

Reference number(s)
1808-A

# SPECIALTY GUIDELINE MANAGEMENT

## AUBAGIO (teriflunomide) teriflunomide

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

#### II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist.

#### III. CRITERIA FOR INITIAL APPROVAL

##### A. Relapsing forms of multiple sclerosis

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

##### B. Clinically isolated syndrome

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome of multiple sclerosis.

#### IV. CONTINUATION OF THERAPY

For all indications: Authorization of 12 months may be granted to members who are experiencing disease stability or improvement while receiving the requested medication.

#### V. OTHER

- A. Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

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B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

**VI. REFERENCES**

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; June 2024.
2. Teriflunomide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2024.