

#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for teriflunomide under the patient's prescription drug benefit.

### **Description:**

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**

teriflunomide is 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.

### **Applicable Drug List:**

teriflunomide

### **Policy/Guideline:**

### **Prescriber Specialty:**

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

#### **Criteria for Initial Approval:**

# A. Relapsing forms of multiple sclerosis

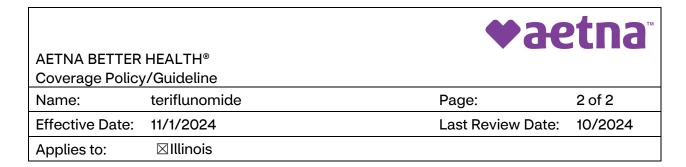
Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) and patient is unable to take the required number of formulary alternatives (3) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

## B. Clinically isolated syndrome

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis and patient is unable to take the required number of formulary alternatives (3) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

# **Continuation of Therapy:**

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



### Other Criteria:

- A. Members will not use teriflunomide concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

# **Approval Duration and Quantity Restrictions:**

Approval: 12 months

Quantity Level Limit: 30 tablets per 30 days

#### **References:**

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