

 <b>Kansas City</b>	<i>Immunopharmacologic Monitoring of Therapeutic Serum Antibodies</i>	
	<b>Policy Number:</b> POL-PP-290 AHS – G2105	<b>Original Creation Date:</b> 7/1/2025
	<b>Version Number:</b> 002	<b>Version Effective Date:</b> 10/1/2025
	<b>Policy Status:</b> Active	<b>Next Review Date:</b> 10/1/2026

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Blue KC reserves the right to review and revise these policies when necessary. When there is an update, we will publish the most current policy to: <https://providers.bluekc.com/ContactUs/PaymentPolicies>.

PROVIDER/ENTITY IMPACTED					
<input checked="" type="checkbox"/> <b>PROFESSIONAL</b>	<input checked="" type="checkbox"/> <b>FACILITY</b>	<input type="checkbox"/> <b>DME</b>	<input type="checkbox"/> <b>AMBULATORY SURGERY</b>	<input checked="" type="checkbox"/> <b>LAB</b>	<input type="checkbox"/> <b>OTHER</b>

LINES OF BUSINESS IMPACTED						
<input checked="" type="checkbox"/> <b>COMMERCIAL</b>	<input checked="" type="checkbox"/> <b>BLUE MEDICARE ADVANTAGE</b>	<input checked="" type="checkbox"/> <b>ACA QHP<sup>1</sup></b>	<input checked="" type="checkbox"/> <b>SMALL GROUP ACA</b>	<input checked="" type="checkbox"/> <b>JAA<sup>2</sup></b>	<input checked="" type="checkbox"/> <b>FEP<sup>3</sup></b>	<input type="checkbox"/> <b>DENTAL</b>

<sup>1</sup> ACA QHP: Affordable Care Act Qualified Health Plan for Individual/Family    <sup>2</sup> JAA: Joint Administrative Account    <sup>3</sup> FEP: Federal Employee Program

Disclaimer
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Blue KC has developed Provider Payment Policies to provide guidance on payment methodologies as they pertain to submitted claims. These policies are written following industry standard recommendations from sources such as:

- Current Procedural Terminology
- Centers for Medicare and Medicaid
- American Medical Association
- National Correct Coding Initiative
- Other professional organizations and societies

Coverage of any service is determined by date of service, a member's eligibility and benefit limits for the service or services rendered, all terms of the Provider Service Agreement, and other standards of coding rules and guidelines.

Final payment is subject to the application of claims adjudication and edits common to the industry.

For confirmation of which services may be eligible for coverage and description of when medical services are considered medically necessary, not medically necessary, or investigational, please contact:

- Blue KC Provider Hotline for Commercial lines of Business 816-395-3929
- Affordable Care Act Provider Hotline 866-859-3822
- Blue Medicare Advantage Provider Hotline 866-508-7140

In the event of a conflict between any policies, the Member's coverage document will govern.

**Description/Application**

To manage loss of response due to the development of anti-drug antibodies, immunopharmacologic monitoring of circulating drug and anti-drug antibody levels has been proposed. The presence of anti-drug antibodies may promote adverse effects and diminish drug efficacy.

Targeted inhibitors of tumor necrosis factor-alpha (TNF) are widely used in the treatment of several inflammatory conditions, including rheumatoid arthritis (RA), spondyloarthritis, inflammatory bowel disease, and psoriasis. Some of these targeted inhibitors include, but are not limited to, infliximab, adalimumab, etanercept, and golimumab.

**Policy**

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

- 1) For individuals with inflammatory bowel disease (IBD), drug and/or antibody concentration testing once every two weeks for anti-tumor necrosis factor (anti-TNF) therapies, vedolizumab therapy, or ustekinumab therapy **may be reimbursed**

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

- 2) For individuals with conditions other than IBD (e.g., spondyloarthritis, rheumatoid arthritis, psoriatic arthritis, and psoriasis), drug and/or antibody concentration testing for anti-TNF therapies **may not be reimbursed**
- 3) For all other situations not addressed above, measurement of the serum drug levels **and/or** measurement of the antibodies to the drugs **may not be reimbursed** for any of the following drugs (alone or as a combination test):
  - a) *adalimumab*
  - b) *certolizumab*
  - c) *etanercept*
  - d) *golimumab*
  - e) *infliximab*
  - f) *infliximab-dyyb*
  - g) *infliximab-abda*
  - h) *rituximab*
  - i) *ustekinumab*
  - j) *vedolizumab*
  - k)

**Coding**

CPT	Code Description
80145	Adalimumab
80230	Infliximab
80280	Vedolizumab
80299	Quantitation of therapeutic drug, not elsewhere specified
82397	Chemiluminescent assay
84199	Unlisted Chemistry procedure

0514U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of adalimumab (ADL) levels in a venous serum in patients undergoing adalimumab therapy, results reported as numerical value as micrograms per milliliter Proprietary test: Procise ADL Lab/Manufacturer: ProciseDx Inc
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 Proprietary test: Procise IFXT Lab/.Manufacturer: ProciseDX Inc

**References and Resources**

Avalon Medical Policy AHS – G2105 Immunopharmacologic Monitoring of Therapeutic Serum Antibodies

**Related Documents**

Avalon Medical Policy AHS - G2098 Immune Cell Function Assay

Avalon Medical Policy AHS – G2155 General Inflammation Testing

**Revision History**

Version	Date	Summary of Revisions
001	07/01/2025	Initial version
002	10/01/2025	Avalon 4 <sup>th</sup> Quarter updates