UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1064-17
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), Ponvory™ (Ponesimod)*, Rebif® (interferon β-1a)*, Tecfidera™ (dimethyl fumarate)*, Vumerity™ (diroximel fumarate)* *Copaxone (brand), Extavia, Ponvory, 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	5/1/2022 Oxford only: 5/1/2022

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), Ponvory™ (Ponesimod), 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 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, Ponvory*, 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.

* Copaxone (brand), Extavia, Ponvory, Rebif, Tecfidera (brand), and Vumerity are typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.

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.
- 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.
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.
15. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021

Program	Prior Authorization/Notification - MS Agents: Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, dimethyl fumarate, Extavia, Gilenya, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tecfidera, Vumerity
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	Removed Zeposia from program as Zeposia specific program

2/1/2022	developed.
10/2021 – effective 5/1/2022	Added Ponvory to program with notation of exclusion.