DISEASE-MODIFYING DRUGS FOR MULTIPLE SCLEROSIS

GLATIRAMER ACETATE (Copaxone®, FINGOLIMOD (Gilenya™)
INTERFERON BETA (Betaseron®, Extavia®, Avonex®, Rebif®),
TERIFLUNOMIDE (Aubagio™)
DIMETHYL FUMARATE (Tecfidera™)

UTILIZATION MANAGEMENT CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS: Disease-Modifying Drugs for Multiple Sclerosis</th>
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<tr>
<td>BRAND (generic) NAMES: Interferon Beta-1b (Betseron, Extavia)</td>
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<td>Interferon Beta-1a (Avonex, Rebif)</td>
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<tr>
<td>Glatiramer acetate (Copaxone)</td>
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<td>Fingolimod (Gilenya)</td>
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<td>Teriflunomide (Aubagio)</td>
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<td>Dimethyl fumarate (Tecfidera)</td>
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FDA-APPROVED INDICATIONS
Glatiramer acetate, interferon beta, fingolimod, teriflunomide and dimethyl fumarate are 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 consistent with multiple sclerosis.

Safety and efficacy in patients with chronic progressive multiple sclerosis have not been established.

COVERAGE AUTHORIZATION CRITERIA

1) Covered diagnoses:
   - Treatment at time of first demyelinating event to delay development or progression to multiple sclerosis;
   - Relapsing-remitting multiple sclerosis;
   - Secondary-progressive multiple sclerosis;
   - Progressive-relapsing multiple sclerosis.

2) Patient must still either be able to walk at least a few steps with or without aid, or alternatively must have some functional arm/ hand use consistent with performing activities of daily living.

3) Patient is not administering combination therapy with any of these disease-modifying drugs for multiple sclerosis.

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4) For Extavia requests, the member must have tried one (1) preferred agent and had an inadequate response to this product or could not tolerate it. Preferred agents include: Betaseron, Rebif, or Copaxone.

5) For Avonex requests, the member must have tried one (1) preferred agent and had an inadequate response to this product or could not tolerate it. Preferred agents include: Betaseron, Rebif, or Copaxone.

6) For members on the Basic Open Formulary, before approval of a nonpreferred agent is given, two (2) preferred agents must be tried. Please consult the formulary list as these agents may change over time.

**DOSAGE AND ADMINISTRATION:**

The recommended dose of Betaseron and Extavia is 0.25 mg injected subcutaneously every other day. Generally, patients should be started at 0.0625 mg subcutaneously every other day, and increased over a six week period to 0.25 mg every other day.

The recommended dosage of Avonex is 30 mcg injected intramuscularly once a week.

Dosages of Rebif shown to be safe and effective are 22 mcg and 44 mcg injected subcutaneously three times per week. Generally, patients should be started at 20% of the prescribed dose and increased over a 4-week period to the targeted dose, either 22 mcg or 44 mcg three times a week.

The recommended dose for Copaxone 20 mg/mL strength is injected subcutaneously once per day. The recommended dose for Copaxone 40 mg/mL strength is injected subcutaneously three times per week at least 48 hours apart.

The recommended dose of Gilenya is 0.5 mg orally once daily, with or without food.

The starting dose for Tecfidera is 120 mg twice a day orally. After 7 days, the dose should be increased to the maintenance dose of 240 mg twice a day orally.

See product information for details on dosage and administration of any of these drugs.

**REFERENCES**


