



5.60.04

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Central Nervous System Drugs	Original Policy Date:	December 1, 2014
Subject:	MS Injectable Drugs	Page:	1 of 6

Last Review Date: June 16, 2022

MS Injectable Drugs

Description

Avonex, Rebif (interferon beta-1a); **Plegridy** (peginterferon beta-1a); **Betaseron**, Extavia (interferon beta-1b); Copaxone* (**glatiramer acetate**), **Glatopa** (**glatiramer acetate**)

Preferred MS injectable products: Avonex, Rebif, Plegridy, Betaseron, generic glatiramer acetate and Glatopa.

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

Background

Plegridy (peginterferon beta-1a), Avonex / Rebif (interferon beta-1a), Betaseron / Extavia (interferon beta-1b), and Copaxone / Glatopa (glatiramer) are multiple sclerosis (MS) disease-modifying agents. They potentially alter the course of disease by lessening the frequency of clinical exacerbations. Avonex and Rebif may also delay the accumulation of physical disability (1-7).

Avonex / Rebif and Betaseron / Extavia are different brands of the same generic entity, interferons beta-1a and b respectively, recombinant forms of human interferon proteins. Plegridy is a PEG (poly-ethylene glycol)-attached form of interferon beta-1a. Copaxone / Glatopa (glatiramer) is a non-interferon polypeptide consisting of four amino acids. Although their precise mechanisms of action are unknown, the agents affect the body through the immune system (1-7).

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Regulatory Status

FDA-approved indications:

Avonex is an interferon beta indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (1).

Betaseron / Extavia is an interferon beta indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (2, 4).

Glatopa is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (7). **Copaxone / Plegridy** is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (3, 5).

Rebif is an interferon beta indicated for the treatment of patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (6).

The MS injectable drugs should be used with precaution in patients with mood or psychiatric disorders and hepatic impairment (1-7).

Live, attenuated vaccines are generally not recommended for a person with MS because their ability to cause disease has been weakened but not totally inactivated (8).

Safety and effectiveness of the MS injectable drugs in patients younger than 18 years of age have not been established (1-7).

Related policies

Acthar Gel, Ampyra, Aubagio, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Ponvory, Tecfidera, Tysabri, Zeposia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

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The MS injectable drugs may be considered **medically necessary** for patients 18 years of age or older for the treatment of relapsing forms of multiple sclerosis and if the conditions indicated below are met.

The MS injectable drugs may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
 - a. **NOT** used in combination with another MS disease modifying agent
 - b. **NOT** given concurrently with live vaccines
2. **Extavia only:** Patient **MUST** have tried generic Copaxone: glatiramer acetate **AND ONE** of the other preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

[Policy Guidelines](#)

Pre - PA Allowance

None

Prior - Approval Limits

Duration 2 years

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Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Plegridy (peginterferon beta-1a), Avonex / Rebif (interferon beta-1a), Betaseron / Extavia (interferon beta-1b), and Copaxone / Glatopa (glatiramer) are multiple sclerosis (MS) disease-modifying agents. They potentially alter the course of disease by lessening the frequency of clinical exacerbations. Avonex and Rebif may also delay the accumulation of physical disability (1-7).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of the MS injectable drugs while maintaining optimal therapeutic outcomes.

References

1. Avonex [package insert]. Cambridge MA: Biogen Inc.; November 2021.
2. Betaseron [package insert]. Whippany NJ: Bayer HealthCare Pharmaceuticals Inc; November 2021.
3. Copaxone [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; April 2022.
4. Extavia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2021.
5. Plegridy [package insert]. Cambridge, MA: Biogen Inc.; March 2022.
6. Rebif [package insert]. Rockland, MA: EMD Serono; November 2021.
7. Glatopa [package insert]. Princeton, NJ: Sandoz Inc; July 2020.
8. Cahill JF, Izzo A, Garg N. Immunization in patients with multiple sclerosis. *Neurological Bulletin*. 2010;2(1):17-21.

Policy History

Date	Action
December 2014	Addition to PA
March 2015	Annual editorial review and reference update
July 2015	Addition of Glatopa
September 2015	Annual review
June 2016	Addition of Zinbryta

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Policy number change from 5.06.22 to 5.60.04

September 2016	Annual review
December 2016	Annual editorial review and reference update Addition of not given concurrently with live vaccines
March 2017	Annual review
June 2017	Annual review
November 2018	Annual editorial review and reference update Zinbryta removed from market
March 2019	Addition of PA Renewal Requirements and changed PA duration from lifetime to 2 years
June 2019	Annual review and reference update
September 2019	Annual review. Revised relapsing MS indication to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
December 2019	Annual review. Addition of requirement to trial preferred products
March 2020	Annual editorial review and reference update
September 2020	Annual review
December 2020	Annual review and reference update. Revised requirement that Copaxone brand and Extavia must t/f glatiramer acetate and another preferred MS medication. Added Appendix 1 with a list of preferred medications
June 2021	Annual review and reference update
December 2021	Annual review and reference update. Removed Medex requirement for brand Copaxone and added brand Copaxone to FE + PA only
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.

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Appendix 1 - List of Preferred Multiple Sclerosis (MS) Medications

Medication Name	Route of Administration
Avonex	Injectable
Betaseron	Injectable
glatiramer acetate* (generic Copaxone) *must try this drug plus one other preferred MS medication oral or injectable	Injectable
Glatopa	Injectable
Plegridy	Injectable
Rebif	Injectable

Medication Name	Route of Administration
Aubagio	Oral**
dimethyl fumarate (generic Tecfidera)	Oral**
Gilenya	Oral**
Mayzent	Oral**
Zeposia	Oral**

** indicates separate criteria will need to be met