


MEDICAL POLICY	Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies (Medicare Only)
Effective Date: 11/1/2022	Medical Policy Number: 345
 11/1/2022	Medical Policy Committee Approved Date: 8/1/2022
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA	
<p>The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.</p>	
Service	Medicare Guidelines
<i>Measurement of Serum Levels and Antibodies to Infliximab, Adalimumab, Ustekinumab or Vedolizumab</i>	<p>Company medical policy for Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies (All Lines of Business Except Medicare)</p> <p>I. These services are considered not medically necessary for Medicare based on the Company medical policy. <u>Services deemed “investigational” are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.</u></p>

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POLICY GUIDELINES

Medicare and Medical Necessity

Medicare requires diagnostic laboratory tests be ordered by a provider who is treating the member for a specific medical problem **and** who will use the test results in the direct management of that specific medical problem.^{1,2} Thus, diagnostic testing must have established clinical utility and analytic validity.

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare’s definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan’s use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be “investigational.” The term “investigational” is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company’s technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are “not medically reasonable or necessary” for Medicare Plan members. (*Medicare Claims Processing Manual, Ch. 23, §30 A*)

Table 1. Available Tests

TEST NAME	ASSOCIATED DRUG
Prometheus® Laboratories Inc.	
Anser™IFX test	Infliximab
Anser™ADA	Adalimumab
Anser® UST	Ustekinumab
Anser® VDZ	Vedolizumab
LabCorp	
DoseASSURE™ ADL	Adalimumab
DoseASSURE™ UST	Ustekinumab
DoseASSURE™ IFX	Infliximab
DoseASSURE™ CTZ	Certolizumab

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DoseASSURE™ ETN	Etanercept
DoseASSURE™ GOL	Golimumab

CPT/HCPCS CODES

Medicare Only	
Not Covered	
80145	Adalimumab
80230	Infliximab
80280	Vedolizumab
<p style="text-align: center;">Unlisted Codes</p> <p style="text-align: center;">All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered.</p>	
80299	Quantitation of therapeutic drug, not elsewhere specified
84999	Unlisted chemistry procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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MEDICAL POLICY CROSS REFERENCES

- Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring (Medicare Only), MP344
- Celiac Disease: Serologic Testing

REFERENCES

1. 42 CFR §410.32(a); Available at: <https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec410-32.pdf>
2. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>