GLATIRAMER ACETATE

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLATIRAMER ACETATE</td>
<td>COPAXONE, GLATOPA</td>
<td>12810</td>
<td></td>
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</tbody>
</table>

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis?

   If yes, approve for 12 months by GPID with the following quantity limits:
   - Glatiramer acetate 20mg/mL: #1mL per day.
   - Glatiramer acetate 40mg/mL: #12 syringes per 28 days.

   If no, do not approve.

   **DENIAL TEXT:** The guideline for GLATIRAMER ACETATE (Copaxone) requires a diagnosis of a relapsing form of multiple sclerosis.

RATIONALE

To ensure appropriate use aligned with FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Copaxone and Glatopa are indicated for the treatment of patients with relapsing-forms of multiple sclerosis.

<table>
<thead>
<tr>
<th>Type of MS</th>
<th>Description</th>
<th>% MS population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically Isolated Syndrome (CIS)</td>
<td>Single neurologic symptomatic attack compatible with MS. Clinically defined MS occurs in about 80% of patients who have demyelinating lesions on MRI.</td>
<td>MS Precursor</td>
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<tr>
<td>Relapsing Remitting MS (RRMS)</td>
<td>Clearly defined acute exacerbations, followed by partial or complete recovery of the deficits.</td>
<td>85%</td>
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<tr>
<td>Secondary Progressive MS (SPMS)</td>
<td>Initiates as RRMS before developing into a more steady disability progression, which may also include occasional relapses. The transition to SPMS generally occurs in people who have been living with RRMS for at least 10 years.</td>
<td>85% of RRMS patients</td>
</tr>
<tr>
<td>Primary Progressive MS (PPMS)</td>
<td>Progression of disability from onset without plateaus or remissions. Does not experience acute attacks.</td>
<td>10%</td>
</tr>
<tr>
<td>Progressive Relapsing MS (PRMS)</td>
<td>Continuous worsening neurologic function with occasional relapses.</td>
<td>5%</td>
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GLATIRAMER ACETATE

FDA APPROVED INDICATIONS (CONTINUED)

DOsing
Glatopa 20 mg per mL and glatiramer acetate injection 40 mg per mL are not interchangeable.

Copaxone
Copaxone is for subcutaneous use only. The dosing schedule depends on the product strength that is selected. The recommended doses are:
- Copaxone 20 mg per mL: administer once per day
- Copaxone 40 mg per mL: administer three times per week and at least 48 hours apart
- Copaxone 20 mg per mL and Copaxone 40 mg per mL are not interchangeable.

Glatopa
Glatopa is for subcutaneous use only. Do not administer intravenously. The recommended dose is:
- Glatopa 20 mg per mL: administer once per day.

REFERENCES

Created: 01/11/18
Effective: 03/01/18