MULTIPLE SCLEROSIS INJECTABLE DRUGS
Avonex, Rebif (interferon beta-1a); Plegridy (peginterferon beta-1a); Betaseron, Extavia (interferon beta-1b); Copaxone, Glatopa (glatiramer); Zinbryta (daclizumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Plegridy (peginterferon beta-1a), Avonex / Rebif (interferon beta-1a), Betaseron / Extavia (interferon beta-1b), Copaxone / Glatopa (glatiramer), and Zinbryta (daclizumab) 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 (1-8).

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 (1-8).

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).

Zinbryta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis.
The use of Zinbryta should be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Zinbryta can cause severe liver injury including life-threatening events, liver failure, and autoimmune hepatitis. Physicians should assess the transaminase and bilirubin levels prior to the initiation of Zinbryta and monitor these levels monthly during Zinbryta therapy and for an additional 6 months after the last dose. Zinbryta is contraindicated in patients with pre-existing hepatic disease or hepatic impairment. Treatment with Zinbryta increases the risk of immune-mediated disorders, such as autoimmune hepatitis and lymphadenopathy. Zinbryta is available only through a restricted distribution program called the Zinbryta REMS Program to ensure periodic monitoring will be maintained to detect potential problems (8).

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 (9).

Safety and effectiveness of the MS injectable drugs in patients younger than 18 years of age have not been established (1-8).

Summary
Copaxone, Glatopa, Plegridy, Rebif and Zinbryta 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 in Avonex, Betaseron, and Extavia has been demonstrated in patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis (1-8).

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
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