



DISEASE-MODIFYING DRUGS FOR MULTIPLE SCLEROSIS

GLATIRAMER ACETATE (Copaxone), FINGOLIMOD (Gilenya) INTERFERON BETA (Betaseron, Extavia, Avonex, Rebif) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Disease-Modifying Drugs for Multiple Sclerosis
BRAND (generic) NAMES:	Interferon Beta-1b (Betaseron, Extavia) Interferon Beta-1a (Avonex, Rebif) Glatiramer acetate (Copaxone) Fingolimod (Gilenya)

FDA-APPROVED INDICATIONS

Glatiramer acetate, interferon beta and fingolimod 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 and have MRI features consistent with multiple sclerosis.

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

COVERAGE AUTHORIZATION CRITERIA for glatiramer acetate, interferon beta, and fingolimod for NEW USERS only:

- 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.
- 4) For Extavia requests, the member must have tried Betaseron or Rebif and had an

inadequate response to this product or could not tolerate it.

5) For Avonex requests, the member must have tried Betaseron or Rebif and had an inadequate response to this product or could not tolerate it.

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 of Copaxone is 20 mg injected subcutaneously once daily.

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

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

REFERENCES:

Betaseron (interferon beta-1b). Product information. Bayer HealthCare Pharmaceuticals, Inc. 2009.

Extavia (interferon beta-1b). Product information. Novartis Pharmaceuticals Corporation. 2009.

Avonex (interferon beta-1a). Product information. Biogen Idec, Inc. 2008.

Rebif (interferon beta-1a). Product information. EMD Serono, Inc. 2009.

Copaxone (glatiramer acetate injection). Product information. Teva Neuroscience, Inc. 2009.

Gilenya (fingolimod capsules). Product information. Novartis Pharmaceuticals Corporation. 2010.