SPECIALTY GUIDELINE MANAGEMENT

BETASERON (interferon beta-1b) EXTAVIA (interferon beta-1b)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Betaseron and Extavia are indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist.

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

B. Clinically isolated syndrome

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome of multiple sclerosis.

IV. CONTINUATION OF THERAPY

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Betaseron or Extavia.

V. OTHER

Members will not use Betaseron or Extavia concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

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Reference number(s) 1840-A

VI. REFERENCES

- 1. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2023.
- 2. Extavia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.

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