Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP355

Section: Medical Policy

Subject: Plasma-based Proteomic Testing in the Management of Pulmonary Nodules

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I. Policy: Plasma-based Proteomic Testing in the Management of Pulmonary Nodules

II. Purpose/Objective:

To provide a policy of coverage regarding Plasma-based Proteomic Testing in the Management of Pulmonary Nodules

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:
Plasma-based proteomic screening has been investigated as a tool to risk-stratify pulmonary nodules. Nodules identified as likely benign would allow members to undergo serial CT scans of their nodules (active surveillance), instead of undergoing invasive procedures such as CT-guided biopsy or surgery. Additionally, proteomic testing may also determine a likely malignancy in clinically low-risk or intermediate-risk pulmonary nodules, thereby permitting earlier detection.

COMMERCIAL and MEDICARE BUSINESS SEGMENT

CRITERIA FOR COVERAGE:

Xpresys Lung 2 (BDX-XL2) (Nodify XL2) (Nodify CDT)

The BDX – XL2 test will be considered medically necessary when **all of the** following criteria are met:

- Member is at least 40 years of age; **and**
- Lung nodule is between 8mm and 30mm in diameter; **and**
- Member has a pre-test cancer risk of 50% or less, as assessed by the Mayo Clinic Model for Solitary Pulmonary Nodules. https://www.mdcalc.com/solitary-pulmonary-nodule-spn-malignancy-risk-score-mayo-clinic-model

Percepta Bronchial Genomic Classifier

The Percepta Bronchial Genomic Classifier will be considered medically necessary when **all of the** following criteria are met:

- Current or former smokers age 21 and greater; **and**
- Physician-assessed low or intermediate pretest risk of malignancy based upon the following clinical characteristic stratification; and:

Low Risk (<10%)	Intermediate Risk (10-60%)	High Risk (>60%)
Nodules < 10 mm <10 pk/yr smoking history	Nodules 10 - 30 mm 10 to 60 pk/yr smoking history	Nodules >30 mm >60 pk/yr smoking history

and:

- Bronchoscopy is non-diagnostic (actionable benign or malignant diagnosis cannot be reached); **and**
- PERCEPTA® BGC results will be utilized to determine whether CT surveillance is appropriate in lieu of further invasive biopsies or surgical procedures as outlined below,

Pre-Test Risk:	Post-Test Risk:	Post-Test Diagnostic Strategy:
Intermediate	Intermediate	Proceed to further work up
Intermediate	Low Risk	CT surveillance
Low Risk	Low Risk	CT surveillance
Low Risk	Very Low Risk	CT surveillance

and:

- Test is ordered by physician certified in PERCEPTA® Certification and Training Registry (CTR)

Per Medicare Coverage:

Patient is monitored for malignancy (suggested monitoring includes serial CT scans at 3 to 6, 9 to 12, and 18 to 24 months, using thin sections and non-contrast, low-dose techniques), **and**

Physician will report outcomes in all risk groups including those monitored initially and those who undergo immediate intervention, **and**

Clinical management is consistent with the post-test diagnostic strategy described above in ≥80% of tested patients.

EXCLUSIONS:
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.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, will be evaluated on a case by case basis.

CODING ASSOCIATED WITH:
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.***

0080U Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy *{BDX-XL2 (Nodify XL2)}*
0092U Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy *{Reveal Lung Nodule Characterization}*
0360U Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy {*Nodify CDT}*
84999 Unlisted chemistry procedure *(Percepta® Bronchial Genomic Classifier or EarlyCDT Lung)*

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.

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Centers for Medicare 7 Medicaid Services MolDX: Percepta© Bronchial Genomic Classifier L36886

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

Devised: 3/22

Revised: 3/23 (Add Exclusion for Nodify CDT, Early CDT); 9/23 (expand coverage to commercial)

Reviewed: