Multibiomarker Disease Activity Blood Test for Rheumatoid Arthritis

Description

Assessment of disease activity in rheumatoid arthritis is an important component of management with a goal of treatment to maintain low disease activity or achieve remission. There are a variety of instruments for measuring rheumatoid arthritis disease activity. The instruments use combinations of physical exam findings, radiologic results, and serum biomarkers to construct a disease activity score. A multibiomarker disease activity instrument is a disease activity measure that is comprised entirely of serum biomarkers. The Vectra DA test is a commercially available multibiomarker disease activity blood test that uses 12 biomarkers to construct a disease activity score ranging from 1 (low disease activity) to 100 (high disease activity).

OBJECTIVE

The objective of this evidence review is to determine whether the use of a multibiomarker disease activity (eg, Vectra DA) blood test as an adjunct or as a replacement of other disease activity measures improves the net health outcome in individuals with rheumatoid arthritis.
POLICY STATEMENT

The use of a multibiomarker disease activity score for rheumatoid arthritis (e.g., Vectra DA score) is considered investigational in all situations.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Screening (other than the preventive services listed in the brochure) is not covered. Please see Section 6 General exclusions.

Benefits are available for specialized diagnostic genetic testing when it is medically necessary to diagnose and/or manage a patient's existing medical condition. Benefits are not provided for genetic panels when some or all of the tests included in the panel are not covered, are experimental or investigational, or are not medically necessary.

FDA REGULATORY STATUS

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. The Vectra DA test (Crescendo Bioscience) is available under the auspices of Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

RATIONALE

Summary of Evidence

For individuals who have RA who receive an MBDA (e.g., Vectra DA) test as an adjunct or as a replacement of other disease activity measures, the evidence includes analyses of archived serum samples from RCTs and prospective cohort studies. The relevant outcomes are test validity, other test performance measures, symptoms, change in disease status, functional outcomes, and quality of life. Analyses comparing Vectra DA with other previously validated disease activity measures such as the DAS28 or to radiographic progression, consisted mostly of correlations, with only 1 study providing sensitivity, specificity, and PPV and NPV. The PPV from this study was 21%. Other analyses of archived serum samples evaluated the use of Vectra DA to predict treatment response. Results from those analyses were inconsistent. The body of evidence on the Vectra DA test is insufficient to determine whether it is as good as or better than other disease activity measures. Additionally, there is no evidence evaluating Vectra DA as an adjunct to other disease activity measures. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Rheumatology

In its guidelines on the treatment of rheumatoid arthritis, the American College of Rheumatology (2015) endorsed the following measures of disease activity: Patient Activity Scale, Routine Assessment of Patient Index Data 3, Clinical Disease Activity Index, Disease Activity Score with 28 joints, and Simplified Disease Activity Index. The guidelines indicated that other measures are...
available to clinicians but that including the new measures was out of scope. The American College of Rheumatology is currently updating the guidelines for rheumatoid arthritis, with an estimated publication date of late 2019 or early 2020.

**European League Against Rheumatism**

The European League Against Rheumatism (2017) updated its guidelines on the management of early arthritis. The League recommended that arthritis activity be assessed at 1- to 3-month intervals to determine target treatment. "Monitoring of disease activity should include tender and swollen joint counts, patient, and physician global assessments, erythrocyte sedimentation rate, and C reactive protein, usually by applying a composite measure." Composite measures recommended include the Disease Activity Score with 28 joints, Clinical Disease Activity Index, and Simplified Disease Activity Index. One item on the research agenda recommended by the League was to evaluate new biomarkers and multibiomarkers for the prognosis and treatment in early arthritis.

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2018) published guidance on the management of adult patients with rheumatoid arthritis. There is no discussion on the use of a multibiomarker disease activity blood test to monitor patients with rheumatoid arthritis.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There are no Medicare national coverage determinations for the Vectra DA test. In July 2013, Palmetto GBA, the Medicare contractor in California, issued a coverage decision for the Vectra DA test. Because all Vectra DA tests are processed out of the Crescendo Bioscience Laboratory in California, the test will be covered for Medicare patients in the U.S.

**REFERENCES**


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.


POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>September 2014</td>
<td>New policy</td>
<td>The use of a multibiomarker disease activity score for rheumatoid arthritis (eg, Vectra DA score) is considered investigational in all situations.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 22, 2015. References 9 and 11-12 added. No change to policy statement</td>
</tr>
<tr>
<td>September 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 26, 2016; references 12-15 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 9, 2018; references 15-16, 18-19, 20 and 23-24 added. Policy statement unchanged. Title changed to &quot;Multibiomarker Disease Activity Blood Test for Rheumatoid Arthritis.&quot;</td>
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<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 23, 2019; references added. Policy statement unchanged.</td>
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