Commercial/Healthcare Exchange PA Criteria

Effective: January 1, 2019

Prior Authorization: Aubagio

Products Affected: Aubagio (teriflunomide), Teriflunomide generic tablets

Medication Description:
Aubagio (teriflunomide) is the active metabolite of leflunomide and is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS). The annual relapse rate was reduced significantly (relative risk reduction, 31%) when compared with placebo during a 108-week, phase 3, randomized, double-blind study (n=1088) of patients (mean age, 37.9 years) with relapsing MS, with or without progression, and with a baseline Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5 (mean, 2.68).

Covered Uses: Aubagio 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

Exclusion Criteria:
1. Concurrent use of Aubagio with other disease-modifying agents used for multiple sclerosis (MS).
2. Severe hepatic impairment

Required Medical Information: Diagnosis

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist or a physician that specializes in MS.

Coverage Duration: 3 years

Other Criteria:
A. Patient has a diagnosis of any of the following relapsing forms of Multiple Sclerosis:
   a. Progressive-relapsing multiple sclerosis (PRMS); OR
   b. Relapsing-remitting multiple sclerosis (RRMS); OR
   c. Secondary progressive multiple sclerosis (SPMS) with documented relapses; OR
   d. Clinically isolated syndrome

References:
A. AUBAGIO® oral tablets, teriflunomide oral tablets. Genzyme Corporation (per FDA), Cambridge, MA, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Update	Update	Coverage Duration: Update to 3 years	07/01/2019
3	Update	Adopted EH Policy, removed from CCI MS Drug Policy Updated indication (CIS) and exclusions (hepatic impairment) to match FDA label	All	6/2/2020
4	Update	Added generic teriflunomide tablets to policy	Products Affected	03/23/2023