GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Approximately one third of multiple sclerosis (MS) patients treated with interferon-beta (IFNb) develop neutralizing antibodies (anti-IFNb antibodies) within two years of initiating treatment. These antibodies reduce or entirely eliminate the effect and clinical efficacy of IFNb. The NAbFeron testing assay (performed by Athena Diagnostics) has been developed for identifying patients where NAb develops during IFNb treatment.

Clinical research indicates interferon-beta therapies such as Betaseron, Rebif, and Avonex can trigger the production of NAb. Diagnostic tests are used to measure the NAb levels in MS patients at 12 and 24 months of IFNb therapy. Currently, the role of testing is meant to be predictive, with positive results potentially identifying patients who may be more unresponsive to IFNb treatment.

While some evidence indicates high level of NAb may cause interferon beta therapy to be less effective, the evidence supporting clinical utility is not strong enough to make specific recommendations. There continue to be studies investigating whether poor patient response to IFNb therapy is definitively related to high NAb titers or if some patients only have partial response to the therapy. NAb that can interfere with efficacy are quantified using in vitro bioassays; however, these assays do not reveal the immunogenic state of the patient and are not predictive of treatment outcome.

POLICY
Neutralizing antibody testing in multiple sclerosis patients is non-covered for all product lines.

HMO, PPO, Individual Marketplace, Elite, Advantage
Paramount has determined that neutralizing antibody testing in multiple sclerosis patients is experimental and investigational and therefore non-covered.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>86382</td>
<td>Neutralization test, viral</td>
</tr>
<tr>
<td>86384</td>
<td>Nitroblue tetrazolium dye test</td>
</tr>
<tr>
<td>87253</td>
<td>Virus isolation, tissue culture, additional studies or definitive Identification (e.g. hemabsorption, neutralization, immunofluorescence stain), each isolate</td>
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REVISION HISTORY EXPLANATION
04/01/10: Updated
01/01/11: No changes
11/21/14: Added CPT codes 86382, 86384, 97253. Changed title from Neutralizing Antibody Testing, NabFeron Antibody Testing, NAb Screen to Neutralizing Antibody Testing in Multiple Sclerosis Patients. Policy reviewed and updated to reflect most current clinical evidence per TAWG committee.
11/12/15: Policy reviewed and updated to reflect most current clinical evidence per TAWG committee.
11/18/16: Policy reviewed and updated to reflect most current clinical evidence per TAWG committee.

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services