# Clinical Policy: Multiple Sclerosis Drugs (Lemtrada, mitoxantrone, Ponvory)

Reference Number: AZ.CP.PHAR.1020
Effective Date: 11.20.19
Last Review Date: 02.24
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

**If reviewing a request for Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tascenso ODT, Tecfidera, Tysabri, Vumerity, Zeposia, must use AHCCCS FFS PA criteria: https://www.azahcccs.gov/Resources/Downloads/PharmacyUpdates/FFS_PharmaPriorAuthCriteria.pdf**

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

The following disease-modifying therapies for multiple sclerosis requiring prior authorization are covered in this policy: alemtuzumab (Lemtrada®), mitoxantrone, ponesimod (Ponvory™).

**AHCCCS preferred drugs** in this class include dimethyl fumarate (Tecfidera®), fingolimod ( Gilenya®), Copaxone® (glatiramer acetate), Avonex®, Rebif Rebidose® (interferon beta-1a),, teriflunomide (Aubagio®), Kesimpta® (ofatumumab), Tysabri® (natalizumab), (Ocrevus® (ocrelizumab).

**AHCCCS non-preferred drugs** in this class include alemtuzumab (Lemtrada®), Betaseron® (interferon beta-1b), cladribine (Mavenclad®), diroximel fumarate (Vumerity®), Glatopa® (glatiramer acetate), interferon beta-1b (Extavia®), mitoxantrone, monomethyl fumarate (Bafiertam™), ozanimod (Zeposia®), peginterferon beta-1a (Plegridy®), siponimod (Mayzent®), , ponesimod (Ponvory®), and fingolimod lauryl sulfate (Tascenso ODT™)

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that Lemtrada, mitoxantrone, and Ponvory, are **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

**A. Lemtrada, mitoxantrone** (must meet all):

**If member is currently on Lemtrada or mitoxantrone, as documented by claims history or medical records (document drug, date, and duration of therapy), refer to Section II. Continued Therapy;*

1. Diagnosis of multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;

4. Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to TWO of the following disease-modifying therapies for MS* (document medication used, date, and duration):
   a. Teriflunomide ( Aubagio®**);
   b. Bafiertam™ **(monomethyl fumarate);
   c. Dimethyl fumarate product(e.g., Tecfidera®**);
   d. Fingolimod product (e.g., Gilenya®**, Tascenso ODT™**);
   e. Copaxone® (e.g., glatiramer acetate**, Glatopa®**);
   f. Interferon-beta-1a (Avonex®, Rebif®);
   g. Interferon-beta-1b (Betaseron®**, Extavia®**);
   h. Kesimpta® (ofatumumab);
   i. Mavenclad®** (cladribine);
   j. Mayzent®** (siponimod);
   k. Mitoxantrone**;
   l. Ocrevus® (ocrelizumab);
   m. Peginterferon beta-1a **(Plegridy®);
   n. Ponvory®** (ponesimod);
   o. Tysabri® (natalizumab);
   p. Vumerity®** (diroximel fumarate);
   q. Zeposia®** (ozanimod);

   **Prior authorization is required for all disease modifying therapies for MS*
   ***Non-preferred; Do not include in denial to provider.*
5. Drug is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
6. Dose does not exceed:
   a. Lemtrada:
      i. First treatment course: 12 mg per day for 5 consecutive days (60 mg total);
      ii. Second or subsequent treatment courses: 12 mg per day for 3 consecutive days (36 mg total);
   b. Mitoxantrone:
      i. 12 mg/m2 every 3 months (total cumulative lifetime dose of 140 mg/m2)

**Approval duration**: **Lemtrada – 12 months** (*1 treatment course only*); **mitoxantrone – 6 months**

**B. Ponvory** (must meet all):
1. Diagnosis of multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Failure of TWO of the following, unless clinically significant adverse effects are experienced or all are contraindicated: fingolimod (Gilenya™), an interferon-beta agent (Avonex®, Rebif®), glatiramer (Copaxone®);

**Prior authorization is required for all disease modifying therapies for MS*

5. Ponvory is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
6. Request meets the following:
   a. Treatment initiation: Dose follows the 14-day titration schedule as outlined in Section V and does not exceed 1 tablet per day;
   b. Treatment maintenance: Dose does not exceed 20 mg (1 tablet) per day.

**Approval duration: 6 months**

**C. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid; or
2. Mitoxantrone for diagnoses other than multiple sclerosis: Refer to the CP.PHAR.258 Mitoxantrone policy; or
3. Tysabri for Crohn's Disease: Refer to the AZ.CP.PHAR.06 Cytokine and CAM Antagonists policy; or
4. Ofatumumab (Arzerra) for diagnoses other than multiple sclerosis: Refer to CP.PHAR.306.

