Policy: 279
Section: Medical Benefit Policy
Subject: Gene Expression Testing to Predict Coronary Artery Disease

I. Policy: Gene Expression Testing to Predict Coronary Artery Disease

II. Purpose/Objective:
To provide a policy of coverage regarding Gene Expression Testing to Predict Coronary Artery Disease

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: The Corus® CAD (coronary artery disease) test (CardioDx, Inc., Palo Alto, CA) is a genetic test which analyzes 23 genes that are involved in the development or response to atherosclerosis. Using an algorithm, a quantitative score is then generated which predicts the likelihood of developing obstructive coronary artery disease.

FOR MEDICARE and MEDICAID BUSINESS SEGMENT:
Palmetto GBA, a national contractor that administers Medicare benefits has determined that the Corus® CAD (coronary artery disease) test (CardioDx, Inc., Palo Alto, CA) is considered reasonable and necessary for the evaluation of members with stable symptoms that have a history of chest pain, suspected anginal equivalent to chest pain, or a high risk of CAD, but no known prior myocardial infarction or revascularization procedures.

LIMITATIONS:
Per the Novitas Solutions LCD Corus® CAD Test (L36713), the following limitations apply:

1. The Corus® CAD test is considered not reasonable and necessary for members who are currently taking steroids, immunosuppressive agents, or chemotherapeutic agents or for members with:
   - acute or previous myocardial infarction;
   - high-risk unstable angina;
   - a history of obstructive CAD;
   - a previous revascularization procedure;
   - a history of a previous invasive procedure to open a blocked or narrow artery;
   - systemic infectious or systemic inflammatory conditions; or
   - diabetes.

2. The Corus® CAD test is considered not reasonable and necessary when used for any of the following:
   - to be used to screen for stenosis among members who are asymptomatic and not considered at high-risk for CAD;
   - to predict or detect response to therapy, or
   - to help select the optimal therapy for members.

EXCLUSIONS:
Unless mandated by state or federal regulation, the Plan does NOT provide coverage for Gene Expression Testing to Predict Coronary Artery Disease because it is considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that 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 tests or technologies.

Unless mandated by state or federal regulation, the Plan does NOT provide coverage for multi-gene next generation panels, (i.e. CardioNext, Familion, RhythmFirst) because they are considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these tests on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven services is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Gene Expression Testing to Predict Coronary Artery Disease

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>84999</td>
<td>Unlisted chemistry procedure</td>
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<tr>
<td>81493</td>
<td>Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score</td>
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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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Winifred S. Hayes- GTE Report- Corus® CAD (CardioDx Inc.). October 3, 2012


Geisinger Technology Assessment Committee. Corus CAD (CardioDx, Inc.). October 2015


Novitas Solutions. Local Coverage Determination (LCD): Corus® CAD Test (L36713)

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

Devised: 8/13

Revised: 8/14 (added Medicare coverage), 7/15 (added Limitation), 7/16 (added exclusion) 7/19 (revise criteria per LCD L36713)

Reviewed: 6/17, 6/18, 6/19, 7/20

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.