Health Plans

Manual: IU Health Plans
Department: Utilization Management
Policy # MP050
Effective Date: 11/01/2025
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Medicare Advantage **X Commercial**

Molecular/Genetic Testing Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for molecular/genetic testing.

II. Scope

This policy applies to all IU Health Plans and Utilization Management staff having decision-making responsibilities where authorization is required for Fully-insured commercial plan.

III. Exceptions

1. Molecular/genetic testing for a germ line or constitutional mutation is allowed only one time per member's lifetime.
2. Using molecular/genetic testing for risk selection or risk classification purposes in providing health coverage is prohibited and not covered.
3. Molecular/genetic testing for asymptomatic general screening of a disease/condition is not covered unless specifically provided under a specific benefit plan or included in policy (example cystic fibrosis testing in female/pregnant patients)
4. Molecular/genetic testing for identification of late onset adult disorders will be covered only if an effective treatment exists that has documented better efficacy if initiated prior to onset of symptoms.
5. Direct-to-consumer (DTC) self-testing home kits and other DTC genetic tests are not covered.
6. Storing or using stored human biological specimens for molecular/genetic testing is considered experimental/not covered and should be under the purview of the responsible IRB (Institutional Review Board) or other comparable body.
7. Testing of anonymous human biological samples is considered not medically necessary/not covered.
8. Any molecular/genetic test which is state mandated such as newborn screen (e.g. phenylketonuria (PKU), cystic fibrosis or congenital hypothyroidism) does not require prior authorization under this policy.
9. Requests for molecular/genetic testing billed using unlisted codes or emerging technology will be evaluated on a case by case basis. Documentation must be provided by the requesting physician satisfying the criteria listed below (in the Policy Statements).

IV. Definitions

Biomarker: The state of Indiana defines biomarker as a characteristic that is objectively measured and evaluated as an indicator of:

1. Normal biological processes
2. Pathogenic processes; or
3. Pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered.

The term includes gene mutations, characteristics of genes, and protein expression.

Biomarker Testing: The state of Indiana defines Biomarker Testing as the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker.
The term includes:

1. single-analyte tests;
2. multiplex panel tests;
3. protein expression; and
4. whole exome, whole genome, and whole transcriptome sequencing.

Nationally Recognized Clinical Practice Guidelines: Nationally recognized clinical practice guidelines means evidence based clinical practice guidelines that were:

1. Developed by an independent organization or medical professional society with:
   a. Transparent methodology and reporting structure
   b. Conflict of interest policy.

2. Established standards of care informed by:
   a. Systemic review of evidence
   b. Assessment of benefit versus risk of alternative care options

3. Include recommendations intended to optimize patient care.

V. State of Indiana Biomarker Guidance

Indiana University Health Plans prioritizes following regulatory guidance in determining medical necessity and coverage of medical care**. For a test to be approved it must meet ALL of the supporting criteria.**

The state of Indiana has provided for coverage of biomarker testing under Indiana Code 27-8-14.3-10. (*As added by P.L.37-2024, SEC.2.*):

Sec. 10. (a) A health plan shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when biomarker testing is supported by medical and scientific evidence, including:

(1) labeled indications for a test approved or cleared by the United States Food and Drug Administration;
(2) indicated tests for a drug approved by the United States Food and Drug Administration;
(3) a warning or precaution on the label of a drug approved by the United States Food and Drug Administration;
(4) a national coverage determination of the Centers for Medicare and Medicaid Services (CMS);
(5) a local coverage determination of a Medicare administrative contractor; or
(6) nationally recognized clinical practice guidelines or consensus statements.

(b) The coverage required by this section must be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(c) Nothing in this section shall be construed to require coverage of biomarker testing for

screening purposes.

(d) If a prior authorization requirement applies to biomarker testing under a health plan, the health plan or a third party acting on behalf of the health plan must:

(1) approve or deny a request for prior authorization for biomarker testing; and

(2) notify the covered individual and any person requesting prior authorization of the biomarker testing on behalf of the covered individual; in not more than five (5) business days after the request in the case of a nonurgent request or in not more than forty-eight (48) hours after the request in the case of an urgent request.

(e) A health plan shall ensure that a covered individual and the practitioner who prescribes biomarker testing for the covered individual have access to a clear, readily accessible, and convenient process for requesting an exception to:

(1) a coverage policy; or

(2) a prior authorization determination;

of the health plan that is adverse to the coverage of biomarker testing for the covered individual. The process required by this subsection shall be made readily accessible on the health plan's website.

