Molecular Diagnostic Testing of Solid Tumors

Policy Number: **M20171213078**

Effective Date: **2/1/2018**

Sponsoring Department: **Health Care Services**

Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's policy for the molecular diagnostic testing of solid tumors for targeted treatment.

Policy:

Background:

The diagnosis and clinical management of patients with cancer is evolving and improving. Molecular testing, such as next generation sequencing (NGS), is a tool to determine targeted therapy for specific diagnoses such as solid tumors. Next generation sequencing uses sequencing of multiple DNA fragments, leading to genetic testing that incorporates large panels. NGS analyzes multiple genes for multiple mutations at the same time. NGS is intended to guide cancer treatment, thereby increasing the

likelihood that patients may benefit from selected treatment. Ongoing studies are examining the clinical utility of NGS and how the test results are utilized by treating physicians.

The National Comprehensive Care Network (NCCN) provide evidence-based, consensus-driven guidance for cancer management and are the most detailed and frequently updated clinical practice guidelines available in any area of medicine. Thus, they may be consulted to guide decision making in the management of cancer.

The NCCN Non-Small Cell Lung Cancer guidelines support broader molecular profiling with the goal of identifying rare mutations for which effective drugs may already be available, or to appropriately counsel patients regarding the availability of clinical trials.
While clinical trials are continuing, the clinical utility of NGS has not been established for all solid tumors at this time.

Commercial and Self-funded: Independent Health covers molecular diagnostic testing of solid tumors utilizing the commercial criteria below.

Note: Many laboratories are developing liquid biopsy assays. For many of these assays, data regarding the clinical validity and clinical utility of these tests is still emerging.
The clinical utility of panels containing over 50 genes has not been established and therefore is not covered.

MediSource, MediSource Connect, Child Health Plus and Essential Plan
MediSource, MediSource Connect Child Health Plus and Essential Plan do not cover molecular diagnostic testing of solid tumors represented by CPT codes, 0022U, 0037U, 0048U, 0239U, 0242U, and 0326U.

MediSource, MediSource Connect Child Health Plus and Essential Plan covers services represented by code 81445 utilizing the commercial criteria below.

Medicare Advantage:
There is currently a Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) for Next Generation Sequencing (CPT codes 0037U, 0239U and 0022U), a Local Coverage Determination LCD for Genomic Sequencing Panels (CPT codes 81445 and 0048U) and a Local Coverage Article. In addition, there is an LCD for Guardant360.

Please refer to the links listed in the Reference section for Medicare Advantage members.

Clinical Indications

Requests for molecular diagnostic testing of solid tumors will be considered by an Independent Health Medical Director for **ALL** of the following:

- **ALL** of the following general requirements:
    - Requests must identify specific genes or immune marker to be tested
    - Member must have an advanced, non-resectable tumor
    - The clinical utility of the requested test for the specific clinical indication must be established
    - The laboratory performing the test must provide evidence of analytical validity and clinical validity through accreditation with the College of American Pathologists (CAP)

- Clinical documentation must accompany the request which identifies the tumor type and clinical stage of the patient
- Requests must clearly state how the results will impact the clinical treatment plan
- Advanced care planning must have been completed with a trained facilitator or a palliative care physician prior to the test
- Documentation that molecular diagnostic testing of solid tumors has not been done previously OR member meets the exception criteria (If authorized, molecular diagnostic testing of solid tumors will be allowed once per member's lifetime. Exception to this requirement will be reviewed by an Independent Health Medical Director. Any additional requests above the once per member's lifetime requirement must meet the above guidelines as if it were a first test request and be based on established scientific peer-reviewed journal articles that indicates clinical benefit to member. The Independent Health Medical Director will determine the merit of presented literature)

