UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1064-16
Program	Prior Authorization/Notification
Medication	Multiple Sclerosis - Aubagio® (teriflunomide), Avonex® (interferon β-1a), Bafiertam™ (monomethyl fumarate), Betaseron® (interferon β-1b), Copaxone® (glatiramer acetate)*, dimethyl fumarate, Extavia® (interferon β-1b)*, Gilenya® (fingolimod), Glatopa™ (glatiramer acetate), glatiramer acetate, Kesimpta (ofatumumab), Mayzent (siponimod)®, Plegridy™ (peginterferon β-1a), Rebif® (interferon β-1a)*, Tecfidera™ (dimethyl fumarate)*, Vumerity™ (diroximel fumarate)* *Copaxone (brand), Extavia, Rebif, Tecfidera (brand), and Vumerity are excluded from coverage for the majority of our benefits. Mavenclad® (cladribine) coverage is provided according to the product specific Mavenclad Prior Authorization/Notification program Zeposia® (ozanimod) coverage is provided according to the product specific Zeposia Prior Authorization/Notification program
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, 2/2019, 5/2019, 10/2019, 1/2020, 11/2020, 1/2021, 8/2021, 12/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

1. Background

Avonex® and Rebif® (interferon β-1a), Betaseron® and Extavia® (interferon β-1b), Plegridy™ (peginterferon β-1a), Copaxone® and Glatopa™ (glatiramer acetate), Aubagio® (teriflunomide), Mayzent® (siponimod), Tecfidera™ (dimethyl fumarate), Bafiertam (monomethyl fumarate), Kesimpta (ofatumumab), and Vumerity™ (diroximel fumarate) are indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Gilenya® (fingolimod) is indicated for the treatment of patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.[6] Due to the risk of a decrease in heart rate and/or atrioventricular conduction after the first dose of Gilenya, all patients should be observed for signs and symptoms of bradycardia for at least 6 hours after their first dose. First-dose monitoring should

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also be performed when restarting Gilenya after discontinuation for more than 14 days and with dose increases. 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, Bafiertam, Betaseron, Copaxone*, dimethyl fumarate, Extavia*, Gilenya, Glatopa, glatiramer acetate, Kesimpta, Mayzent, Plegridy, Rebif*, Tecfidera*, or Vumerity*** will be approved based on the following criterion:

   a. Diagnosis of multiple sclerosis (MS)

   Authorization will be issued for 12 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: Copaxone (brand), Extavia, Rebif, Tecfidera (brand), and Vumerity 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]. Cambridge, MA: Biogen Inc.; March 2020.
2. Rebif [package insert]. Rockland, MA: EMD Serono, Inc.; October 2020.
3. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; March 2021.
4. Copaxone [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; July 2020.
5. Extavia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2020.
6. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019.
7. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; April 2021.
8. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; January 2021.
9. Plegridy [package insert]. Cambridge, MA: Biogen Inc.; January 2021.
10. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; July 2020.
11. Mayzent [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2021.
12. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; January 2021.

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13. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; May 2021.
14. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

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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.
2/2019	Annual review. Updated references.
5/2019	Added Mavenclad and Mayzent to criteria.
10/2019	Added Copaxone to coverage exclusion statement.
1/2020	Added Vumerity to criteria. Updated background and references.
11/2020	Added Bafiertam, Kesimpta, and Zeposia to the program. Updated list of medications typically excluded from coverage. Changed authorization duration to 12 months. Updated background and references.
1/2021	Removed Mavenclad from program as Mavenclad specific program developed.
8/2021 – effective 1/1/2022	Rebif noted as an excluded drug. Removed notation that Glatopa is an excluded drug. References updated.
12/2021 – effective 2/1/2022	Removed Zeposia from program as Zeposia specific program developed.

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