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PHARMACY POLICY STATEMENT **Kentucky Medicaid**	
DRUG NAME	Betaseron (interferon beta-1b)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Extavia QUANTITY LIMIT— 14 mL per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Betaseron (interferon beta-1b) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS, SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS

For **initial** authorization:

1. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
2. Chart notes have been provided confirming diagnosis of Multiple Sclerosis based on McDonald Diagnostic Criteria; AND
3. Documentation of trial and failure of or contraindication to Avonex, Copaxone/Glatopa, Extavia, or Rebif) for at least 30 days submitted with chart notes.
4. **Dosage allowed:** Start 0.0625 mg (0.25 mL) subcutaneously every other day for week 1 and 2; then 0.125 mg (0.5 mL) subcutaneously every other day for week 3 and 4; then 0.1875 mg (0.75 mL) subcutaneously every other day week 5 and 6; then 0.25 mg (1 mL) subcutaneously every other day for week 7 and thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member has documented biological response to treatment.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Betaseron (interferon beta-1b) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Multiple Sclerosis - Clinically isolated syndrome (CIS)

DATE	ACTION/DESCRIPTION
06/13/2017	New policy for Betaseron created. Not covered diagnosis added.

References:

1. Betaseron [package insert]. Whippany, NJ; Bayer HealthCare Pharmaceuticals Inc.: Revised April 2016.
2. Betaseron. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed April 7, 2017.
3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.
4. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Annals of Neurology. 2011;69(2):292-302. doi:10.1002/ana.22366.

Effective date: 08/09/2017
Revised date: 06/13/2017