VI. Policy Statements

IU Health Plans considers **molecular/genetic tests** necessary for **one of the following** indications:

1. All of the following:
   - **a.** The member demonstrates signs/symptoms of a genetically linked disease, or the member/member's fetus has a direct and documented risk factor for development of a genetically-linked disease, or the member has a malignancy or physical condition for which an established treatment is associated with a specific mutation.
   - **b.** A molecular/genetic test, specific mutation, or set of mutations have been established in peer- reviewed scientific literature to be reliably associated with the specific diseases being evaluated for (condition or response to treatment identified).
   - **c.** The results of the molecular/genetic test will specifically determine medication, treatment, and/or clinical management decisions. Results are furnished for the diagnosis, direct care, and treatment of a medical condition and not mainly for the convenience of the member, provider, or laboratory.
   - **d.** The ordered test must directly impact clinical decision making and patient management.
2. Any molecular/genetic test which is state mandated (*see Exceptions section above*).
3. Prenatal genetic screening of a parent or prospective parent to determine carrier status for the following conditions is considered medically necessary. Screening of female/pregnant person initially and then screen partner if female/pregnant person is positive for carrier status and if partner carrier status is unknown: If done by cell free DNA testing, please use MP010 Non Invasive Prenatal Testing)
   - **a.** Cystic fibrosis, common variants (current standard includes 23 of the more common gene mutations)
   - **b.** Spinal muscular atrophy
   - **c.** Fetal aneuploidy Testing

CODES-CPT/HCPCS/ICD 10

Code	Description
0118U	Transplantation medicine, quantification of donor derived cell-free DNA using whole genome next generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA
0396U	Proprietary Lab Analysis for Spectrum-PGT-M from Natera- preimplantation genetic testing of embryo prior to IVF. Evaluates liklihood that embryo carries single gene that can cause CF, SMA, or hemophilia
81220	Genetic analysis procedure Cystic Fibrosis CFTR (cystic fibrosis transmembrane conductance regulator
81221	CFTR known familial variants
81222	CFTR duplication/deletion variants
81223	CFTR full gene sequence
81224	CFTR intron 8 poly-T analysis (eg male infertility)
81228	CMA or molecular karotype- entire genome evaluation to detect variation in the number of copies of gene sequences (CNV-copy number variants) that may be associated with developmental delays or disabilities
81329	Genetic analysis SMN1/SMN2
81479	Unlisted molecular pathology procedure
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure
87999	Unlisted microbiology procedure
88299	Unlisted cytogenetic study

VII. Procedures

None

VIII. References/Citations

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) MoIDX: Biomarkers in Cardiovascular Risk Assessment L36523. Contractor:Wisconsin Physicians Service Insurance Corporation. Revision Effective

3/21/2024.. LCD - MolDX: Biomarkers in Cardiovascular Risk Assessment (L36523) (cms.gov)
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) MoIDX: Breast Cancer Index (BCI) Gene Expression Test L37913. Contractor:Wisconsin Physicians Service Insurance Corporation. Revision Effective 2/23/2023. LCD - MolDX: Breast Cancer Index® (BCI) Gene Expression Test (L37913) (cms.gov)
3. MedicineNet. Definition of Genomics, Reviewed March 29, 2021. http://www.medterms.com/script/main/art.asp?articlekey=23242
4. National Comprehensive Cancer Network. (n.d.) *Biomarkers Compendium.* Biomarkers Compendium (nccn.org)
5. State of Indiana. Indiana Code for 2024. Title 27; Article8; Chapter 14.3 Coverage for Biomarker Testing. IGA | 2024 Indiana Code
6. Underhill-Blazey, M., & Klehm, M. (2020). Genetic Discrimination: The Genetic Information Nondiscrimination Act's Impact on Practice and Research. *Clinical Journal of Oncology Nursing*, *24*(2), 135–137. https://doi.org/10.1188/20.cjon.135-137
9. U.S. Department of Health and Human Services; National Institute of Health: National Institute on Aging. Causes of Alzheimer's Disease-Alzheimer's Disease Genetics Fact Sheet. Content Reviewed December 24, 2019. Alzheimer's Disease Genetics Fact Sheet | National Institute on Aging (nih.gov)

IX. Forms/Appendices

None

X. Responsibility

Medical Director