Medical Coverage Policy | Preauthorization via Web-Based Tool for Genetic Testing

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 09|15|2015

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.

MEDICAL CRITERIA

As defined in online authorization tool:

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

Generally InterQual criteria is used to determine medical necessity. However, for those policies specifically listed in the Related Policies section of this policy, BCBSRI medical criteria is used. Additionally, the following criteria is used to determine medical necessity for those services that are filed with a CPT Unlisted molecular pathology procedure code, Unlisted multianalyte assay with algorithmic analysis code, Unlisted chemistry procedure code, or a CPT Tier 2 Molecular Pathology Procedure code.

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.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

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 contact Utilization Management at the number below:

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

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

Genetic testing, using panels of genes, without 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.

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

The clinical utility of Next Generation Sequencing Panel tests is uncertain and therefore, Next Generation Sequencing Panel tests are not medically necessary. 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.

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.

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.

BACKGROUND

Not applicable

CODING

BlueCHiP for Medicare and Commercial Products

NOTE: Effective December 1, 2016, the services identified in blue font below will require prior authorization through the BCBSRI online prior authorization tool.

The following codes require prior authorization:
Genetic testing CPT codes:
81161, 81162, 81170, 81200 – 81350, 81400 - 81408, 81479, 81504, 81507, 81519, 81599, **83080**, 84999

Genetic Testing HCPCS codes:
S3840, S3841, S3844, S3845, S3846, S3849, S3850, S3852, S3866

The following codes are considered not medically necessary:
81227, 81246, 81355
Next Generation Sequencing
81410 – 81471

The following code is used to represent the Progensa® PCA3 Assay. It is covered for BlueCHiP for Medicare and not medically necessary for Commercial products.
81313

The following code is used to represent the MammaPrint® test. It is covered for BlueCHiP for Medicare and not medically necessary for Commercial products. (Effective 7/1/2016)
S3854

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

PUBLISHED

Provider Update, November 2015
Provider Update, September 2013
Provider Update, February 2013
Provider Update, January 2012
Provider Update, August 2011
Provider Update, September 2009
Provider Update, September 2008

REFERENCES

Not applicable