



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 line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	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.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

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

SEE ALSO: MPA G2105 Immunopharmacologic Monitoring of Therapeutic Serum Antibodies

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 **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
0514U Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing adalimumab therapy, results reported as a numerical value as micrograms per milliliter (mcg/mL)
0515U Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of infliximab (IFX) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (mcg/mL)

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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 supersede 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), 3/25 (add Avalon policy cross reference)

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

CMS UM Oversight Committee Approval: 12/23, 5/24, 4/25

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

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>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.