of Tennessee

Policy

Reimbursement Policy

Immunopharmacologic Monitoring of Therapeutic Serum Antibodies

I. Policy Description

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 (Bendtzen, 2024; Tighe & McNamara, 2017).

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 (Bendtzen, 2024).

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in "Applicable State and Federal Regulations" section of this policy document.

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 **MEETS COVERAGE CRITERIA.**

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 **DOES NOT MEET COVERAGE CRITERIA**.
3) For all other situations not addressed above, measurement of the serum drug levels **and/or** measurement of the antibodies to the drugs **DOES NOT MEET COVERAGE CRITERIA** 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

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
80299	Quantitation of therapeutic drug, not elsewhere specified
82397	Chemiluminescent assay
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 (µg/mL) 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 (µg/mL)

	Proprietary test: Procise IFXT™ Lab/Manufacturer: ProciseDx Inc

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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