



Geisinger Health Plan Policies and Procedure Manual

Policy: MP326

Section: Medical Benefit Policy

Subject: Biomarker Testing for Rheumatoid Arthritis

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Biomarker Testing for Rheumatoid Arthritis

II. Purpose/Objective:

To provide a policy of coverage regarding Biomarker Testing for Rheumatoid Arthritis

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.

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:

Assessment of disease activity is an important component of management of rheumatoid arthritis. Disease activity is determined using a combination of physical exam, radiologic findings, and serum biomarkers that result in a disease activity score. The current standards include Disease Activity Score with 28 joints (DAS28), Clinical Disease Activity Index, Patient Activity Scale, Patient Activity Scale II, Simplified Disease Activity Index, and the Routine Assessment of Patient Index Data 3.

The Vectra DA test is a commercially available test using 12 serum biomarkers to report a disease activity score that ranges from 1 (low disease activity) to 100 (high disease activity). Proponents describe it as an adjunct to other disease activity measures, to identify patients at high risk of progression. This testing would then guide a more aggressive treatment strategy.

INDICATIONS:**FOR MEDICARE BUSINESS SEGMENT:**

Palmetto GBA, the Medicare contractor in California, has issued a coverage decision for the Vectra DA test. Per CMS rules, since all Vectra DA tests are processed out of the Crescendo Bioscience Laboratory in California, the test will be covered for Medicare patients in the United States.

EXCLUSIONS:

Unless otherwise noted, the Plan does **NOT** provide coverage for Vectra DA because it is considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established measures of disease activity.

Medicaid Business Segment:

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: Biomarker Testing for Rheumatoid Arthritis

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

81490 Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score.

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 supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Singh, JA, Saag, KG, Bridges, SL, Jr., et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis care & research. 2016 Jan;68(1):1-25.

Hirata, S, Li, W, Kubo, S, et al. Association of the multi-biomarker disease activity score with joint destruction in patients with rheumatoid arthritis receiving tumor necrosis factor-alpha inhibitor treatment in clinical practice. Modern rheumatology / the Japan Rheumatism Association. 2016 Nov;26(6):850-6.

Hirata, S, Li, W, Defranoux, N, et al. A multi-biomarker disease activity score tracks clinical response consistently in patients with rheumatoid arthritis treated with different anti-tumor necrosis factor therapies: A retrospective observational study. *Modern rheumatology / the Japan Rheumatism Association*. 2015 May;25(3):344-9.

Li, W, Sasso, EH, van der Helm-van Mil, AH, Huizinga, TW. Relationship of multi-biomarker disease activity score and other risk factors with radiographic progression in an observational study of patients with rheumatoid arthritis. *Rheumatology* 2016 Feb;55(2):357-66.

Markusse, IM, Dirven, L, van den Broek, M, et al. A multibiomarker disease activity score for rheumatoid arthritis predicts radiographic joint damage in the BeSt study. *J Rheumatol*. 2014;41:2114-9.

Hambardzumyan, K, Bolce, RJ, Saevarsdottir, S, et al. Association of a multibiomarker disease activity score at multiple time-points with radiographic progression in rheumatoid arthritis: results from the SWEFOT trial. *RMD open*. 2016;2(1):e000197.

Eastman, PS, Manning, WC, Qureshi, F, et al. Characterization of a multiplex, 12-biomarker test for rheumatoid arthritis. *Journal of pharmaceutical and biomedical analysis*. 2012 Nov;70:415-24.

Fleischmann, R, Connolly, SE, Maldonado, MA, Schiff, M. Estimating disease activity using multi-biomarker disease activity scores in patients with rheumatoid arthritis treated with abatacept or adalimumab. *Arthritis Rheumatol*. 2016 Apr 25.

Centola, M, Cavet, G, Shen, Y, et al. Development of a multi-biomarker disease activity test for rheumatoid arthritis. *PLoS One*. 2013;8:e60635.

Curtis, JR, Wright, GC, Strand, V, Davis, CS, Hitraya, E, Sasso, EH. Reanalysis of the Multi-Biomarker Disease Activity Score for Assessing Disease Activity in the Abatacept Versus Adalimumab Comparison in Biologic-Naive Rheumatoid Arthritis Subjects with Background Methotrexate Study: Comment on the Article by Fleischmann et al. *Arthritis Rheumatol*. 2017 Apr;69(4):863-5.

Hayes Inc. Medical Technology Directory. Vectra DA Test (Crescendo Bioscience Inc.) for Management of Patients with Rheumatoid Arthritis. March 2020

Brahe, CC, Johansen, JJ, et al.. Predictive value of a multi-biomarker disease activity score for clinical remission and radiographic progression in patients with early rheumatoid arthritis: a post hoc study of the OPERA trial. *Scand. J. Rheumatol.*, 2018 Jul 10;48(1).

Curtis, JJ, Brahe, CC, et al. Predicting risk for radiographic damage in rheumatoid arthritis: comparative analysis of the multi-biomarker disease activity score and conventional measures of disease activity in multiple studies. *Curr Med Res Opin*, 2019 Feb 20;1-11:1-11.

Johnson TM, Register KA, Schmidt CM, et al. Correlation of the Multi-Biomarker Disease Activity Score With Rheumatoid Arthritis Disease Activity Measures: A Systematic Review and Meta-Analysis. *Arthritis Care Res* 2019; 71(11): 1459-1472

Ma MHY, Defranoux N, Li W, et al. A multi-biomarker disease activity score can predict sustained remission in rheumatoid arthritis. *Arthritis Res Ther*. 2020.

Abdelhafiz D, Baker T, Glasgow DA, Abdelhafiz A. Biomarkers for the diagnosis and treatment of rheumatoid arthritis - a systematic review. *Postgrad Med*. 2023; 135(3):214-223.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 2/19

Revised:

Reviewed: 2/20, 2/21, 2/22, 2/23, 2/24

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

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.

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.