Reference number(s)
3260-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☑
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Multiple Sclerosis

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Marketplace Formulary (MF).

Plan Design Summary

This program applies to the multiple sclerosis products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with Aubagio, Avonex, Bafiertam, Copaxone, Extavia, Gilenya, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, and Vumerity. This program also applies to members who are new to treatment with Briumvi, Kesimpta, Mavenclad, Mayzent, or Zeposia for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Multiple Sclerosis (MS) Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Betaseron (interferon beta-1b) • dimethyl fumarate (generic) • fingolimod (generic) • glatiramer acetate (generic) • Glatopa (glatiramer acetate) • teriflunomide (generic) • Tysabri (natalizumab)
Target	• Aubagio (teriflunomide) • Avonex (interferon beta-1a) • Bafiertam (monomethyl fumarate) • Briumvi (ublituximab-xiiy) • Copaxone (glatiramer acetate) • Extavia (interferon beta-1b) • Gilenya (fingolimod) • Kesimpta (ofatumumab) • Mavenclad (cladribine) • Mayzent (siponimod) • Plegridy (peginterferon beta-1a) • Ponvory (ponesimod) • Rebif (interferon beta-1a) • Tascenso ODT (fingolimod) • Tecfidera (dimethyl fumarate) • Vumerity (diroximel fumarate) • Zeposia (ozanimod)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Aubagio

Coverage for Aubagio is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event with generic teriflunomide, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic teriflunomide.

Avonex, Plegridy, or Rebif

Coverage for Avonex, Plegridy, or Rebif is provided when the member has a documented inadequate response or intolerable adverse event with at least three of the preferred products.

Bafiertam or Vumerity

Coverage for Bafiertam or Vumerity is provided when both of the following criteria are met:

- Member has a documented intolerable adverse event with dimethyl fumarate (including intolerable gastrointestinal adverse events from dimethyl fumarate).
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than dimethyl fumarate.

Briumvi or Kesimpta

Coverage for Briumvi or Kesimpta is provided when either of the following criteria is met:

- Member is currently receiving therapy with Briumvi or Kesimpta, excluding when Briumvi or Kesimpta is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products.

Copaxone

Coverage for Copaxone is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to generic glatiramer acetate or Glatopa, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic glatiramer acetate or Glatopa.

Extavia

Coverage for Extavia is provided when both of the following criteria are met:

- There is a documented clinical reason that the member must use Extavia over Betaseron. (Please note that Extavia and Betaseron are the exact same products with different labels and brand names.)
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than Betaseron.

Gilenya or Tascenso ODT

Coverage for Gilenya or Tascenso ODT is provided when both of the following criteria are met:

- Member meets either of the following criteria:
  - Member has had a documented intolerable adverse event with generic fingolimod, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - The requested product is Tascenso ODT and the member is unable to swallow generic fingolimod capsules.
- Member meets either of the following criteria:
  - Member has had a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic fingolimod.
  - Member is less than 18 years of age.

Mavenclad

Coverage for Mavenclad is provided when either of the following criteria is met:

- Member is currently receiving therapy with Mavenclad, excluding when Mavenclad is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products.

Mayzent or Zeposia

Coverage for Mayzent or Zeposia is provided when either of the following criteria is met:

- Member is currently receiving therapy with Mayzent or Zeposia, excluding when Mayzent or Zeposia is obtained as samples or via manufacturer's patient assistance programs.
- Member meets both of the following:
  - Member has a documented intolerable adverse event with fingolimod.
  - Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than fingolimod.

Ponvory

Coverage for Ponvory is provided when both of the following criteria are met:

- Member has a documented intolerable adverse event with fingolimod.
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than fingolimod.

Tecfidera

Coverage for Tecfidera is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event with generic dimethyl fumarate, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic dimethyl fumarate.

References

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; June 2024.
2. Avonex [package insert]. Cambridge, MA: Biogen Inc.; July 2023.
3. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; March 2024.
4. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2023.
5. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc; November 2024.
6. Copaxone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023.
7. Dimethyl fumarate [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC.; June 2024.
8. Extavia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.
9. Fingolimod [package insert]. Weston, FL: Apotex Corporation; June 2024.
10. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
11. Glatiramer acetate 20 mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2024.
12. Glatiramer acetate 40 mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2024.
13. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; December 2023.
14. Kesimpta [package insert]. East Hanover, NJ: Novartis; April 2024.
15. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.
16. Mavenclad [package insert]. Rockland, MA: EMD Serono; May 2024.
17. Mayzent [package insert]. East Hanover, NJ: Novartis; June 2024.
18. Plegridy [package insert]. Cambridge, MA: Biogen, Inc.; July 2023.
19. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; June 2024.
20. Rebif [package insert]. Rockland, MA: EMD Serono Inc.; July 2023.
21. Tascenso ODT [package insert]. Swindon, UK. Catalent Pharma Solutions (UK); July 2024.
22. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
23. Teriflunomide [package insert]. East Windsor, NJ: Aurobindo Pharma Limited; February 2024.
24. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; September 2024.

25. Zeposia [package insert]. Summit, NJ: Celgene Corp.; June 2024.

Document History

Written: Specialty Clinical Development (NU) 09/2019

Revised: NU 11/2019 (added Vumerity), NU 07/2020 (added Zeposia and Bafiertam), NU 08/2020 (added Kesimpta and generic Tecfidera), IP 09/2020 (2021 FE, no change), 12/2020 (added GF Kesimpta, Mayzent, Zeposia), 02/2021 (moved Tecfidera to targeted), JC 04/2021 (added Ponvory as targeted), TE 08/2021 (annual), TE 09/2021 (2022 FE, no change), AM 04/2022 (PUE update), AM 08/2022 (annual), AM 09/2022 (2023 FE, moved Rebif to targeted), AM 11/2022 (Gilenya targeted, fingolimod preferred), ST 04/2023 (Briumvi and Tascenso ODT to targeted), ST 08/2023 (annual), ST 09/2023 (2024), AR 08/2024 (annual), AR 09/2024 (2025), AR 11/2024 (removed Aubagio and Copaxone 40mg from preferred and added both to the targeted product, added teriflunomide to preferred)

Reviewed: CDPR/AN 10/2019, AN 11/2019, AN 08/2020, ABM 09/2020, MA 12/2020, AN 02/2021, AN 04/2021, SAM 08/2021, AN 10/2021, CH 04/2022, SG 08/2022, AN 09/2022, AN 12/2022, AN 04/2023, AN 08/2023, AN 09/2023, AN 08/2024, AN 10/2024, SNG 11/2024

External Review: 11/2019, 10/2020, 04/2021, 11/2021, 05/2022, 10/2022, 12/2022, 05/2023, 11/2023, 11/2024