Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP357

Section: Medical Policy

Subject: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer

II. Purpose/Objective:

To provide a policy of coverage regarding Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer

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

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- 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:
DetermaRX is a molecular stratification test to identify patients with IA-IIA non-squamous non-small cell lung cancer (NSCLC) who may be at low- or high-risk of having a recurrence or metastatic disease. The DetermaRx 14-Gene Lung Cancer Assay is quantitative PCR analysis designed to be used on formalin-fixed, paraffin embedded lung cancer tissue. The test relies on an algorithmic interpretation of the quantitative PCR data on RNA from 11 cancer-related target genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1)

INDICATIONS:

Medicare Business Segment:

CMS considers the use of molecular diagnostic laboratory tests (tests of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), and / or proteins) as a predictive classifier for non-small cell lung cancer (NSCLC). (e.g., DetermaRx Molecular Classifier) to be medically necessary when all of the following criteria are met:

- The member has a non-squamous NSCLC with a tumor size < 5cm, and there are no positive lymph nodes (i.e. Stages I and IIa); and
- The member is sufficiently healthy to tolerate chemotherapy; and
- Adjuvant platinum-containing chemotherapy is being considered for the member; and
- The test is ordered by a physician who is treating the patient for NSCLC (generally a medical oncologist, surgeon, or radiation oncologist) to help in the decision of whether or not to recommend adjuvant chemotherapy

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 may 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.***

0288U Oncology (lung) MRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score.
0388U Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection
0397U Oncology (non-small cell lung cancer), cell-free DNA from plasma, targeted sequence analysis of at least 109 genes, including sequence variants, substitutions, insertions, deletions, select rearrangements, and copy number variations
0436U Oncology (lung), plasma analysis of 388 proteins, using aptamer-based proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy

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:

LCD - MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer (L38443)

Kratz JR, He J, Van Den Eeden SK, et al. A practical molecular assay to predict survival in resected non-squamous, non-small-cell lung cancer: development and international validation studies. Lancet. 2012;379(9818):823-832.

Woodard GA, Wang SX, Kratz JR, et al. Adjuvant chemotherapy guided by molecular profiling and improved outcomes in early stage, non-small-cell lung cancer. Clin Lung Cancer. 2018;19(1):58-64.

Kratz JR, Eeden SKVD, He J, Jablons DM, Mann MJ. A prognostic assay to identify patients at high risk of mortality despite small, node-negative lung tumors. Journal of the American Medical Association. 2012;308(16):1629-1631.

Woodard GA, Gubens MA, Jahan TM, et al. Prognostic molecular assay might improve identification of patients at risk for recurrence in early-stage non-small-cell lung cancer. Clin Lung Cancer. 2014;15(6):426-432.

Dormady S, Broder MS, Putcha GV, et al. The impact of a fourteen-gene molecular assay on physician treatment decisions in non-small-cell lung cancer. Int J Clin Oncol. 2015;20(1):59-69.

Sutic M, Vukic A, et al. Diagnostic, Predictive, and Prognostic Biomarkers in Non-Small Cell Lung Cancer (NSCLC) Management. J. Pers. Med. 2021, 11(11), 1102.

Gupta A Woodard GA, et al. Improved outcomes and staging in non-small-cell lung cancer guided by a molecular assay. Future Oncology 2021; 17(34)34

Mino-Kenudson M, Schalper K, et al. Predictive Biomarkers for Immunotherapy in Lung Cancer: Perspective From the International Association for the Study of Lung Cancer Pathology Committee. J Thoracic Oncology 2022;17(12):1335-1354

Fick CN, Dunne EG, et al. Genomic profiling and metastatic risk in early-stage non–small cell lung cancer. JTCVS Open Special Issue: Precision Therapy in Lung Cancer: Invited Expert Opinions 2023;16(C):9-16

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

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Revised: 7/24

Reviewed: 7/23

CMS UM Oversight Committee Approval: 12/23, 7/24