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**POLICY LAST UPDATED:** 10|20|2015

## OVERVIEW

Assessment of disease activity in rheumatoid arthritis (RA) is an important component of treatment management, as one of the main goals of treatment is to maintain low disease activity or remission. There are a variety of available instruments for measuring RA disease activity. One potential approach is the use of a multibiomarker disease activity (MBDA) score. The Vectra DA test is a commercially available MBDA blood test that uses 12 biomarkers to construct a disease activity score ranging from 0 to 100. It is one of numerous disease activity measures that are available for RA.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Prior authorization review is not required.

## POLICY STATEMENT

### BlueCHiP for Medicare

The use of a multi-biomarker disease activity score for rheumatoid arthritis (e.g., Vectra DA score) is covered.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

### Commercial Products

The use of a multi-biomarker disease activity score for rheumatoid arthritis (e.g., Vectra DA score) is considered not medically necessary due to a lack of peer-reviewed scientific literature validating the efficacy of the service.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for laboratory tests or when services are not medically necessary.

## BACKGROUND

RA is a disorder characterized by chronic joint inflammation leading to painful symptoms, progressive joint destruction, and loss of function. The disorder is relatively common and is associated with a high burden of morbidity for affected patients.

Treatment of RA has undergone a shift from symptom management to a more proactive strategy of minimizing disease activity and delaying disease progression. The goal of treatment is to reduce irreversible joint damage that occurs from ongoing joint inflammation and synovitis by keeping disease activity as low as

possible. The availability of an increasing number of effective disease-modifying antirheumatic drugs has made achievement of remission, or sustained low disease activity, a feasible goal in a large proportion of patients with RA. This treatment strategy has been called a “tight control” approach.

The concept of tight control in the management of RA has gained wide acceptance as evidence from clinical trials have demonstrated that outcomes are improved with a tight control strategy. In a tight control strategy, treatment targets are used that are mainly based on measures of disease activity.

For a strategy of tight control to be successful, a reliable and valid measurement of disease activity is necessary. There are numerous disease activity measurements that can be used in clinical care. Composite measures include information from multiple sources, including patient self-report, physician examination and/or biomarker measurement. Composite measures are the most comprehensive but have the disadvantage of being more cumbersome and difficult to complete. Patient-reported measures are intended to be simpler, and rely only on information that patients can provide expeditiously, but have the disadvantage of being more subjective. Measurements that rely only on biomarkers are objective and do not require patient input but do involve the cost and inconvenience of laboratory tests.

The most widely used and validated in clinical research is the DAS28 score. This is a composite measure that includes examination of 28 joints for swelling and tenderness, combined with a patient report of disease activity and measurement of C-reactive protein (CRP) (or erythrocyte sedimentation rate). This score has been widely validated and used for both research and clinical care and is often considered the criterion standard for measuring disease activity. However, it requires a thorough joint examination, patient-reported symptoms, and laboratory testing. Therefore, there have been many attempts to create a valid disease activity measure that is simpler. Some measures include only patient self-report and thus can be completed quickly in the setting of an office visit. An example of this type of measure is the Simplified Disease Activity Index (SDAI). Another approach is to use only serum biomarkers, which only requires a blood draw. The Vectra DA is this type of biomarker-based measure. Proponents of a biomarker approach have argued that this is simpler and avoids the subjectivity of physical examination and patient report. Based on the developer's recommendation, the Vectra DA test should be limited to 2 services per patient per year.

The Vectra DA test (Crescendo Bioscience, South San Francisco, CA) consists of 12 individual biomarkers. These are:

- Interleukin-6 (IL-6)
- Tumor necrosis factor receptor type I (TNFR1)
- Vascular cell adhesion molecule 1 (VCAM-1)
- Epidermal growth factor (EGF)
- Vascular endothelial growth factor A (VEGF-A)
- YKL-40
- Matrix metalloproteinase 1 (MMP-1)
- Matrix metalloproteinase 3 (MMP-3)
- CRP
- Serum amyloid A (SAA)
- Leptin
- Resistin

There are no U.S. Food and Drug Administration (FDA)-approved MBDA tests for measuring disease activity in RA. Commercially available tests are laboratory-developed tests that are not subject to FDA approval. Clinical laboratories may develop and validate tests in-house (“home-brew”) and market them as a laboratory service; such tests must meet the general regulatory standards of the Clinical Laboratory Improvement Act.

## **BlueCHiP for Medicare**

An assessment of Vectra DA was completed and Medicare has determined that the test meets criteria for analytical and clinical validity, as well as the clinical utility requirement as a reasonable and necessary Medicare benefit.

## **Commercial Products**

The limited body of evidence on the Vectra DA test is not sufficient to determine whether it is as good as or better than other disease activity measures, and it is possible that it is not as accurate as the DAS28. As a result, the Vectra DA test is considered not medically necessary for use as a measure of disease activity in patients with RA.

## **CODING**

The following CPT code is covered for BlueCHiP for Medicare and not medically necessary for Commercial products:  
81490

## **RELATED POLICIES**

Not applicable

## **PUBLISHED**

Provider Update, January 2016

## **REFERENCES**

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