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| Reference number(s) |
| 1840-A              |

## 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 Indications

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. 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 the treatment of clinically isolated syndrome of multiple sclerosis.

##### III. 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.

##### IV. OTHER CRITERIA

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

##### V. REFERENCES

1. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; March 2021.
2. Extavia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2020.

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- AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed (April 2021).