Molecular Diagnostic Testing of Hematologic Malignancies

Policy Number:	**M20171213079**
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 hematologic malignancies 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 and hematologic malignancies. 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.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined below.

Commercial and Self-funded: Independent Health covers molecular diagnostic testing of hematologic malignancies utilizing the commercial criteria below**.**

Targeted genomic sequence analysis panel, hematolymphoid neoplasm, DNA analysis(CPT 81450, 81451, 81455) are useful representations of the aggregate of these gene tests and may be used as long as the panel contains, at a minimum, 5 or more gene tests for molecular biomarkers determined to meet established criteria (for example, National Comprehensive Cancer Network (NCCN))

MediSource, MediSource Connect, Child Health Plus and Essential Plan: do not cover targeted genomic sequence analysis panel, hematolymphoid neoplasm, DNA analysis, 5-50 genes, represented as code 81451.

MediSource, MediSource Connect, Child Health Plus and Essential Plan cover targeted genomic sequence analysis panel, hematolymphoid neoplasm represented by code 81450, 81455 utilizing the Commercial criteria below.

Medicare Advantage: There is currently a Centers for Medicare and Medicaid (CMS) Local Coverage Determination (LCD) for genomic sequencing panels for the treatment of hematolymphoid diseases (CPT code 81450, 81455) and a Local Coverage Article (LCA) for genomic sequence analysis panels in the treatment of hematolymphoid diseases. Please refer to the links listed in the Reference section for Medicare Advantage members.

Clinical Indications

Requests for molecular diagnostic testing of hematologic malignancies 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 markers to be tested
    - 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 malignancy 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 hematologic malignancies has not been done previously OR member meets the exception criteria (If authorized, molecular diagnostic testing of hematologic malignancies 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)

- The requested panel contains, at a minimum, 5 or more gene tests for molecular biomarkers and meets established criteria (for example, National Comprehensive Cancer Network [NCCN])

- **1 or more** of the following clinical indications:
  - Acute myelogenous leukemia (AML), as indicated by **1 or more** of the following:
    - Newly diagnosed patients with AML who are undergoing induction therapy, and who are suitable candidates for post-induction transplantation or consolidation therapy at the time of testing, and meet **1 or more** of the following cytogenetic criteria:
      - Normal karyotype
      - Core binding factor
    - Previously diagnosed patients with AML, who have not responded to induction chemotherapy, or who have progressed following induction. The patient must be a candidate for transplantation at the time of the test
    - Patients with AML, who have responded to treatment, either chemotherapy or transplantation, with evidence of relapses
  - Myelodysplastic syndromes (MDS), as indicated by **1 or more** of the following:
    - Patients with clinical signs or symptoms of myelodysplastic syndromes (MDS) or myelodysplastic/myeloproliferative overlap syndromes (MDS/MPN), in whom clinical, laboratory, and pathologic assessment are nondiagnostic
    - Newly diagnosed MDS or MDS/MPN patients and **1 or more** of the following:
      - Stratification by International Prognostic Scoring System (IPSS) or Revised IPSS as intermediate risk
      - MDS with ringed sideroblasts/refractory anemia with ringed sideroblasts
  - Myeloproliferative neoplasms (MPN), as indicated by **1 or more** of the following:
    - Diagnosis of patient with clinical signs or symptoms of myeloproliferative neoplasm (MPN) or myelodysplastic/myeloproliferative overlap syndromes (MDS/MPN) and **ALL** of the following:
      - Clinical, laboratory, and pathologic assessment are nondiagnostic
      - Chronic myeloid leukemia excluded (BCR-ABL1 negative)
    - Risk stratification in newly diagnosed primary myelofibrosis (PMF) not already classified as high-risk by Dynamic International Prognostic Scoring System (DIPSS) Plus
    - Monitoring of higher-risk myelofibrosis (INT-1, INT-2, High-Risk) with progression on therapy

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

- Repeat Genomic Sequential Analysis Panel testing is not reasonable and necessary in MDS after initial diagnosis and risk stratification
- The clinical utility of molecular panels containing over 50 genes has not been established and therefore is not covered

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

Acute myelogenous leukemia (AML), also known as acute myeloid leukemia, is a type of cancer that affects the bone marrow and blood. In AML, the abnormal immature marrow cells multiply and survive better than normal marrow cells, thus blocking the production of healthy cells. Patients with AML therefore typically present with anemia thrombocytopenia, and neutropenia.

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.

Myelodysplastic Syndromes (MDS) comprise a heterogeneous group of malignant hematopoietic stem cell disorders characterized by dysplastic and ineffective blood cell production and a variable risk of transformation to acute leukemia. Patients with MDS have varying reductions in the production of red blood cells, platelets, and mature granulocytes that may also exhibit functional (i.e., qualitative) defects; these abnormalities often result in anemia, bleeding, and increased risk of infection. Myeloproliferative Neoplasms (MPN) exhibit terminal myeloid cell expansion in the peripheral blood, resulting in various combinations of erythrocytosis, leukocytosis, thrombocytosis, bone marrow hypercellularity/fibrosis, and splenomegaly. MPNs include polycythemia vera, essential thrombocythemia, chronic myeloid leukemia, primary myelofibrosis, chronic neutrophilic leukemia, and chronic eosinophilic leukemia.

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

N/A

Non-Regulatory references

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Regulatory References

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Centers for Medicare and Medicaid (CMS) [web site]. Local Coverage Article (LCA): Billing and Coding: Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases (A56793). Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56793&ver=34 (Accessed February 2, 2026.)

New York State Department of Health [web site]. Laboratory Fee Schedule. Available at: https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.emedny.org%2FProviderManuals%2FLaboratory%2FPDFS%2FLaboratory_Fee_Schedule.xls&wdOrigin=BROWSELINK (Accessed February 2, 2026.)

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
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11/1/2021	Health Care Services	Reviewed
11/1/2020	Health Care Services	Revised
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