Clinical Policy Title:	Multiple Sclerosis
Policy Number:	RxA.018
Drug(s) Applied:	Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), dalfampridine (Ampyra), dimethyl fumarate (Tecfidera), fingolimod (Tascendo ODT, Gilenya 0.25 mg), teriflunomide, glatiramer acetate injections (Copaxone, glatiramer acetate, Glatopa), Kesimpta (ofatumumab), Mayzent, Mavenclad (cladribine), Rebif (interferon beta-1a), Vumerity (diroximel fumarate)
Original Policy Date:	02/07/2020
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Clinical Policy

The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all)**:**

1. Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions);
2. For Rebif: Trial and failure of two (2) preferred disease modifying therapy, unless contraindicated or clinically significant adverse effects are experienced: Avonex, Bafiertam, Betaseron, dimethyl fumarate, any one of the glatiramer acetate injections (Copaxone, glatiramer acetate, Glatopa), Kesimpta, Vumerity;
3. For Mavenclad: Trial and failure of one (1) preferred disease modifying therapy, unless contraindicated or clinically significant adverse effects are experienced: Avonex, Bafiertam, Betaseron, any one of the glatiramer acetate injections (Copaxone, glatiramer acetate, Glatopa), Kesimpta;
4. Prescribed by or in consultation with a neurologist;

Approval Duration
All Lines of Business (except Medicare): 12 months
Mavenclad: 1 month (Total: 2 courses per lifetime)

Continued Therapy Approval

A. Multiple Sclerosis (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration
All Lines of Business (except Medicare): 12 months
Mavenclad: 1 month (Total: 2 courses per lifetime)

References

1. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. March 2017. Available at:https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed September 04, 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788. Full guideline available at: https://cdn-links.lww.com/permalink/wnl/a/wnl_2018_04_19_raegrant_neurology2017835181r1_sdc3.pdf. Accessed September 04, 2023.
3. Olek, M.J. & Mowry, E. Initial disease-modifying therapy for relapsing-remitting multiple sclerosis in adults. In: UpToDate, Gonzalez-Scarano, F. & Dashe, J.F. (Eds), UpToDate, Waltham, MA; 2020, December 15. Available at: www.uptodate.com. Accessed September 04, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy reviewed and updated: 1. Indication updated to be more specific 2. References	5/2020	5/20/2020
Policy reviewed and updated: 1. Clinical policy title & lines of business updated. 2. Initial criteria for approval and duration updated. 3. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 4. Appendix D updated. 5. References updated.	02/01/2021	03/09/2021
Policy was reviewed. 1. References were reviewed and updated.	08/20/2021	09/14/2021
Policy was reviewed. 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance”…". 3. Appendix A: Updated to include abbreviation ALT and to remove abbreviation FDA. 4. Disclaimer about contraindicatio“s "Contraindications listed reflect statements made in the manufactu’er's package insert”.." was added to Appendix C. 5. Appendix D, General information: Updated to remove unavailable generic disease-modifying therapies for MS natalizumab, ocrelizumab, alemtuzumab, rituximab, interferon beta-1a, interferon beta-1b, ofatumumab,	02/01/2022	04/18/2022

peginterferon beta-1a, diroximel fumarate, fingolimod, monomethyl fumarate, ozanimo3iponimodmod, teriflunomide. 6. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A.6 and Continued Therapy Criteria II.A.3: Updated to add no signs of active infections based on reviewer's feedback. 2. References were reviewed and updated.	10/27/2022	01/17/2023
Policy was reviewed: 1. Updated Lines of Business Policy Applies to All lines of business (except Medicare). 2. Dosage form updated. 3. Statement about provider sample was updated. 4. Initial Approval Criteria, I.A: Updated to remove prior age criteria "Age ≥ 18 years". 5. Continued Therapy Approval Criteria, II.A.1: updated to "Member is currently receiving…" 6. Initial and Continued Therapy Approval criteria was updated to remove dosing criteria. 7. Approval duration was updated to All Lines of Business (except Medicare): 12 months. 8. Appendix B: Therapeutic alternatives was removed. 9. Appendix C: Contraindications/Boxed Warnings was removed. 10. Renamed Appendix D as Appendix B: General information. 11. References were reviewed and updated.	09/04/2023	10/19/2023
Policy review: 1. Merged all MS drugs with same indication under one policy	3/1/2024	2/28/2024