Clinical Policy: Teriflunomide (Aubagio)

Reference Number: PA.CP.PHAR.262
Effective Date: 01/18
Last Review Date: 04/18 Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for teriflunomide (Aubagio®).

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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Aubagio is **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of a relapsing form of multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Failure of one of the following (a or b) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced or patient has been previously established and stabilized on therapy:
   a. Avonex or Plegridy and any of the following: glatiramer (Copaxone, Glatopa), Tecfidera, Gilenya;
   b. Any 2 of the following agents: glatiramer acetate (Copaxone, Glatopa), Tecfidera, Gilenya;
5. Member will not use other disease modifying therapies for MS concurrently;
6. At the time of request, member is not receiving leflunomide;
7. Dose does not exceed 14 mg/day (1 tablet/day).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale score or reduction in relapses or magnetic resonance imaging lesions);
3. Member is not using other disease modifying therapies for MS concurrently;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Teriflunomide, an immunomodulatory agent with anti-inflammatory properties, inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in de novo pyrimidine synthesis. The exact mechanism by which teriflunomide exerts its therapeutic effect in multiple sclerosis in unknown but may involve a reduction in the number of active lymphocytes in the central nervous system.

Formulations:

Aubagio is available as 7 mg (light greenish-bluish grey to pale greenish-blue, hexagonal, film-coated) and 14 mg (pale blue to pastel blue, pentagonal, film-coated) tablets with dose strength imprinted on one side and engraved with corporate logo on other side.

FDA Approved Indication(s):

Aubagio is a de novo pyrimidine synthesis inhibitor/oral tablet indicated for:
- Treatment of patients with relapsing forms of multiple sclerosis.

Appendices

Appendix A: Abbreviation Key

FDA: Food and Drug Administration
MS: multiple sclerosis

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed contraindication; references reviewed and updated.	01.05.18	

References

1. Aubagio Prescribing Information. Cambridge, MA: Genzyme Corporation; November 2016. Available at http://www.aubagio.com. Accessed June 14, 2017.
2. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. July 2016. Accessed January 5, 2018.