MS Injectable Drugs

**Description**

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

Bolded medications are the preferred products

**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).

**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 to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis (2,3).

Glatopa is indicated for the treatment of patients with relapsing forms of multiple sclerosis (4-5). 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 (7).

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 are available for subcutaneous injection and 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, Lemtrada, Mavenclad, Mayzent, Ocrevus, Tecfidera, Tysarbi

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

Copaxone, Glatopa, Plegridy and Rebif 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.
Avonex, Betaseron and Extavia may be considered medically necessary if a first clinical episode of MS has a MRI that is consistent with MS 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. **Copaxone brand and Extavia only:** Patient **MUST** have tried at least TWO of the preferred products 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
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**

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>December 2014</td>
<td>Addition to PA</td>
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<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>July 2015</td>
<td>Addition of Glatopa</td>
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<td>September 2015</td>
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<tr>
<td>June 2016</td>
<td>Addition of Zinbryta</td>
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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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.