EFFECTIVE DATE: 01|01|2017
POLICY LAST UPDATED: 12|20|2016

OVERVIEW

Genetic testing is a technique used to identify people at risk for a specific genetic disease, predict the possibility of future genetic disease, or to determine the risk for transmitting such a disease to their offspring. Testing may also be used as part of the process to identify, confirm, or predict the possibility of a specific medical condition and develop a treatment plan.

This policy indicates genetic testing services that

- require/recommend preauthorization via the Clear Coverage online tool
- not medically necessary
- not covered
- covered

MEDICAL CRITERIA

Generally InterQual criteria is used to determine medical necessity for a majority of genetic testing, and is found in the Clear Coverage online authorization tool:

https://www.bcbsri.com/BCBSRIWeb/Login.do?redirectTo=/providers/preauth/preauthProviderOverview.jsp

The following criteria is used in the online authorization tool when separate criteria is not identified for the test being performed.

Genetic testing is considered medically necessary to establish a molecular diagnosis of an inheritable disease when all of the following are met:

- The member displays clinical features; and
- The genetic disorder is associated with a potentially significant disability or has a lethal natural history; and
- After history, physical examination, pedigree analysis, genetic counseling and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain; and
- The results of the test will be used specifically for diagnosis; and
- The disease is treatable or preventable; and
- The result of the test will directly influence the treatment being delivered to the patient, including increasing the intensity of surveillance/treatment of that disease including family planning; and
- The providing laboratory must be approved by the U.S. Food and Drug Administration (FDA) or other governmental agencies; and
- Peer-reviewed literature is available that provides evidence for the indications and performance of the test or the indication for the test is in accordance with the guidelines of the American College of Medical Genetics.

Genetic screening is considered medically necessary when all of the following are met:

- To determine if the member is at direct risk of inheriting the mutation in question; and

- The genetic disorder is associated with a potentially significant disability or has a lethal natural history; and
- A specific mutation, or set of mutations, has been established in the scientific literature to be reliably associated with the disease; and
- The results of the test will be used specifically for diagnosis or the result of the test will directly influence the treatment being delivered to the patient, including increasing the intensity of surveillance/treatment of that disease or have an impact on family planning; and
- The providing laboratory must be approved by the FDA or other governmental agencies; and
- Peer-reviewed literature is available that provides evidence for the indications and performance of the test or the indication for the test is in accordance with the guidelines of the American College of Medical Genetics.

Carrier testing is considered medically necessary when all of the following are met:
- To determine if the member is at direct risk of transmitting the mutation in question to their offspring; and
- The genetic disorder is associated with a potentially significant disability or has a lethal natural history; and
- A specific mutation, or set of mutations, has been established in the scientific literature to be reliably associated with the disease; and
- The results of the test will have an impact on family planning; and
- The providing laboratory must be approved by the FDA or other governmental agencies; and
- Peer reviewed literature is available that provides evidence for the indications and performance of the test or the indication for the test is in accordance with the guidelines of the American College of Medical Genetics.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products.

Prior authorization is required for each component of panel testing when it is not a next generation sequencing panel and when the panel is represented by multiple CPT codes. Each individual CPT code must be entered into and processed through the online authorization tool independently.

Requests for genetic testing should be obtained via the BCBSRI online preauthorization tool, which is available only to BCBSRI-participating providers. All other providers need to fax a preauthorization request to Utilization Management at (401) 272-8885.

If a genetic test or family is not found in the online authorization tool, please fax a request to our Utilization Management Dept at (401) 272-8885.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Genetic testing is considered medically necessary when the criteria in the online authorization tool has been met.

Genetic testing, using panels of genes or using next generation sequencing, is considered not medically necessary. Individual components of a panel may be submitted for review and may be considered medically necessary when criteria is met.

The clinical utility of Next Generation Sequencing Panel tests is uncertain. Therefore, Next Generation Sequencing Panel tests are considered not medically necessary for BlueCHiP for Medicare and are not covered for Commercial Products.

Exception: Testing represented by CPT code 81420 is a covered service for BlueCHiP for Medicare and Commercial Products.

There are additional genetic testing codes within this policy that are considered not medically necessary as there is insufficient peer-reviewed literature documenting efficacy. See coding section for details.

Laboratories are not allowed to obtain clinical authorization on behalf of the ordering physician. In no circumstance shall a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory, to facilitate any portion of the authorization process, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a physician/provider provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the laboratory and may not be billed to the member.

COVERAGE

BlueCHiP for Medicare and Commercial Products

Benefits may vary between groups/contracts. Please refer to the Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable genetic testing coverage/benefits.

BACKGROUND

Molecular Pathology

Molecular pathology procedures, commonly referred to as genetic testing, are medical laboratory procedures involving the analyses of nucleic acid to detect variants in genes that may be indicative of germline (eg, constitutional disorders) or somatic (eg, neoplasia) conditions, or to test for histocompatibility antigens (eg, HLA). Code selection is typically based on the specific gene(s) that is being analyzed. Genes are described using Human Genome Organization (HUGO) approved gene names.

Next Generation Sequencing

Genomic sequencing procedures (GSPs) and other molecular multianalyte assays GSPs are DNA and RNA sequence analysis methods that simultaneously assay multiple genes or genetic regions relevant to a clinical situation. They may target specific combinations of genes or genetic material, or assay the exome or genome. The technology used for genetic sequencing is commonly referred to as next generation sequencing (NGS) or massively parallel sequencing (MPS).

MultiAnalyte Assays

Multianalyte Assays with Algorithmic Analyses (MAAAs) are procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (eg, proteins, polypeptides, lipids, carbohydrates). Algorithmic analysis using the results of these assays as well as other patient information (if used) is then performed and typically reported as a numeric score(s) or as a probability. MAAAs are typically unique to a single clinical laboratory or manufacturer.

CODING

See the attached grid for BlueCHiP for Medicare and Commercial coverage of Genetic Testing Codes.

Grid of GT codes Coverage for Policy.x

RELATED POLICIES

Gene Expression Profiling and Protein Biomarkers for Prostate Cancer Management

Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer

Genetic Testing for Mental Health Conditions
Molecular Markers in Fine Needle Aspirates of the Thyroid
Newborn Metabolic, Endocrine and Hemoglobinopathy, and Newborn Hearing Loss Screening Programs Mandate
PathfinderTG® Molecular Testing
Proteomics-Based Testing Related to Ovarian Cancer

PUBLISHED

Provider Update, February 2017
Provider Update, November 2015
Provider Update, September 2013
Provider Update, February 2013
Provider Update, January 2012
Provider Update, August 2011
Provider Update, September 2009

REFERENCES

Not applicable