# Aubagio (teriflunomide)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|---|
| Aubagio (teriflunomide) | May be subject to quantity limit |

## APPROVAL CRITERIA

Requests for Aubagio (teriflunomide) may be approved when the following criterion is met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease).

Aubagio (teriflunomide) may not be approved for the following:

I. Use in combination with other MS disease modifying agents (including Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Tecfidera, Tascenso ODT, Tysabri, Vumerity and Zeposia); **OR**
II. Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C); **OR**
III. Use in combination with leflunomide (Arava); **OR**
IV. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
V. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis if initiating therapy; **OR**
VI. Individual is using to treat non-active secondary progressive multiple sclerosis.

**Note:**
Aubagio has black box warnings for hepatotoxicity and risk of teratogenicity. Clinically significant and potentially life-threatening liver injury, including acute liver failure requiring transplant, has been reported in individuals treated with Aubagio. Transaminase and bilirubin levels should be obtained within 6 months before initiation of therapy. ALT levels should be monitored at least monthly for 6 months. If liver injury is suspected, therapy should be discontinued, and an accelerated elimination procedure should be initiated. In addition, there is a risk of major birth defects associated with Aubagio resulting in a contraindication in pregnant women or women of childbearing potential who are not using reliable contraception. Exclude pregnancy before starting Aubagio in females of reproductive potential. Advise females of reproductive potential to use effective contraception during Aubagio treatment and during an accelerated elimination procedure after Aubagio treatment. Stop Aubagio and use an accelerated elimination procedure if the individual becomes pregnant.

**Key References**:


1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 7, 2022.
2. Devonshire V, Havrdova E, Radue EW, et al. Relapse and disability outcomes in patients with multiple sclerosis treated with fingolimod: subgroup analyses of the double-blind, randomised, placebo-controlled FREEDOMS study. *Lancet Neurol*. 2012; 11:420-28. DOI: http://dx.doi.org/10.1016/S1474-4422(12)70056-X.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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. *Neurology*. 2018; 90: 777-788. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: September 7, 2022.


Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.