Medica Coverage Policy

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<th>Policy Name:</th>
<th>Testing for Neutralizing Antibodies to Interferon Beta in the Management of Multiple Sclerosis</th>
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<td>Effective Date:</td>
<td>10/16/2017</td>
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**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

Testing for neutralizing antibodies to Interferon beta in the management of multiple sclerosis is investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

**Note:** This policy is no longer scheduled for routine review of the scientific literature.

**Description**

Neutralizing antibody (NAb) testing is a laboratory test performed on a blood sample to evaluate the presence or absence of antibodies to interferon beta (IFN-ß). Interferon beta is a well-established therapy for multiple sclerosis (MS). However, prolonged treatment of MS with IFN-ß is associated with the development of both binding antibodies (BAbs) and neutralizing antibodies (NAbs). NAbs are a subset of BAbs that bind to the IFN-ß molecule and to the active receptor site, thereby blocking the biological effects of the drug. Therefore, the presence of NAbs may be associated with a reduction in the radiographic and clinical effectiveness of IFN-ß treatment. BAbs do not appear to disrupt the clinical effect of IFN-ß, but may serve as a warning indicator prior to nAb development.

In general, binding assays and bioassays are the two types of analytic methods used to determine the presence of antibodies in response to a biologic agent. Binding assays measure and detect both binding and neutralizing antibodies. Bioassays, however, are specifically used to detect antibodies that result in a loss or neutralization of the biological activity of the foreign protein. There are two commonly employed types of bioassays for the detection of NAbs against IFN-ß: the cytopathic effect (CPE) assay (NAbFeron, Athena Diagnostics, Worcester, MA) and the myxovirus protein A (MxA) induction assay. However, these assays are not universally available and have methodological difficulties that limit standardization.

**FDA Approval**

The currently available bioassays utilize in-house reagents and methods that are not commercially marketed. Therefore, they are not subject to FDA regulations. However, the laboratories are regulated under and certified by the Clinical Laboratory Improvement Amendments (CLIA) of 1988 by the U.S. Center for Medicare and Medicaid Services.
Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
86382 – neutralization test, viral
83520 – immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
86352 – cellular function assay involving stimulation (eg, mitogen or antigen) and detection of biomarker (eg, ATP)
87253 – virus isolation; tissue culture, additional studies or definitive identification (eg, hemabsorption, ultralization, immunofluorescence stain), each isolate

Original Effective Date: 4/1/2011

Re-Review Date(s): 10/15/2014
7/19/2017
3/6/2020 – administrative update; format