## II. Continued Therapy

**A. All Drugs in Section I for Multiple Sclerosis** (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Documentation supports that member is currently receiving Lemtrada, mitoxantrone, or Ponvory for respective indication(s) listed under Section I. Initial Approval Criteria as documented by claims history or medical records (document drug, date, and duration of therapy);
2. Documentation of positive clinical response to therapy;
3. Drug is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
4. Dose does not exceed maximum limit in Section I. Initial Approval.

**Approval duration: 12 months** (*Lemtrada: 1 treatment course only*)

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid; or

3. Mitoxantrone for diagnoses other than RRMS and SPMS: Refer to the CP.PHAR.258 Mitoxantrone policy; or
4. Tysabri for Crohn's Disease: Refer to the AZ.CP.PHAR.06 Cytokine and CAM Antagonists policy; or
5. Ofatumumab (Arzerra) for diagnoses other than multiple sclerosis: Refer to CP.PHAR.306.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – AZ.CP.PMN.53 for Arizona Medicaid or evidence of coverage documents;
**B.** Ocrevus: Rheumatoid arthritis;
**C.** Ocrevus: Lupus nephritis/systemic lupus erythematosus.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CIS: clinically isolated syndrome
FDA: Food and Drug Administration
MS: multiple sclerosis
PPMS: primary progressive MS
RRMS: relapsing-remitting MS
SPMS: secondary progressive MS

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Avonex®, Rebif® (interferon beta-1a) | *Avonex*: 30 mcg IM Q week<br>*Rebif*: 22 mcg or 44 mcg SC TIW | *Avonex*: 30 mcg/week<br>*Rebif*: 44 mcg TIW |
| glatiramer acetate (Copaxone®,) | 20 mg SC QD or 40 mg SC TIW | 20 mg/day or 40 mg TIW |
| fingolimod (Gilenya™) | 0.5 mg PO QD | 0.5 mg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

| Drug | Contraindications | Boxed Warnings |
|---|---|---|
| Alemtuzumab (Lemtrada) | • Hypersensitivity or anaphylactic reactions to alemtuzumab or any of the excipients in Lemtrada, infection with human immunodeficiency virus, active infection | Autoimmunity, infusion reactions, stroke, and malignancies |

## CLINICAL POLICY

Multiple Sclerosis Drugs (Multiple Sclerosis Drugs (Lemtrada, mitoxantrone, Ponvory)

| Drug | Contraindications | Boxed Warnings |
|---|---|---|
| Mitoxantrone (Novantrone) | • Prior hypersensitivity to mitoxantrone | Cardiotoxicity, secondary leukemia |
| Ocrelizumab (Ocrevus) | • Active Hepatitis B virus infection<br>• History of life-threatening infusion reaction to Ocrevus | None |
| Natalizumab (Tysabri) | • Patients who have or have had progressive multifocal leukoencephalopathy<br>• Patients who have had a hypersensitivity reaction to Tysabri | Progressive multifocal leukoencephalopathy |
| Ponvory (Ponesimod) | • In the last 6 months, patients who have experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure; patients who have presence of Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker | None |

*Appendix D: General Information*

- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), diroximel fumarate (Vumerity®), monomethyl fumarate (Bafiertam), fingolimod (Gilenya®, Tascenso ODT™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), ocreliuzmab (Ocrevus™), cladribine (Mavenclad®), siponimod (Mayzent®), and ozanimod (Zeposia®), ponesimod (Ponvory™), and ofatumumab (Kesimpta®).
- Of the disease-modifying therapies for MS that are FDA-labeled for CIS, only the interferon products, glatiramer, and Aubagio have demonstrated any efficacy in decreasing the risk of conversion to MS compared to placebo. This is supported by the American Academy of Neurology 2018 MS guidelines.
- The American Academy of Neurology 2018 MS guidelines recommend the use of Gilenya, Tysabri, and Lemtrada for patients with highly active MS. Definitions of highly active MS vary and can include measures of relapsing activity and MRI markers of disease activity, such as numbers of gadolinium-enhanced lesions.

- Lemtrada is available only through a restricted program under a REMS called the Lemtrada REMS Program because of the risks of autoimmunity, infusion reactions, and malignancies.
- Because of the risk of progressive multifocal leukoencephalopathy, Tysabri is only available through a REMS program called the TOUCH® Prescribing Program.
- In May 2010, the manufacturers of Ocrevus discontinued the Ocrevus clinical developmental program in rheumatoid arthritis due to unfavorable overall benefit to risk profile. The program was initially suspended in March following recommendation from an independent data and safety monitoring board, which concluded that the safety risk outweighed the benefits observed in patients with rheumatoid arthritis based on an infection related safety signal which included serious infections, some of which were fatal, and opportunistic infections.
- The BELONG phase 3 study (Mysler EF et al., 2013) evaluating use of Ocrevus in patients with lupus nephritis due to systemic lupus erythematosus was also terminated early due to an imbalance of serious and opportunistic infections in the Ocrevus treated patients versus the placebo arm. From an analysis of an incomplete data set, there was no statistically significant differentiation between the Ocrevus and placebo response rates.

