This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		Medicare Part B: Add-on
			IVL						

Reference #
4264-D

EXCEPTIONS CRITERIA

MULTIPLE SCLEROSIS PRODUCTS

PREFERRED PRODUCTS: AUBAGIO, AVONEX, BETASERON, COPAXONE, DIMETHYL FUMARATE, GILENYA, GLATIRAMER, GLATOPA, KESIMPTA, MAYZENT, OCREVUS, REBIF, TYSABRI, VUMERITY AND ZEPOSIA

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the multiple sclerosis products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product 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 a targeted product.

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

Table. Multiple sclerosis (MS) products

	Products
Preferred*	• **Aubagio** (teriflunomide) • **Avonex** (interferon beta 1a) • **Betaseron** (interferon beta-1b) • **Copaxone** (glatiramer) • **dimethyl fumarate** • **Gilenya** (fingolimod) • **glatiramer** • **Glatopa** (glatiramer acetate) • **Kesimpta** (ofatumumab) • **Mayzent** (siponimod) • **Ocrevus** (ocrelizumab) • **Rebif** (interferon beta-1a) • **Tysabri** (natalizumab) • **Vumerity** (diroximel fumarate) • **Zeposia** (ozanimod)
Targeted	• **Bafiertam** (monomethyl fumarate) • **Extavia** (interferon beta-1b)

© 2023 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		Medicare Part B: Add-on
			IVL						

Reference #
4264-D

	• **Ponvory** (ponesimod) • **Tecfidera** (dimethyl fumarate)

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

II. EXCEPTION CRITERIA

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

A. Bafiertam

Coverage for Bafiertam is provided when the member meets both of the following criteria:

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

B. Extavia

Coverage for Extavia is provided when the member meets both of the following criteria:

1. 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, which are made in the same manufacturing facility.)*
2. Member has had a documented inadequate response or intolerable adverse event with at least two of the preferred products other than Betaseron.

C. Ponvory

Coverage for Ponvory is provided when the member meets both of the following criteria:

1. Member has a documented intolerable adverse event with Gilenya, Mayzent, or Zeposia.
2. Member has had a documented inadequate response or intolerable adverse event with at least two of the preferred products other than Gilenya, Mayzent, or Zeposia.

D. Tecfidera

Coverage for Tecfidera is provided when the member meets both of the following criteria:

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

© 2023 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		Medicare Part B: Add-on
			IVL						

Reference #
4264-D

REFERENCES

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; April 2022.
2. Avonex [package insert]. Cambridge, MA: Biogen Inc.; December 2020.
3. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC. July 2020.
4. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; November 2021.
5. Copaxone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2022.
6. Dimethyl fumarate [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2022.
7. Extavia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2022.
8. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2022.
9. Glatiramer acetate 20mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2022.
10. Glatiramer acetate 40mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2022.
11. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; April 2022.
12. Kesimpta [package insert]. East Hanover, NJ: Novartis; September 2022.
13. Mayzent [package insert]. East Hanover, NJ: Novartis; June 2022.
14. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; August 2022.
15. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; February 2022.
16. Rebif [package insert]. Rockland, MA: EMD Serono Inc.; November 2021.
17. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; August 2022.
18. Tysabri [package insert]. Cambridge, MA: Biogen Idec, Inc; June 2022.
19. Vumerity [package insert]. Walthan, MA: Alkermes Inc. February 2022.
20. Zeposia [package insert]. Summit, NJ: Celgene Corp. April 2022.

© 2023 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.