Aubagio (teriflunomide)
Policy Number: C3890-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
10/1/2013	2/12/2020	2/12/2021
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J8499-(NOC)	RxPA	Q2 2020 20200422C3890-A

PRODUCTS AFFECTED:
Aubagio (teriflunomide)

DRUG CLASS:
MS agents- pyrimidine synthesis inhibitors

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Specialty Pharmacy

AVAILABLE DOSAGE FORMS:
Aubagio 7mg tab, 14mg tab

FDA-APPROVED USES:
for the treatment of relapsing forms of MS (relapsing-remitting MS, progressive-relapsing MS, and secondary progressive MS with relapse)

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
Multiple Sclerosis

REQUIRED MEDICAL INFORMATION:
A. MULTIPLE SCLEROSIS (MS)

1. Documentation of diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria (relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS)
   AND
2. Documentation that Aubagio (teriflunomide) will not be used concurrently with any other disease modifying therapy OR leflunomide
   AND
3. (a) Negative TB test within the 12 months for initial and continuation of therapy requests
   OR

(b) If member tests positive for latent TB, there must be documentation showing member completed a treatment course for TB OR that member has been cleared by an infectious disease specialist to begin treatment with Enbrel
OR
(c) For members who have tested positive for latent TB and have been treated, a negative chest x-ray is required every 12 months
AND

4. Documentation of baseline MRI, normal complete blood count, transaminase and bilirubin levels within 6 months prior to initiation of Aubagio
AND
5. If member is female and of child bearing potential: A documented negative pregnancy test prior to initiating therapy is required.
AND
6. IF NON-FORMULARY/NON-PREFERRED: Documentation of inadequate response (6 months of therapy), intolerance or FDA labeled contraindication to ALL preferred formulary disease modify therapies. Inadequate response is defined as increase frequency, severity and/or sequelae of relapses, changes in MRI or increase in disability progression.

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

QUANTITY:
1 tablet per day (30 tablets per 30 days)

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified neurologist or multiple sclerosis specialist

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
A. MULTIPLE SCLEROSIS:

1. Member compliance with therapy as verified by Prescriber and member's medication fill history (review Rx history for compliance)
AND
2. Prescriber compliance with current FDA safety-monitoring guidelines for teriflunomide: Monthly liver function tests for 6 months after initiation of therapy (Subsequent liver-function testing after 6 months should be performed at the discretion of the prescribing physician), CBC (if there are any signs or symptoms of hematologic toxicity), Blood pressure (periodically)
AND
3. Stabilization or positive response to Aubagio (teriflunomide) treatment. Demonstrated efficacy evidenced by ANY of the following: A decrease in frequency, severity, sequelae relapses from baseline, Beneficial effect on MRI measures of disease severity, OR improvement in patient reported MS related symptoms
AND
4. If member is female and of child bearing potential: A documented negative pregnancy test prior to reauthorization of therapy is required.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Aubagio (teriflunomide) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

Non-FDA approved indications, Hypersensitivity to Aubagio® (teriflunomide) or any ingredient in the formulation, severe hepatic impairment, Pregnancy, breastfeeding, individuals wishing to parent children during the course of the treatment, and women of childbearing potential not using reliable contraception, Total bilirubin, ALT, or AST greater than 2 times the upper limit of normal, Patients with pre-existing acute or chronic liver disease, or those with serum alanine aminotransferase (ALT) greater than two times the upper limit of normal (ULN) before initiating treatment, should not normally be treated with teriflunomide, Significantly impaired bone marrow function or, significant anemia, leukopenia or thrombocytopenia, Persistent significant or severe infection, Liver function impairment or known history of hepatitis, Human immunodeficiency virus [HIV] positive.

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:
None

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Aubagio (teriflunomide) [prescribing information]. Cambridge, MA: Genzyme Corporation; September 2019.
2. Clinical Pharmacology [database online]. Aubagio. Tampa, FL: Gold Standard, Inc.; 2020. URL: http://www.clinicalpharmacology.com.
3. FDA approves new multiple sclerosis treatment Aubagio. [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2012 Sep 12 [2 p]. Available: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm319277.htm.
4. O'Connor P, Wolinsky JS, Confavreux C, et al, for the TEMSO Trial Group. Randomized trial of oral teriflunomide for relapsing multiple sclerosis. N Engl J Med. 2011;365(14):1293-1303.
5. Freedman MS, Wolinsky JS, Wamil B, et al. Teriflunomide added to interferon-beta in relapsing multiple sclerosis: a randomized phase II trial. Neurology. Jun 5 2012;78(23):1877-1885.
6. Genzyme. Genzyme reports top-line results for TENERE study of oral Teriflunomide in relapsing multiple sclerosis [press release]. Cambridge, MA: Genzyme; 2011 [December 20].

Available from: http://www.businesswire. com/news/genzyme/20111219006550/en. Accessed June 2013
7. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Available at: https://download.lww.com/wolterskluwer_vitalstream_com/PermaLink/WNL/A/WNL_2018_04_19_RAEGRANT_NEUROLOGY2017835181R1_SDC3.pdf. Published April 2018. Accessed January 2020.