Pharmacy Policy Bulletin: J-0637 Aubagio (teriflunomide) – Commercial and Healthcare Reform	
Number: J-0637	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0637-011	**Original Date:** 12/05/2012
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Aubagio (teriflunomide)
FDA-Approved Indication(s):	• Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Background:	• Aubagio is an immunomodulatory agent with anti-inflammatory properties, inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in de novo pyrimidine synthesis. The exact mechanism by which Aubagio exhibits its therapeutic effect in MS is unknown but may involve a reduction in the number of activated lymphocytes in the central nervous system.
	• Clinically isolated syndrome is the first episode of neurological symptoms caused by inflammation and demyelination in the central nervous system. Relapsing-remitting MS (RRMS) is characterized by clearly defined attacks of new or increasing neurologic symptoms. The attacks are followed by periods of partial or complete recovery (remissions). Secondary progressive disease follows an initial relapsing remitting course, with disability gradually increasing over time.
	• Assessments are required prior to initiating Aubagio including liver function tests, pregnancy test, complete blood count, blood pressure monitoring, and tuberculosis screening.
	• Prescribing Considerations:
	  ○ Aubagio is to be prescribed under the supervision of a neurologist.
	  ○ Aubagio has a black box warning for hepatotoxicity and embryofetal toxicity.
	  ○ Aubagio is contraindicated in severe hepatic impairment, pregnancy, and current leflunomide treatment.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Aubagio (teriflunomide) may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of a multiple sclerosis (ICD-10: G35), classified as one (1) of the following **(1., 2., or 3.):**

1. Clinically isolated syndrome

2. Relapsing-remitting disease

3. Secondary progressive disease

C. If the request is for brand Aubagio, the member has experienced therapeutic failure or intolerance to generic teriflunomide.

II. Reauthorization

When a benefit, reauthorization of Aubagio (teriflunomide) may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(1., 2., or 3.):**

1. Disease stability

2. Disease improvement

3. Delayed disease progression

B. If the request is for brand Aubagio, the member has experienced therapeutic failure or intolerance to generic teriflunomide.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Combination use of disease modifying MS agents (Aubagio, Gilenya, interferons, Copaxone, Tysabri, etc.) will not be authorized.

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 24 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; June 2024.
2. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed January 28, 2025.
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. *Neurol*. 2018 April 24;90(17):1-228.