- **1 or more** of the following clinical indications:
  - Non-small Cell Lung Cancer and **1 or more** of the following:
    - Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed is considered medically necessary when used to guide treatment decision making in individuals with non-small cell lung cancer
    - Genomic Sequential Analysis Panel represented by CPT 81445 and 0037U will be considered reasonable and necessary in the evaluation of tumor tissue in **1 or more** of the following clinical circumstances:
      - Newly diagnosed patients with advanced (stage IIIB or IV) NSCLC, who are not treatable by resection or radiation with curative intent, and who are suitable candidates for therapy at the time of testing
      - Previously diagnosed patients with advanced (stage IIIB or IV) NSCLC, who have not responded to at least one systemic therapy, or who have progressed following resection. The patient must be a candidate for treatment at the time of the testing
      - Previously diagnosed patients with advanced (stage IIIB or IV) NSCLC, who have been resistant to at least one targeted therapy, are able to undergo tumor tissue biopsy for testing, and who are suitable candidates for additional treatment at the time of testing
  - All Other Solid Tumors and **1 or more** of the following:
    - Panels containing from 5 to 50 genes may be covered when **1 or more** of the following criteria are met:
      - A subset of at least 5 constituent genes or variants is recommended for decision-making for the underlying diagnosis by the National Cancer Comprehensive Network
      - In certain circumstances, coverage may be approved with the submission of two peer-reviewed journal articles of studies designed to demonstrate the clinical utility of using the genomic information in question for clinical management of the member's diagnosis and stage of cancer and support the conclusion that use of the information is reasonably likely to provide a health benefit to the member. **The Independent Health Medical Director will determine the merit of presented literature**

Requests for Liquid Biopsy may be covered for **ALL** of the following:

- **ALL** of the following general requirements:
  - The member is unfit for invasive tissue sampling OR there is insufficient material obtained with invasive biopsy
  - The results of the liquid biopsy will affect the treatment and management of the member's care
  - Unless stated otherwise below, criteria for each indication is stated in a National Comprehensive Cancer Network (NCCN) guideline
- **1 or more** of the following indications:
  - Non-small cell lung cancer (NSCLC) with **1 or more** of the following:
    - Previous biopsy-confirmed, newly diagnosed non-small-cell lung cancer (NSCLC) including adenocarcinoma, large cell, squamous cell, and NSCLC not otherwise specified
    - Non-small-cell lung cancer (NSCLC) that is progressing on or after chemotherapy or immunotherapy, and member has never been tested for molecular and biomarker analysis
  - Metastatic Stage IV colorectal cancer
  - Pancreatic cancer and **1 or more** of the following:
    - Previous biopsy-confirmed, newly diagnosed metastatic pancreatic cancer
    - Metastatic pancreatic cancer that is progressing on or after chemotherapy or immunotherapy, and member has never been tested for molecular and biomarker analysis
  - Metastatic prostate cancer
  - HR-positive/HER2-negative breast cancer

NOT COVERED for **ANY** of the following:

- Liquid biopsy for all other indications besides those listed above, **considered investigational**
- For Commercial and Self-funded lines of business (does not apply to Medicare): FoundationOne Liquid CDx is considered experimental due to a lack of scientific evidence for all indications
- Molecular panels containing over 50 genes
- Tests represented by the codes 81445 and 0037U will not be covered for the same member

Pre-Authorization Required? Yes ☒ No ☐

1. The ordering /rendering laboratory is responsible for securing Prior Authorization for Medically Necessary molecular diagnostic testing. Independent Health's Utilization Management Department can be reached by calling (716) 631-3282.

2. The ordering / referring physician is responsible for submitting all relevant member-level clinical information to the rendering laboratory to support the Prior Authorization request.

3. Claims received for molecular diagnostic testing lacking Prior Authorization will deny to the responsibility of the rendering laboratory, and Independent Health members shall not be billed. Therefore, it is imperative for rendering laboratories, with clinical information supplied by ordering / referring physicians, to secure and verify Prior Authorization in accordance with the process above and clinical requirements above.

Definitions

Analytic Validity is the ability to accurately and reliably measure the genotype (or analyte) of interest in the clinical laboratory, and in specimens' representative of the population of interest, or the technical test performance.

Clinical Utility of a genetic test refers to the evidence of improved measurable clinical outcomes, its usefulness and added value to patient management decision-making compared with current management without genetic testing.

Next-generation sequencing (NGS) is defined as any several high-throughput DNA sequencing methods that rely on parallel analysis of multiple DNA fragments (e.g., whole genome sequencing, exome sequencing).

References

Related Policies, Processes and Other Documents
Genetic Testing and Genetic Counseling, M011001298

Non-Regulatory references
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Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Article: Billing and Coding: Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (A56867). Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56867&Cntrctr=275 Accessed July 1, 2025

Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Determination (LCD): Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (L37810). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37810&ver=17&articleId=56867&Date=&DocID=A56867&SearchType=Advanced&bc=EQAAAAIAEAAA&= Accessed July 1, 2025

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
4/1/2026	Health Care Services	Revised
12/1/2025	Health Care Services	Revised – Formatting only
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11/1/2020	Health Care Services	Revised
12/1/2019	Medical Management	Revised
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