CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Aubagio (teriflunomide)
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 a trial and failure of **TWO** preferred brand MS products; AND
5. Member has had baseline liver function testing within the past 6 months and does not have severe hepatic impairment; AND
6. Member has tested negative for tuberculosis; AND
7. Member is not taking leflunomide.
8. **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.

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.
07/19/2022	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.
09/26/2024	Added trial and failure of two preferred brand MS products

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://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed August 18, 2021.
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

Effective date: 01/01/2025
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