Glatiramer Acetate (Copaxone, Glatopa)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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 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.

Glatiramer acetate is a medication prescribed for adults with various relapsing forms of multiple sclerosis (MS). These forms include clinically isolated syndrome, relapsing-remitting MS, and active secondary progressive MS. Clinical studies have demonstrated that glatiramer acetate can decrease the frequency of relapses in patients with relapsing-remitting MS. Additionally, for individuals who have experienced a single clinical episode and show MRI findings suggestive of MS, this drug has been found to lower the likelihood of the condition progressing to definitive MS. Glatiramer acetate is administered subcutaneously (SUBQ) using a prefilled syringe or a compatible injection device.

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.

"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 Initial Clinical Review

Initial Indication-Specific Criteria

Multiple Sclerosis

The Plan considers Glatiramer Acetate (Copaxone, Glatopa) when recent (within the last 3 months) clinical chart documentation provided indicates the member meets ALL of the following:

1. The medication is prescribed by or in consultation with a neurologist or physician who specializes in the treatment of multiple sclerosis; *AND*
2. Is 18 years of age or older; *AND*
3. 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. For glatiramer products (i.e., glatiramer acetate, brand Glatopa [glatiramer acetate]) - the member is unable to use, or has tried and failed Copaxone (glatiramer acetate),[c] *AND*
5. Glatiramer Acetate 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 glatiramer acetate [Copaxone, Glatopa]); *AND*
6. Glatiramer acetate is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.
    - *The recommended dose is either:*
        - *i. 20 mg/mL administered subcutaneously once daily; or*
            1. *20 mg/mL: 30 syringes per 30 days*
        - *ii. 40 mg/mL administered subcutaneously three times per week at least 48 hours apart.*
            1. *40 mg/mL: 12 syringes per 28 days*

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

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Multiple Sclerosis

The Plan considers Glatiramer Acetate (Copaxone, Glatopa) when recent (within the last 6 months) clinical chart documentation provided indicates the member meets BOTH 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]

Glatiramer Acetate (Copaxone, Glatopa) 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 for the treatment of primary progressive multiple sclerosis (PPMS). In a randomized controlled trial with 934 participants with PPMS, there was no significant difference between glatiramer acetate (Copaxone, Glatopa) than placebo in delay time to sustained accumulated disability (HR 0.87, 95% CI 0.71-1.07, p=0.1753). Power was reduced by the lower than expected event rate and higher than expected drop-out rate. There are no other studies to support the safety and efficacy of glatiramer acetate (Copaxone, Glatopa) for the management of PPMS.
- Use in combination with other disease-modifying therapies for multiple sclerosis.
- Use in members under 18 years of age. The safety and efficacy of glatiramer acetate (Copaxone, Glatopa) has not been adequately assessed in those less than 18 years of age. In a small study (n=30), glatiramer acetate (Copaxone, Glatopa) was found to be effective in improving MRI disease activity-free status, compared to interferon. More studies are needed to support the safety and efficacy in this population.
- Use for indications other than FDA-approved relapsing forms of multiple sclerosis.

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