosing, clarified monotherapy restriction, and modified approval duration to 6 months for initial and 12 months for re-auth.</td>
<td>08.16</td>
<td>09.16</td>
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<tr>
<td>Converted to new template. Added age requirement as safety and efficacy have not been established in pediatric populations. Removed MRI requirement as it is a non-specific diagnostic test (plus, specialist involvement in care is required). Added 2 contraindications which can be objectively confirmed and can lead to severe adverse reactions (e.g., death or requiring hospitalization). Added PPMS as a diagnosis not covered.</td>
<td>06.17</td>
<td>08.17</td>
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<td>2Q 2018 annual review: No significant changes. References reviewed and updated.</td>
<td>01.05.18</td>
<td>05.18</td>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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