

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

|                  |                                |
|------------------|--------------------------------|
| <b>DRUG NAME</b> | <b>Aubagio (teriflunomide)</b> |
| BENEFIT TYPE     | Pharmacy                       |
| STATUS           | Prior Authorization Required   |

Aubagio is a pyrimidine synthesis inhibitor that was approved by the FDA in 2012. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Aubagio has a black box warning for hepatotoxicity and teratogenicity.

Aubagio (teriflunomide) will be considered for coverage when the following criteria are met:

#### Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of a relapsing form of MS, to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
4. Member has had baseline liver function testing within the past 6 months and does not have severe hepatic impairment; AND
5. Member has tested negative for tuberculosis; AND
6. Member is not taking leflunomide.
7. **Dosage allowed/Quantity limit:** 7 mg or 14 mg orally once daily. (30 tablets per 30 days).

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes must include documentation of positive clinical response such as reduced relapse rate, disability progression, or disease activity on MRI.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Aubagio (teriflunomide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

| DATE       | ACTION/DESCRIPTION   |
|------------|--|
| 06/12/2017 | New policy for Aubagio created. Not covered diagnosis added.                                       |
| 12/06/2017 | Age coverage expanded. Confirmation of diagnosis based on McDonald criteria is no longer required. |

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|-------------------|---|
| <b>07/19/2022</b> | Transferred to new template. Updated and added references. Made correction to move CIS from exclusion to indication. Added LFT monitoring and TB test. Added concomitant leflunomide exclusion. Created renewal criteria. |
| <b>06/24/2025</b> | Annual review; no updates.  |

## References:

1. Aubagio [package insert]. Cambridge, MA; Genzyme, Inc. 2024.
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3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in *Neurology*. 2019 Jan 8;92(2):112]. *Neurology*. 2018;90(17):777-788
4. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: <https://cdn.sanity.io/files/y936aps5/production/76159995e7f4c6c0c2e6de5c4ba6a5881ab368f7.pdf>. Accessed June 23, 2025.
5. He D, Zhang C, Zhao X, et al. Teriflunomide for multiple sclerosis. *Cochrane Database Syst Rev*. 2016;3:CD009882. Published 2016 Mar 22. doi:10.1002/14651858.CD009882.pub3
6. Zhang Y, Yin H, Zhang D, Xu Y, Peng B, Cui L. Real-world outcomes of teriflunomide in relapsing-remitting multiple sclerosis: a prospective cohort study [published online ahead of print, 2022 Apr 11]. *J Neurol*. 2022;1-9. doi:10.1007/s00415-022-11118-7
7. Papp V, Buron MD, Siersma V, et al. Real-world outcomes for a complete nationwide cohort of more than 3200 teriflunomide-treated multiple sclerosis patients in The Danish Multiple Sclerosis Registry. *PLoS One*. 2021;16(5):e0250820. Published 2021 May 18. doi:10.1371/journal.pone.0250820

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Revised date: 06/24/2025