Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MP299

Section: Medical Benefit Policy

Subject: Measurement of Serum Antibodies to Infliximab, Adalimumab, and Vedolizumab

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I. Policy: Measurement of Serum Antibodies to Infliximab, Adalimumab and Vedolizumab

II. Purpose/Objective:
To provide a policy of coverage regarding Measurement of Serum Antibodies to Infliximab, Adalimumab, and Vedolizumab

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Prometheus® Laboratories Inc. offers non-radiolabeled fluid-phase HMSA tests called the Anser™IFX test for infliximab, Anser™ VDZ for vedolizumab, and Anser™ADA for adalimumab. These tests measure antidrug antibodies in the presence of detectable drug levels, improving upon a major limitation of the ELISA method. These tests measure serum concentrations and antidrug antibodies. The detection and quantitative measurement of antidrug antibodies has historically been difficult to establish.

EXCLUSIONS: Measurement of antibodies to infliximab (Remicade), adalimumab (Humira), or vedolizumab (Entyvio) either alone or as a combination test which includes the measurement of medication serum levels, is considered experimental, investigational or unproven or is **NOT COVERED.** The clinical value of these measurements for individuals receiving infliximab, vedolizumab or adalimumab therapy has not been established.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Measurement of Serum Antibodies to Infliximab, Vedolizumab and Adalimumab

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

84999 Unlisted chemistry procedure

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/15

Revised: 5/18(add Anser VDZ exclusion)

Reviewed: 5/16, 10/17, 5/19