Molecular Diagnostic Testing, Genetic Testing and Genetic Counseling

Policy Number: **M011001298**

Effective Date: **5/9/2002**

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)

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for **molecular diagnostic testing**, **genetic testing**, both germline and somatic, including but not limited to diagnostic, predictive, and reproductive genetic testing and requirements for genetic counseling.

Policy:

Commercial, Self-Funded, Medicare Advantage, MediSource, MediSource Connect, Child Health Plus and Essential Plan:

Genetic Counseling:
Members with a history of a familial genetic disease or other need for such testing should consult an appropriate genetics counselor. Genetic testing is appropriate only when offered in a setting with adequately trained health care professionals to provide appropriate pre- and post-testing counseling.

Molecular Diagnostic Testing and Genetic Testing:
Only requests for molecular diagnostic and genetic testing that have shown **clinical validity** and **clinical utility** are considered. Each individual gene requested will be considered for its clinical utility and relevance. Independent Health considers molecular diagnostic and genetic testing medically necessary to establish a molecular diagnosis of **germline mutation** or **somatic mutation** when the following criteria are met:

- The member displays clinical features of a germline or somatic condition that requires treatment; AND
- The result of the test will directly impact the treatment being delivered to the member; AND
- After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain; AND.
- Documentation must include physician's order when request is submitted by lab; AND
- Documentation of member's informed consent must be presented with test order.

Based upon assessment of the peer-reviewed literature, including the American College of Obstetricians and Gynecologists and the American College of Medical Genetics, preconception or prenatal carrier screening for spinal muscular atrophy (SMA) and Cystic Fibrosis is considered medically necessary as part of routine care. Carrier testing for SMA and Cystic Fibrosis should only be performed once per lifetime.

Note: Requests for genetic testing resulting from a member acquired home test (such as Ancestry.com or 23andme, Inc.) will not be considered an indication for molecular diagnostic testing.

Multigene Panel Testing:

Multigene panel testing, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered ONLY:

- For the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making; AND
- Results of the testing must directly impact treatment or management of the member.

Multigene panel testing is ideally offered in the context of professional genetic expertise for pre-and post-test counseling. Individuals with the recommended expertise include certified genetic counselors, as well as clinicians who have had extensive training and/or expertise in identification and management of germline or somatic syndromes.

- **NOTE:** Molecular diagnostic and genetic tests for germline or somatic diseases are covered only once. Molecular diagnostic and genetic testing of members is excluded if the testing is performed primarily for the medical management of family members not covered by the member's contract.
- **NOTE:** Whole exome sequencing is not covered for MediSource, MediSource Connect, Child Health Plus and Essential Plan.

Background:
Some molecular diagnostic and genetic tests have solid scientific evidence for support and use while others have no proven utility, and some are investigational.

Therefore, it is important that prior to agreeing to such testing, members should be given sufficient information about the test to be able to make informed decisions about the results and how those results might affect future treatment.

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 above.

Pre-Authorization Required? Yes ☒ No ☐

Prior authorization is required; failure to obtain authorization may result in a sanction to the ordering provider.

1. The rendering laboratory is responsible for securing Prior Authorization for Medically Necessary molecular diagnostic testing. Independent Health's Prior Authorization form is available at:

   https://ihprovider.healthtrioconnect.com/app/docMgr/single/downloadDocument?xsesschk=bab717256b644f69a209563709ab55af&documentId=f546db5e761b43d98bae9c070ed523f4

   and 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 that rendering laboratories, with clinical information supplied by ordering / referring physicians, secure and verify Prior Authorization in accordance with the process above and clinical requirements above.

Molecular diagnostic testing and genetic testing codes requiring preauthorization may be located on the Independent Health Provider Portal in the Office Management section.

Definitions

Clinical utility is the evidence of improved measurable clinical outcomes, and a test's usefulness and added value to patient management and decision making compared with current management in the absence of testing.

