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**

Aubagio 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.

#### 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 the 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 Aubagio.

## V. OTHER CRITERIA

- **A.** Members will not use Aubagio 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.

#### VI. REFERENCE

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; December 2022.

#### **PAHUB Questions**

- 1. Is this an initial request? If YES, go to 3. If NO, go to 2.
- 2. Has the patient experienced disease stability or improvement while receiving teriflunomide? *If YES, approve x 12 months. If NO, refer to Medical Director.*

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- 3. Has the patient been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse)? If YES, go to 5. If NO, go to 4.
- 4. Has the patient been diagnosed with clinically isolated syndrome of multiple sclerosis? *If YES, go to 5. If NO, refer to Medical Director.*
- 5. Will the patient be using teriflunomide concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying)? If YES, refer to Medical Director. If NO, go to 6.
- 6. Is the patient 18 years of age or older? If YES, approve x 12 months. If NO, go to 7.
- 7. Do the benefits of taking teriflunomide outweigh the risks? *If YES, approve x 12 months. If NO, refer to Medical Director.*

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