Clinical Policy: Multiple Sclerosis Agents

Reference Number: OH.PHAR.PPA.41
Effective Date: 01.20
Last Review Date: 07.20
Line of Business: Medicaid

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

Description

CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, INJECTABLE

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AVONEX® (interferon beta-1a) BETASERON® (interferon beta-1b) COPAXONE® (glatiramer) REBIF® (interferon beta-1a)	EXTAVIA® (interferon beta-1b) GLATOPATM (glatiramer) PLEGRIDY® (peginterferon beta-1a)

CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GILENYA® (fingolimod)	AUBAGIO® (teriflunomide) MAVENCLAD® (cladribine) MAYZENT® (siponimod)† TECFIDERA® (dimethyl fumarate) VUMERITY™ (diroximel fumarate)

†Must review liver function tests (LFTS) complete blood count (CBC), ophthalmic examination, varicella zoster virus antibodies, and electrocardiogram (ECG) prior to initiation. Must confirm member is not CYP2C9*3*3 genotype. Dose limited to 2mg/day.

CNS AGENTS: MULTIPLE SCLEROSIS POTASSIUM CHANNEL BLOCKERS*

NO PA REQUIRED "PREFERRED"	CLINICAL PA REQUIRED "PREFERRED"
AMPYRA® (dalfampridine)	

FDA Approved Indication(s)

- Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved indications

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 health plans affiliated with Centene Corporation® that the medications listed in the above tables are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias
2. Age ≥ 18 years;
   * Please note: Age ≥ 12 years for Extavia
3. Member has had a trial and failure to no less than 30 days of at least one medication, with the same route of administration, not requiring prior approval unless one of the following:
   a. Allergy to medications not requiring prior approval
   b. Contraindication to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior authorization
4. If medication is Mayzent prescriber must provide confirmation that the following have been completed prior to initiation:
   a. Review of liver function tests (LFT's)
   b. Complete blood count (CBC)
   c. Ophthalmic examination
   d. Confirmation member is not genotype CYP2C9 *3/*3
   e. Dose does not exceed 2mg/day
5. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 12 months

II. 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 policy – CP.CPA.09 CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

MS: multiple sclerosis

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®	Avonex: 30 mcg IM Q week Rebif: 22 mcg or 44 mcg SC TIW	Avonex: 30 mcg/week Rebif: 44 mcg TIW

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(interferon beta-1a)		
glatiramer acetate (Copaxone®, Glatopa®)	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW
Gilenya™ (fingolimod)	0.5 mg PO QD	0.5 mg/day
Ampyra® (dalfampridine)	10 mg PO BID (approximately 12 hours apart)	20 mg/day
Betaseron® (interferon beta-1b)	250 mcg SC QOD	250 mcg QOD

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

- Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

IV. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Extavia® (interferon beta- 1b)	250mg SC QOD	250 mcg QOD
Plegridy® (peginterferon beta-1a)	63 mcg on day 1, 94 mcg on day 15, and 125 mcg on day 29 and every 14 days thereafter	125 mcg/2 weeks
Aubagio® (teriflunomide)	7 mg or 14 mg PO QD	14 mg/day
Mavenclad® (cladribine)	Refer to prescribing information or Micromedex	Refer to prescribing information or Micromedex
Mayzent® (siponimod)	**All patients:** Day 1 and 2: 0.25 mg PO QD; Day 3: 0.5 mg PO QD Day 4: 0.75 mg PO QD **CYP2C9 genotypes *1/*1, *1/*2, or *2/*2**	2 mg/day
Tecfidera® (dimethyl fumarate)	120mg PO BID for 7 days, followed by 240 mg PO BID	480 mg/day
Vumerity (diroximel fumarate)	231mg PO BID for 7 days, then increase to target dose of 462mg PO BID	924mg/day

V. Product availability

Drug Name	Availability
Extavia® (interferon beta-1b)	Single-use vial: 0.3 mg
Betaseron® (Interferon beta-1b)	Single-use vial: 0.3 mg
Copaxone® (glatiramer)	Single-dose, prefilled syringe: 20 mg/mL, 40 mg/mL
Glatopa™ (glatiramer)	Single-dose, prefilled syringe: 20 mg/mL, 40 mg/mL
Plegridy® (peginterferon beta-1a)	Single-dose prefilled pen or syringe: 63 mcg/0.5 mL, 94 mcg/0.5 mL, 125 mcg/0.5 mL
Aubagio® (teriflunomide)	Tablets: 7 mg, 14 mg
Gilenya® (fingolimod)	Capsules: 0.25 mg, 0.5 mg
Avonex® (interferon beta- 1a)	Single-use vial: 30 mcg Single-use prefilled autoinjector or syringe: 30 mcg/0.5 mL
Rebif® (interferon beta-1a)	Single-dose autoinjector or prefilled syringe: 8.8 mcg/0.2 mL, 22 mcg/0.5 mL, 44 mcg/0.5 mL
Ampyra® (dalfampridine)	Tablet: 10 mg
Tecfidera® (dimethyl fumarate)	Delayed-release capsules: 120 mg, 240 mg
Mavenclad® (cladribine)	Tablet: 10 mg
Mayzent® (siponimod)	Tablets: 0.25 mg, 2 mg
Vumerity™ (diroximel fumarate)	Delayed release capsules 231mg

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.19	
Added Vumerity (diroximel fumarate) to list of non-preferred oral agents	07.20	

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.

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.