Policy: MP326
Section: Medical Benefit Policy
Subject: Biomarker Testing for Rheumatoid Arthritis

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit 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.

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.


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:


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

**Devised:** 2/19

**Revised:**

**Reviewed:** 2/20