Medica Coverage Policy

**Policy Name:** Measurement of Serum Drug & Antibody Levels to Infliximab, Adalimumab, Ustekinumab & Vedolizumab  
**Effective Date:** 1/20/2020

**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

Serum drug and antibody levels to monitor biologics for inflammatory bowel disease (e.g., infliximab, adalimumab, ustekinumab, vedolizumab, and biosimilars) are investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Note:** See also related Medica Coverage Policy, *Serological Markers for Diagnosis and Management of Inflammatory Bowel Disease (IBD) or Irritable Bowel Syndrome (IBS).*

**Description**

Infliximab, adalimumab, ustekinumab, and vedolizumab are monoclonal antibody drugs used to treat inflammatory disease, such as inflammatory bowel disease (e.g., Crohn’s disease, ulcerative colitis). During use, some patients develop anti-drug antibodies that neutralize the anti-inflammatory action of these drugs. This response may diminish the potential long-term efficacy of these drugs. Blood tests to measure and monitor both the serum drug level and antibody level to these drugs have been proposed as a mechanism to determine a patient’s loss of response to the drug.

**FDA Approval**

Laboratory tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes the CLIA regulations and does not market the test for distribution.

The Anser IFX (infliximab), Anser ADA (adalimumab), Anser UST (ustekinumab), and Anser VDZ (vedolizumab) tests are developed by Prometheus Laboratories Inc., which is an accredited CLIA laboratory.
Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
- 80145 – Adalimumab
- 80230 – Infliximab
- 80280 – Vedolizumab
- 84999 – Unlisted chemistry procedure

Original Effective Date: 4/1/2011

Re-Review Date(s):
- 10/22/2013
- 3/18/2015
- 12/21/2016
- 12/18/2019
- 2/19/2020 – administrative update; format