## V. Dosage and Administration

| Drug | Dosing Regimen | Maximum Dose |
|---|---|---|
| Alemtuzumab (Lemtrada) | IV infusion for 2 or more treatment courses:<br>• First course: 12 mg/day on 5 consecutive days<br>• Second course: 12 mg/day on 3 consecutive days 12 months after first course<br>• Subsequent courses as needed: 12 mg/day on 3 consecutive days 12 months after any prior course | See regimen |
| mitoxantrone | 12 mg/m$^2$ given as a short (approximately 5 to 15 minutes) intravenous infusion every 3 months | Cumulative lifetime dose of $\geq$ 140 mg/m$^2$ |
| Ocrelizumab (Ocrevus) | Initial 300 mg intravenous infusion with a second 300 mg intravenous infusion two weeks later, followed by subsequent doses of 600 mg via intravenous infusion every 6 months | 600 mg/6 months |
| Natalizumab (Tysabri) | 300 mg IV every 4 weeks | 300 mg/4 weeks |

| Drug | Dosing Regimen | Maximum Dose |
|---|---|---|
| Ponvory (Ponesimod) | Treatment initiation:<br>• Days 1 and 2: 2 mg PO QD<br>• Days 3 and 4: 3 mg PO QD<br>• Days 5 and 6: 4 mg PO QD<br>• Day 7: 5 mg PO QD<br>• Day 8: 6 mg PO QD<br>• Day 9: 7 mg PO QD<br>• Day 10: 8 mg PO QD<br>• Day 11: 9 mg PO QD<br>• Day 12, 13, and 14: 10 mg PO QD<br><br>Treatment maintenance:<br>• Day 15 and thereafter: 20 mg PO QD<br><br>Missed doses:<br>• If fewer than 4 consecutive doses are missed:<br>o During titration: Resume treatment with the first missed titration dose and resume the titration schedule at that dose and titration day.<br>o During maintenance: Resume treatment with the maintenance dosage.<br><br>• If 4 or more consecutive doses are missed during titration or maintenance:<br>o Treatment should be reinitiated with Day 1 of the titration regimen (new starter pack). | 20mg |

## VI. Product Availability

| Drug | Availability |
|---|---|
| Alemtuzumab (Lemtrada) | Single-use vial: 12 mg/1.2 mL |
| mitoxantrone | Multidose vial: 20 mg/10 mL, 25 mg/12.5 mL, 30 mg/15 mL |
| Ocrelizumab (Ocrevus) | Single-dose vial: 300 mg/10 mL |

| Drug | Availability |
|---|---|
| Natalizumab (Tysabri) | Single-use vial: 300 mg/15 mL |
| Ponesimod (Ponvory) | Tablets, starter pack: 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, 9 mg, 10 mg Tablets, maintenance dose bottle: 20 mg |

## VII. References

1. Lemtrada Prescribing Information. Cambridge, MA: Genzyme Corporation; August 2022. Available at http://www.lemtrada.com. Accessed February 1, 2024.
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8. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002; 58(2): 169-178.
9. 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://www.aan.com/Guidelines/home/GetGuidelineContent/904.
10. Biogen. Roche and Biogen Idec announce their decision to discontinue the ocrelizumab clinical development programme in patients with rheumatoid arthritis. Press release published May 19, 2010. Available at: https://investors.biogen.com/news-releases/news-release-details/roche-and-biogen-idec-announce-their-decision-discontinue. Accessed February 1, 2024.
11. Mysler EF, Spindler AJ, Guzman R, et al. Efficacy and safety of ocrelizumab in active proliferative lupus nephritis: Results from a randomized, double-blind, phase III study. Arthritis & Rheumatism. 2013; 65(9): 2368-2379.

