Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP299

Section: Medical Benefit Policy

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

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

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

II. Purpose/Objective:
To provide a policy of coverage regarding Measurement of Serum Antibodies to Infliximab, Adalimumab, Ustekinumab 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
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- 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:
The measurement of serum concentrations and of antibodies has been proposed as a way to detect individuals with inadequate response to treatment with monoclonal antibodies and tumor necrosis factor drugs. Several commercial laboratory companies including, but not limited to Prometheus® Laboratories Inc. offers non-radiolabeled fluid-phase HMSA tests (e.g., Anser™IFX test for infliximab, Anser™ VDZ for vedolizumab, Anser UST for ustekinumab 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.

INDICATIONS:
1. Drug and/or antibody concentration testing for anti-tumor necrosis factor (anti-TNF) therapies in members with inflammatory bowel disease is considered medically necessary in the following situations:
    a. At the end of induction for all anti-TNFs
    b. At least once during maintenance therapy
    c. At the end of induction in primary non-responders
    d. In members with confirmed secondary loss of response

2. Drug and/or antibody concentration testing for vedolizumab or ustekinumab therapies in members with inflammatory bowel disease is considered medically necessary in the following situations:
    a. In non-responders at the end of induction
    b. In members with confirmed secondary loss of response

EXCLUSIONS:
Measurement of serum concentrations and/or antibodies to adalimumab (Humira), certolizumab (Cimzia); etanercept (Enbrel); golimumab (Simponi) either alone or as a combination test for any other reason not listed under Indications is considered experimental, investigational or unproven or is **NOT COVERED.**

Medicaid Business Segment:
Coverage may be considered on a per-case basis through a Program Exception

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

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.***

80145 Adalimumab
80230 Infliximab
80280 Vedolizumab
82397 chemoluminescent assay
80299 Quantitation of therapeutic drug, not elsewhere specified [when specified as measurement of serum concentrations of monoclonal antibody (MAB) drugs, with associated chemiluminescent assay (82397)]
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); 1/20 (clarify description and exclusion); 6/20 (add exclusion, revise title); 1/22 (add coverage indications)

Reviewed: 5/16, 10/17, 5/19. 6/21, 3/23, 3/24

CMS UM Oversight Committee Approval: 12/23, 5/24

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies