interferon beta 1-b (Betaseron)

Policy # 00453
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider interferon beta 1-b (Betaseron®‡) to be eligible for coverage when the patient selection criterion is met.

Patient Selection Criterion
Coverage eligibility for interferon beta 1-b (Betaseron) will be considered when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of interferon beta 1-b (Extavia®‡) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of interferon beta 1-b (Betaseron) WITHOUT clinical evidence or patient history that suggests the use of interferon beta 1-b (Extavia) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.**

Background/Overview
Both Betaseron and Extavia contain the same active ingredient, interferon beta-1b. The two drugs also share the same indication for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Betaseron and Extavia are both dosed the same, and they also share the same clinical studies in their respective package inserts.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA).
Extavia was approved by the FDA in August of 2009 and is distributed by Novartis. Betaseron was approved in July of 1993 and is manufactured by Bayer Health Care.

Rationale/Source
The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests Extavia will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using Betaseron over Extavia.
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10/02/2014 Medical Policy Committee review
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**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.