UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Multiple Sclerosis Agents -ARIZONA

Program	Prior Authorization
Medication	Multiple Sclerosis - Aubagio® (teriflunomide), Copaxone (glatiramer acetate), Gilenya® (fingolimod), glatiramer acetate, Glatopa (glatiramer acetate), Plegridy (peginterferon β-1a), Tecfidera™ (dimethyl fumarate), Avonex® (interferon β-1a), Rebif® (interferon β-1a), Betaseron/Extavia® (interferon β-1b)
Markets in Scope	Arizona

1. Background:

Plegridy (peginterferon β-1a) is indicated for the treatment of patients with relapsing forms of multiple sclerosis. Copaxone® and Glatopa™ (glatiramer acetate), Aubagio (teriflunomide), and Tecfidera™ (dimethyl fumarate) are indicated for treatment of patients with relapsing forms of multiple sclerosis.

Gilenya® (fingolimod) is indicated for the treatment of patients with relapsing forms of multiple sclerosis.[6] Due to the risk of a decrease in heart rate and/or atrioventricular conduction after first dose of Gilenya, all patients should be observed for signs and symptoms of bradycardia for 6 hours after their first dose. Novartis, the manufacturer of Gilenya, provides a First-Dose Observation program at no cost to the patient through the GILENYA™ Go Program™. To find a first-dose observation center, visit http://www.gilenya.com/c/ms-pill/first-day or http://maps.concentra.com/gilenya-fdo/

Avonex (interferon β-1a), Rebif (interferon β-1a), and Betaseron/Extavia (interferon β-1b) are indicated for treatment of patients with relapsing forms of multiple sclerosis.

2. Coverage Criteria:

A. <u>Authorization</u>

1. **Gilenya, Copaxone (Brand), Avonex, Rebif Rebidose, Betaseron** will be approved based on the following criterion:

   a. Diagnosis of multiple sclerosis (MS)

Authorization will be issued for 12 months.

2. **Aubagio, Glatopa, glatiramer acetate, Plegridy, Tecfidera, Rebif, Extavia** will be approved based on the following:

a. **Initial Authorization**

i. Diagnosis of multiple sclerosis (MS)

-AND-

ii. Patient has a history of failure, contraindication, or intolerance to a trial of at least **three** of the preferred alternatives.

Authorization will be issued for 12 months.

b. **Reauthorization**

i. Documentation of positive clinical response to Aubagio, Glatopa, glatiramer acetate, Plegridy, Tecfidera, Rebif, or Extavia therapy

Authorization will be issued for 12 months.

3. References:

1. Copaxone [package insert]. Teva Pharmaceuticals USA, Inc. North Wales, PA. August 2016.
2. Gilenya [package insert]. Novartis Pharmaceuticals Corp. East Hanover, NJ. December 2017.
3. Aubagio [package insert]. Genzyme Corp. Cambridge, MA. November 2016.
4. Tecfidera [package insert]. Biogen Inc. Cambridge, MA. December 2017.
5. Glatopa [package insert]. Sandoz Inc. Princeton, NJ. April 2016.
6. Plegridy [package insert]. Biogen Inc. Cambridge, MA. October 2016.
7. Avonex [package insert]. Biogen Inc. Cambridge, MA. March 2016.
8. Rebif [package insert]. EMD Serono, Inc. Rockland, MA. November 2015.
9. Betaseron [package insert]. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. April, 2016
10. Extavia [package insert].Novartis Pharmaceuticals Corp. East Hanover, NJ. May 2016.

Program	Prior Authorization – MS Agents
Change Control	
Date	Change

8/2017	New policy specific to Arizona.
2/2018	Revised diagnosis language to match ICD-10 code to maintain consistency across Dx to Rx and manual review. Updated references.
2/2018 v2	Added glatiramer to non-preferred section
3/2018	Added reauthorization criteria for non-preferred drugs to allow for continuation of ongoing therapy if patient has had a positive clinical response.