## CLINICAL POLICY
Multiple Sclerosis Drugs (Multiple Sclerosis Drugs (Lemtrada, mitoxantrone, Ponvory)

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J1826 | Injection, interferon beta-1a, 30 mcg |
| Q3027 | Injection, interferon beta-1a, 1 mcg for intramuscular use |
| Q3028 | Injection, interferon beta-1a, 1 mcg for subcutaneous use |
| J1830 | Injection interferon beta-1b, 0.25 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered) |
| J1595 | Injection, glatiramer acetate, 20 mg |
| J0202 | Injection, alemtuzumab, 1 mg |
| J9293 | Injection, mitoxantrone HCl, per 5 mg |
| J2323 | Injection, natalizumab, 1 mg |
| J2350 | Injection, ocrelizumab, 1 mg |
| J9302 | Injection, ofatumumab, 10 mg |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 11.20.19 | 11.19 |
| 1Q 2020 annual review: added Vumerity for diagnosis of CIS, RRMS, and SPMS; starting and references reviewed and updated | 01.14.20 | 01.20 |
| Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization; Added EDSS table; Modified continued approval duration to 6 months for the first re-authorization and 12 months for second/subsequent re-authorizations; Added re-direction to the Novantrone policy CP.PHAR.258 if request is for diagnoses other than RRMS and SPMS; Added re-direction to the AZ.CP.PHAR.06 Cytokine and CAM Antagonists policy if Tysabri for Crohn's Disease; added Bafiertam (pending FDA approval) and Zeposia for diagnosis of CIS, RRMS, and SPMS; added Appendix B: Therapeutic Alternatives; added Coding Implications; Lemtrada: clarified that only 1 treatment course may be approved per authorization; Mavenclad: clarified that only 1 treatment course may be approved per authorization and 2 courses lifetime total; references reviewed and updated. | 04.11.20 | 04.20 |

## CLINICAL POLICY

Multiple Sclerosis Drugs (Multiple Sclerosis Drugs (Lemtrada, mitoxantrone, Ponvory)

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| For Bafiretam- Drug is now FDA approved - criteria and reference updated per FDA labeling; | 7.7.20 | 07.20 |
| RT2: added new subcutaneous dosage form Kesimpta to the policy for the treatment of multiple sclerosis.<br>Added list of AHCCCS preferred/non-preferred drugs; Updated format to break down by drug; For Betaseron and Rebif requests, removed the following criteria: failure of one of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: glatiramer (Copaxone 20 mg or Glatopa 40 mg) or Gilenya, AND Avonex; For SPMS for Extavia, Aubagio, Bafiertam, Mayzent, Plegridy, Tecfidera, Vumerity, Zeposia, Mavenclad, Novantrone, Ocrevus, and Tysabri, removed criteria for failure of the preferred disease modifying therapies for MS such as glatiramer (Copaxone 20 mg or Glatopa 40 mg), Gilenya, an interferon-beta agent (Avonex®, Betaseron®, Rebif®); references reviewed and updated. | 02.12.21 | 02.21 |
| 2Q 2021 annual review: no significant changes; RT4: added new IM dosage form and updated Dosing and Administration to indicate that Plegridy can be administered SC or IM; Aubagio, Lemtrada: updated Appendix C with additional contraindications per revised PI; Tecfidera, Vumerity, Bafiertam: updated Appendix C; Avonex: updated Appendix C to indicate the albumin contraindication only applies to the vial for Avonex per revised PI; removed Avonex vial per PI | 04.14.21 | 05.21 |
| Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st. | 5.10.21 | 04.21 |
| Per November SDC- not able to add recommendations for Extavia. References updated for Betaseron and Extavia. | 01.29.22 | 02.22 |
| 2Q 2022 annual review: removed references to the brand product Novantrone as it is no longer on market; added rheumatoid arthritis and lupus nephritis/systemic lupus erythematosus as diagnoses not covered due to safety concerns resulting in termination of the respective clinical studies of ocrelizumab; added J2350 for ocrelizumab in Coding Implications section; RT4 added Tascenso ODT; Added section on Ponvory (Ponesimod). References reviewed and updated. | 04.20.22 | 05.22 |
| Effective 10/1: updated policy to remove Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity, Zeposia, that are on AHCCCS Fee-For-Service Prior Authorization criteria; updated criteria to align with AHCCCS FFS PA criteria for Mavenclad. | 09.12.22 | 10.22 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| (Vumerity, Bafiertam, Kesimpta, Tecfidera, Plegridy, Aubagio, Mayzent), Zeposia: refer to Section II. Continued Therapy if there is evidence that member has been on Lemtrada, mitoxantrone, or Tysabri as documented by claims history or medical records (document drug, date, and duration of therapy); removed requirement of documentation of baseline relapses/EDSS; added a link to AHCCCS FFS PA criteria | | |
| Removed Tascenso ODT from policy – refer to AHCCCS FFS Criteria | 02.03.23 | 02.23 |
| 1Q 2024 annual review: removed Tysabri and Ocrevus from policy – refer to AHCCCS FFS criteria; updated AHCCCS preferred and non-preferred drug list; reviewed and updated references. | 02.01.24 | |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

## CLINICAL POLICY

Multiple Sclerosis Drugs (Multiple Sclerosis Drugs (Lemtrada, mitoxantrone, Ponvory)

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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