NEUTRALIZING ANTIBODY TESTS FOR INTERFERON

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Individuals undergoing interferon therapy may develop neutralizing antibodies (NABs) that bind to the interferon and inhibit or reduce its therapeutic benefit.

The NAbFeron® test has been investigated in the detection of neutralizing antibodies to interferon beta 1A or interferon beta 1B in individuals with multiple sclerosis and hepatitis C.
NEUTRALIZING ANTIBODY TESTS FOR INTERFERON (cont.)

Criteria:

- NAbFeron antibody testing for detection of antibodies to interferon beta is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

NEUTRALIZING ANTIBODY TESTS FOR INTERFERON (cont.)

Resources: (cont.)

beta antibodies in multiple sclerosis patients. *Eur Cytokine Netw.* 2003 Jul-Sep 2003;14(3):154-
157.


9. Vartanian TK, Zamvil SS, Fox E, Sorensen PS. Neutralizing antibodies to disease-modifying
49.

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