UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Multiple Sclerosis Agents

Program	Prior Authorization
Medication	Multiple Sclerosis - Aubagio® (teriflunomide), Copaxone (glatiramer acetate), Gilenya® (fingolimod), Glatopa (glatiramer acetate), Plegridy (peginterferon β-1a), Tecfidera™ (dimethyl fumarate), Avonex® (interferon β-1a), Rebif® (interferon β-1a), Betaseron/Extavia® (interferon β-1b), glatiramer acetate
Markets in Scope	California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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:

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A. Authorization

1. **Aubagio, glatiramer, Gilenya, Glatopa, Plegridy, or Tecfidera** will be approved based on the following criterion:

    a. Diagnosis of multiple sclerosis (MS)

Authorization will be issued for 12 months.

2. **Avonex, Rebif, Betaseron/Extavia, or Copaxone [BRAND NECESSARY REQUESTS]**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 Avonex, Rebif, Betaseron/Extavia, or Copaxone [BRAND NECESSARY REQUESTS] 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
9/2009	Criteria taken from previously approved AmeriChoice and Unison policy (RX06, Biological Multiple Sclerosis Agents). Policy reformatted.
12/ 2010	Extavia added to the Non-Preferred Product list
6/2011	Gilenya added to the Non-Preferred list. Replaced the old AmeriChoice logo with the new UnitedHealthcare Community Plan logo. Changed the Therapeutic Sub-Class in the document header to “Biologic Response Modifiers”.
6/2012	This policy (MS Drugs – Avonex, Rebif, Copaxone) was combined with the Gilenya policy to create one single MS Drugs policy. No changes were made to the clinical criteria for these drugs.
9/2012	Gilenya: added preferred alternative options of natalizumab and mitoxantrone. Added option for patients with severe needle phobia.
6/2013	Converted policy to new UnitedHealthcare enterprise wide formatting. Removed Gilenya from policy due to UnitedHealthcare alignment, an individual Gilenya policy was approved in March 2013. Oral agents (Gilenya, Aubagio, Tecfidera have individual policies) Added alternative option for approving preferred agents that includes patients who had a first clinical episode with MRI

	features consistent with multiple sclerosis Added non-preferred criteria for Betaseron and Extavia
12/ 2014	Copaxone is now listed without specifying the 20 mg strength because the 40 mg is also a preferred product. Removed criterion regarding first clinical episode with MRI features consistent with MS to align across the UnitedHealthcare enterprise.
9/2015	Annual Review – No change
9/2016	Updated policy template. Added note that only Copaxone 40mg is preferred. Added Glatopa to list of agents included in the policy.
10/2016	Removed Avonex and Rebif and added Plegridy to policy
2/2017	Added non-preferred MS agents to the policy and added non-preferred review criteria.
4/2017	Removed Zinbryta from this policy since it follows a drug-specific policy
10/2017	Annual review. Updated references.
12/2017	Moved brand Copaxone 40mg to a non-preferred status. Copaxone 20mg remains non-preferred. Generic is now preferred for both strengths.
2/2018	Revised diagnosis language to match ICD-10 code to maintain consistency across Dx to Rx and manual review. Updated references.
3/2018	Added reauthorization criteria for non-preferred drugs to allow for continuation of ongoing therapy if patient has had a positive clinical response.