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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Vectra DA (Multiple Biomarker Disease Activity [MBDA])

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	9/17/2021 Noridian retired: *Billing and Coding: MolDX: Vectra™ DA (A54505)*. These services still need to meet medical necessity as outlined in the coverage article and will require review. Coverage articles are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD A54505 for determining medical necessity.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disorder that primarily involves synovial joints. It is debilitating disease that if uncontrolled, may lead to joint destruction, functional disability, and premature death. It is thus important to detect RA early, and to control the disease as soon as possible after diagnosis to delay its progression and preserve physical function.

Treatment of RA has shifted from symptom management, to reducing the disease activity and delaying its progression. Recent guidelines recommend treating RA promptly and aggressively aiming for remission as a therapeutic target (tight control or treatment-to-target strategy). Tight control may be defined as a treatment strategy tailored to the disease activity in individual patients with RA with the aim of achieving a predefined level of

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low disease activity, or preferably remission within a reasonable period of time. The availability of an increasing number of biologic and non-biologic effective disease-modifying anti-rheumatic drugs (DMARDs) has allowed the achievement of this treatment goal, but requires close monitoring of the disease activity, which is the cornerstone of tight control (Bakker 2007, Anderson 2012, Curtis 2012, Peabody 2013, Segurado 2014, Michaud 2015).

There are a number of composite tools available for assessing RA disease activity, six of which have been recommended by the American College of Rheumatology (ACR): Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (DAS28), Patient Activity Scale (PAS), PAS-II, Routine Assessment of Patient Index Data with 3 measures (RAPID-3), and Simplified Disease Activity Index (SDAI). These indices are based on information obtained from clinical, laboratory, and physical measures that include quantitative joint counts, patient reported outcomes, physician examination, and laboratory test including erythrocyte sedimentation rate (ESR) and C- reactive protein (CRP). These composite measurements are of great importance, but are complicated, may have intra- and inter-observer variability, are unable detect subclinical synovial damage, and may be influenced by cumulative damage and other conditions unrelated to RA (Anderson 2012, Curtis 2012, Owens 2015).

More recently, researchers have been investigating biomarkers to complement the clinical assessment of RA and improve the evaluation of disease activity. No single biomarker has been found to accurately assess RA activity, and it is hypothesized that a combination of biomarkers that measure diverse pathways to RA may have the potential of providing objective information on disease activity (Curtis 2012, Hirata 2013).

Vectra DA (Crescendo Bioscience, South San Francisco, CA), is a commercially available blood test that measures the serum concentration of 12 biomarkers and combines them into an algorithm to generate a multibiomarker disease activity (MBDA) score. The biomarkers included in Vectra DA test are: VCAM-1 (vascular cell adhesion molecule-1), EGF (epidermal growth factor), VEGF-A (vascular endothelial growth factor A), IL-6 (interleukin-6), TNF-RI (tumor necrosis factor receptor, type 1), MMP-1 (matrix metalloproteinase-1 or collagenase-1), MMP-3 (matrix metalloproteinase-3 or stromelysin-1), YKL-40, SAA (serum amyloid), CRP (C-reactive protein), leptin, and resistin. The score generated by the test is believed to represent the level of RA disease activity on a scale of 1 (lowest activity) to 100 (greatest activity). According to the manufacturer a score between 45 and 100 indicates high level of disease activity; 30 to 44 indicates moderate disease activity; and 1 to 29 indicates a low level of disease activity. Vectra DA test is not intended or validated to diagnose RA, but as an aid in the assessment of disease activity in adults RA patients when used in conjunction with standard clinical assessment (Curtis, 2012, Peabody 2013, Michaud 2015, Vectra.com).

Medical Technology Assessment Committee (MTAC)

12/21/2015: MTAC REVIEW

Vectra DA Test for Rheumatoid Arthritis

Evidence Conclusion: There is insufficient evidence to determine whether MBDA is as good as or better than other established indices used to measure RA disease activity. The published studies show a moderate correlation between Vectra DA and DAS28-CRP in classifying patients into low vs. moderate to high disease. There is insufficient evidence to determine the clinical validity of Vectra DA test and its ability to predict outcomes. There is insufficient evidence to determine that Vectra DA test results have an impact on the management of patients with rheumatoid arthritis and/or improve their health outcomes.

Articles: The literature search revealed a study on the analytic validity of MBDA test score, four studies on the clinical validity of the MBDA Vectra Da test, and few small simulating studies or surveys on the clinical utility of the test. The following two studies on the clinical validity of MBDA test studies were selected for critical appraisal: Bakker MF, Cavet G, Jacobs JW, et al. Performance of a multi-biomarker score measuring rheumatoid arthritis disease activity in the CAMERA tight control study. *Ann Rheum Dis.* 2012 Oct; 71(10):1692-1697. See Evidence Table 1. Curtis JR, van der Helm-van Mil AH, Knevel R, et al. Validation of a novel multibiomarker test to assess rheumatoid arthritis disease activity. *Arthritis Care Res (Hoboken).* 2012 Dec; 64(12):1794-1803. See Evidence Table 2.

> The use of Vectra DA (Multiple Biomarker Disease Activity [MBDA]) test for monitoring disease activity in patients with rheumatoid arthritis does not meet the *Kaiser Permanente Technology Assessment Criteria.*

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare - Considered Not Medically Necessary

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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
01/06/2016	01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC], 07/11/2023[MPC], 10/01/2024[MPC]	01/06/2016

[MPC] Medical Policy Committee

Revision History	Description

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