Clinical validity is the accuracy of a test for a specific clinical purpose, such as diagnosis or prediction of a risk of a disorder.

Genetic testing involves the analysis of genes and chromosomes to detect disease-related genotypes and to determine germline or somatic mutations in genes. Genetic testing can be used to predict risk of disease, identify carriers and establish prenatal and clinical diagnosis or prognosis.

Genetic counseling is the process by which patients or relatives, at risk of a germline or somatic disorders, are advised of the consequences and nature of the disorder, the probability of developing or transmitting it, and the options open to them in management of the disease and/or family planning.

Germline mutation is a gene change in a body's reproductive cell (egg or sperm) that becomes incorporated into the DNA of every cell in the body of the offspring. Germline mutations are passed on from parents to offspring. Also called hereditary mutation.

Molecular diagnostic testing is a term widely used in clinical genetics encompassing the diverse testing methods that use molecular biology techniques to identify disease-causing genetic alterations. Examples of molecular genetic tests include genotyping to detect specific pathogenic variants; sequencing of a gene to detect pathogenic variants; amplification or hybridization methods (e.g., qPCR, array CGH, MLPA) to detect copy number variants involving one or more genes; methylation-specific techniques to detect epigenetic changes that influence gene expression; and exome and genome sequencing.

Somatic mutation is an alteration in DNA that occurs after conception. Somatic mutations can occur in any of the cells of the body except the germ cells (sperm and egg) and therefore are not passed on to children. These alterations can (but do not always) cause cancer or other diseases.

References

Related Policies, Processes and Other Documents
ALLOMAP® (formerly Laboratory Testing for Monitoring Acute Rejection in Cardiac Transplant Patients), Policy No. M110415115

Oncotype Dx Colon Cancer, Policy No. M20130118014

Preimplantation Genetic Testing, Policy No. M20210312010

Provider Financial Sanction Policy, Policy No. M20160226008

Non-Regulatory references

American College of Obstetricians and Gynecologists Committee on Genetics. ACOG Committee Opinion No. 691 [web site]: Carrier Screening for Genetic Conditions. Reaffirmed 2023. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/03/carrier-screening-for-genetic-conditions Accessed August 1, 2024.

National Academies of Sciences, Engineering, and Medicine. 2017. An Evidence Framework for Genetic Testing. Washington, DC: The National Academies Press.

National Cancer Institute (NCI)[web site]. NCI Dictionary of Cancer Terms. Germline mutation. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=46384 Accessed August 1, 2024.

National Cancer Institute (NCI)[web site]. NCI Dictionary of Cancer Terms. Somatic mutation. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=46586 Accessed August 1, 2024.

National Center for Biotechnology Information, U.S. National Library of Medicine [web site]. GeneReviews Glossary. Available at: https://www.ncbi.nlm.nih.gov/books/NBK5191/#IX-M Accessed August 1, 2024.

National Comprehensive Cancer Network (NCCN) [web site]. National Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal Cancer. Version 2.2023 — October 30, 2023. Available at: https://www.nccn.org/ Accessed August 1, 2024.

Prior TW; Professional Practice and Guidelines Committee. Carrier screening for spinal muscular atrophy. Genet Med. 2008 Nov;10(11):840-2.

Weil J. Genetic counselling in the era of genomic medicine. As we move towards personalized medicine, it becomes more important to help patients understand genetic tests and make complex decisions about their health. EMBO Rep. 2002 Jul;3(7):590-3. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1084197/pdf/kvf144.pdf Accessed August 1, 2024.

Regulatory References

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest). Email response 11/14/2018.

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☐

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10/1/2024	Health Care Services	Revised
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1/1/2019	Medical Management	Revised
11/1/2018	Medical Management	Revised
6/1/2018	Medical Management	Revised
3/1/2018	Medical Management	Revised
9/1/2017	Medical Management	Revised
8/1/2017	Medical Management	Revised
5/1/2017	Medical Management	Revised
2/1/2017	Medical Management	Revised
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