MS Injectable Drugs

Description

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

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 to slow the accumulation of physical disability and decrease 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 (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).

Copaxone / Glatopa / Plegridy is indicated for the treatment of patients with relapsing forms of multiple sclerosis (4,5, 7).

Rebif is an interferon beta indicated for the treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability (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).

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

**Related policies**
Aubagio, Gilenya, 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.*

The MS injectable drugs may be considered **medically necessary** for patients 18 years of age or older for Copaxone / Glatopa, Plegridy and Rebif for the treatment of relapsing forms of multiple sclerosis or for Avonex, Betaseron and Extavia for a first clinical episode of MS and MRI features consistent with MS.

The MS injectable drugs may be considered **investigational** in patients less than 18 years of age or who do not meet the criteria for medical necessity.

**Prior-Approval Requirements**

**Age** 18 years of age and older
Diagnoses

Patient must have **ONE** of the following:

**Copaxone / Glatopa, Plegridy and Rebif**

Relapsing Multiple Sclerosis (MS)

**AND the following:**

Not used in combination with another MS disease modifying agent

**Avonex, Betaseron and Extavia**

Relapsing Multiple Sclerosis (MS)

**OR**

A first clinical episode of MS and MRI features consistent with MS

**AND the following:**

Not used in combination with another MS disease modifying agent

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

Duration  
Lifetime

**Rationale**

The MS injectable drugs are indicated for the treatment of patients with relapsing forms of
multiple sclerosis to decrease the frequency of clinical exacerbations and / or delay the accumulation of physical disability. Efficacy has been demonstrated in patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis (Avonex, Betaseron, and Extavia) (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

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<td>March 2015</td>
<td>Annual editorial review and reference update</td>
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Keywords