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), Bafiertam™ (monomethyl fumarate), Rebif® (interferon β-1a), Betaseron/Extavia® (interferon β-1b), glatiramer acetate, Kesimpta (ofatumumab), Mayzent® (siponimod), Vumerity (diroximel fumarate), Zeposia (ozanimod) ®
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

1. Background:

Avonex (interferon β-1a), Betaseron (interferon β-1b), Copaxone (glatiramer acetate), Extavia (interferon β-1b), Glatopa (glatiramer acetate), Mayzent (siponimod), Plegridy (peginterferon β-1a), Rebif (interferon β-1a), Tecfidera (dimethyl fumarate), Bafiertam (monomethyl fumarate), Zeposia (ozanimod), 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 relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2. Coverage Criteria:

A. <u>Authorization</u>

1. **Aubagio, Copaxone (glatiramer), Glatopa, Gilenya, Mayzent, Plegridy, or Tecfidera (dimethyl fumarate)** will be approved based on the following criterion:
NOTE: Brand Copaxone and Brand Tecfidera are non-preferred

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a. Diagnosis of multiple sclerosis (MS)

Authorization will be issued for 12 months.

2. **Avonex, Rebif, Betaseron/Extavia, Kesimpta, or Zeposia** will be approved based on the following:

   a. **Initial Authorization**

      i. Diagnosis of multiple sclerosis (MS)

      -AND-

      ii. **One** of the following:

         (a) Patient has a history of failure, contraindication, or intolerance to a trial of at least **two** of the preferred alternatives

         -OR-

         (b) Patient is currently on Avonex, Rebif, Betaseron/Extavia, Kesimpta, or Zeposia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

Authorization will be issued for 12 months.

   b. **Reauthorization**

      i. Documentation of positive clinical response to Avonex, Rebif, Betaseron/Extavia, Kesimpta, or Zeposia therapy

Authorization will be issued for 12 months.

3. **Vumerity or Bafiertam** will be approved based on the following:

   a. **Initial Authorization**

      i. Diagnosis of multiple sclerosis (MS)

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-AND-

ii. **One** of the following:

(a) Patient has a history of failure, contraindication, or intolerance to a trial of at least **two** of the preferred alternatives, **one of which must be a preferred dimethyl fumarate product**

-OR-

(b) Patient is currently on Vumerity or Bafiertam therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

Authorization will be issued for 12 months.

b. **Reauthorization**

i. Documentation of positive clinical response to Vumerity or Bafiertam therapy

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.
- Supply limits may be in place.

4. References:

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1. Copaxone [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; July 2020.
2. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019.
3. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; September 2019.
4. Tecfidera [package insert]. Cambridge, MA: Biogen Inc. February 2020.
5. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; January 2020.
6. Mavenclad [package insert]. Rockland, MA: EMD Serono, Inc.; April 2019.
7. Mayzent [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
8. Plegridy [package insert]. Cambridge, MA: Biogen Inc.; March 2020.
9. Avonex [package insert]. Cambridge, MA: Biogen Inc.; March 2020.
10. Rebif [package insert]. Rockland, MA: EMD Serono, Inc.; June 2020.
11. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2019.
12. Extavia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2019.
13. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; August 2020.
14. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LL; April 2020.
15. Zeposia [package insert]. Summit, NJ: Celgene Corporation; March 2020.
16. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

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

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	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.

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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.
1/2019	Moved Glatopa to a non-preferred status. Added step therapy language to reauthorization criteria. Updated Glatopa and brand Copaxone requests to modify step therapy language to ensure a step through generic glatiramer.
10/2019	Added Mayzent to the program. Changed trial of preferred products from three to two. Updated background and references.
1/2020	Removed brand Copaxone from the program since brand requests should be evaluated using multisource brand criteria. Added Glatopa to the preferred product section.
4/2020	Added Vumerity to the program. Updated background and references.
10/2020	Added Bafiertam, Kesimpta, and Zeposia to the program. Updated background and references. Changed Tecfidera to “a preferred dimethyl fumarate product” within preferred product criteria.
12/2020	Added COT language criteria for non-preferred products

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