Oscar Clinical Guideline: Plegridy (peginterferon beta-1a) (PG229, Ver. 3)

Plegridy (peginterferon beta-1a)

Summary

Multiple sclerosis (MS) is a chronic, inflammatory, demyelinating disease of the central nervous system. It typically presents in young adults (generally diagnosed before 50 years of age) with symptoms such as vision problems, muscle weakness, numbness, and difficulty with balance and coordination. The most

common form is relapsing-remitting MS (occurring in about 85% of patients), characterized by acute attacks followed by periods of remission. Treatment goals include reducing relapses, slowing disability progression, and managing symptoms. Disease-modifying therapies (DMTs) are the primary treatment approach and include injectable medications (e.g., interferons, glatiramer acetate), oral medications (e.g., dimethyl fumarate, fingolimod, teriflunomide, etc.), and infusion therapies (e.g., natalizumab, ocrelizumab).

MS is a progressive disease, meaning that symptoms tend to worsen over time, and it can be classified into several types, including relapsing-remitting MS (RRMS), primary progressive MS (PPMS), and secondary progressive MS (SPMS).

Currently, there is no cure for MS, but various treatment options are available to manage symptoms, slow the progression of the disease, and improve quality of life.

- Disease-modifying therapies (DMTs) are a class of medications that target the immune system to reduce inflammation and slow down the progression of the disease. The type of DMT prescribed will depend on the type and severity of MS, as well as the individual's medical history and preferences. Some common DMTs include interferon beta, glatiramer acetate, dimethyl fumarate, and fingolimod.
- High dose corticosteroids, such as high dose intravenous methylprednisolone or oral prednisone can be prescribed to reduce inflammation during acute MS relapses.
- Symptomatic treatments are also available to manage specific symptoms of MS, such as muscle spasms, bladder problems, and depression. Physical therapy, occupational therapy, and speech therapy can help individuals with MS maintain mobility, independence, and communication skills.

Plegridy (peginterferon beta-1a) is a pegylated form of interferon beta-1a indicated for relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. It is administered via subcutaneous or intramuscular injection every 14 days. The pegylation of interferon beta-1a reduces clearance, increases systemic exposure, and prolongs the half-life of the drug, allowing for less frequent dosing compared to non-pegylated interferon beta-1a preparations (e.g., Avonex, Rebif). Plegridy (peginterferon beta-1a) works by modulating the immune system and reducing inflammation in the central nervous system, though its exact mechanism of action in MS is not fully understood.

Definitions

"Clinically isolated syndrome" refers to a first episode of neurologic symptoms lasting at least 24 hours caused by inflammation or demyelination in the central nervous system.

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information

2. Clinical pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"Disease-modifying therapy" is a medication that modifies the course of MS by reducing relapses and slowing disability progression.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"MRI" or "Magnetic Resonance Imaging" refers to a medical imaging technique that creates detailed three-dimensional (3D) images of the organs and tissues in your body. A brain MRI can reveal areas of active MS disease called lesions within the central nervous system.

"Multiple sclerosis" is a chronic autoimmune disease of the central nervous system characterized by inflammation, demyelination, and neurodegeneration.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Primary progressive MS" refers to worsening neurologic function from the onset of symptoms, without early relapses or remissions.

"Relapse" is defined as the appearance of new symptoms or the worsening of existing symptoms lasting at least 24 hours in the absence of fever or infection.

"Relapsing-remitting MS" refers to a disease course characterized by clearly defined attacks of new or increasing neurologic symptoms followed by periods of partial or complete recovery.

"[s]" indicates state mandates may apply.

"Secondary progressive MS" is a disease course following relapsing-remitting MS that is characterized by a progressive worsening of neurologic function over time with or without relapses.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Plegridy (peginterferon beta-1a) medically necessary when ONE of the following criteria are met:

1. Authorization may be granted for pediatric members less than 18 years of age with multiple sclerosis when there is documentation that the benefits outweigh the risks*; OR*
   Note: If approved, the requested product will be authorized for up until the member reaches 18 years of age.
2. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review or Subsequent Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Multiple Sclerosis - Adults

The Plan considers Plegridy (peginterferon beta-1a) medically necessary when recent (within the last 3 months) clinical chart documentation provided indicates the member meets ALL of the following:

1. Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of multiple sclerosis; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has ONE (1) of the following forms of multiple sclerosis:
   a. Relapsing-remitting (RRMS)*; or*
   b. Active secondary progressive disease (SPMS)*; or*
   c. Clinically isolated syndrome (CIS); *AND*
4. Plegridy (peginterferon beta-1a) will be used as monotherapy for multiple sclerosis (i.e., member is not using and will not use other disease-modifying MS therapies while on Plegridy [peginterferon beta-1a]); *AND*
5. Plegridy (peginterferon beta-1a) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.
   The requested medication is being used within the Plan's Quantity Limit of:
   - *The recommended maintenance dose is 125 mcg injected subcutaneously or intramuscularly every 14 days after an initial titration schedule (63 mcg on day 1, 94 mcg on day 15, and 125 mg on day 29)*
     i. *For subcutaneous injection: 1 mL (two 0.5 mL prefilled syringes or autoinjectors) per 28 days.*
     ii. *For intramuscular injection: 1 mL (two 0.5 mL prefilled syringes) per 28 days.*
     iii. *For the initial titration regimen: 1 box every 28 days*

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.[5]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Multiple Sclerosis - Adults

The Plan considers Plegridy (peginterferon beta-1a) medically necessary when recent (within the last 6-months) clinical chart documentation provided indicates the member meets ALL of the following:

1. The requested medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; *AND*
2. The member has experienced at least ONE (1) of the following:
    a. Improvement in at least ONE (1) objective measure, such as:
        i. Reduced disease activity on MRI*; and/or*
        ii. Improved or stable disability scores*; and/or*
        iii. Reduced relapse rate*; and/or*
        iv. Improved fatigue or walking assessments; *AND/OR*
    b. The member has shown stabilization or improvement in at least ONE (1) MS symptom, such as:
        i. Motor function*; and/or*
        ii. Fatigue*; and/or*
        iii. Vision*; and/or*
        iv. Bowel/bladder function*; and/or*
        v. Spasticity*; and/or*
        vi. Walking/gait*; and/or*
        vii. Pain/numbness/tingling.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[5]

Experimental or Investigational / Not Medically Necessary[5]

Plegridy (peginterferon beta-1a) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational,unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Use in combination with other disease-modifying therapies for multiple sclerosis. There is limited knowledge about the use of combining DMTs for MS.

- Treatment of non-relapsing forms of multiple sclerosis (e.g., primary progressive MS). The safety and efficacy of Plegridy (peginterferon beta-1a) has not been established in those with PPMS.
- Use for the treatment of other neurological conditions not related to multiple sclerosis. Use as a treatment for cancer or as an adjunct to cancer therapies. There are not high quality studies to support the use of Plegridy (peginterferon beta-1a) for the management of any other neurological condition other than MS.
- Use for the treatment of viral infections, including chronic viral hepatitis. While literature supports the use of interferon products for the management of viral hepatitis (e.g., Hepatitis C), interferon beta products are not approved for management of these conditions.
- Use in the management of other autoimmune disorders not related to multiple sclerosis. There are not high quality studies to support the use of Plegridy (peginterferon beta-1a) for the management of autoimmune disorders (e.g., Crohn's disease, ulcerative colitis) not related to MS.

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