UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1064-8
Program	Prior Authorization/Notification
Medication	Multiple Sclerosis - Aubagio® (teriflunomide), Avonex® (interferon β-1a), Betaseron® (interferon β-1b), Copaxone® (glatiramer acetate), Extavia® (interferon β-1b)*, Gilenya® (fingolimod), Glatopa™ (glatiramer acetate)*, Plegridy™ (peginterferon β-1a), Rebif® (interferon β-1a), Tecfidera™ (dimethyl fumarate) * Extavia and Glatopa are excluded from coverage for the majority of our benefits.
P&T Approval Date	5/2011, 5/2012, 11/2012, 07/2013, 08/2013, 5/2014, 10/2014, 10/2015, 10/2016, 10/2017, 2/2018
Effective Date	5/1/2018; Oxford only: 5/1/2018

1. Background

Avonex® and Rebif® (interferon β-1a), Betaseron® and Extavia® (interferon β-1b), and Plegridy™ (peginterferon β-1a) are 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.[1-5, 8-10]

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/

2. Coverage Criteria:

A. Authorization

1. **Aubagio, Avonex, Betaseron, Copaxone, Extavia*, Gilenya, Glatopa*, Plegridy, Rebif** or **Tecfidera** will be approved based on the following criterion:

   a. Diagnosis of multiple sclerosis (MS) **Authorization will be issued for 60 months.**

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Exclusion: Extavia and Glatopa, are excluded from coverage for the majority of our benefits.
- Supply limits and/or Step Therapy may be in place.

4. References:

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

Program	Prior Authorization/Notification - MS Agents: Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Plegridy, Rebif or Tecfidera
Change Control	
5/2014	Annual review. Updated background. Expanded authorization to 60 months, removed reauthorization criteria, and simplified criteria to allow coverage for all agents with relapsing forms of MS.
10/2014	Addition of Plegridy to criteria.
10/2015	Annual review. Added Glatopa (glatiramer acetate) to criteria. Removed list of medication before the initial authorization. Updated background and references.
10/2016	Removed Plegridy from coverage exclusion statements. Updated references.
10/2017	Annual review. Updated references.
2/2018	Revised diagnosis language to match ICD-10 code to maintain consistency across Dx to Rx and manual review. Updated references.
12/2018	Administrative change to add statement regarding use of automated processes.