Blue Cross and Blue Shield of Nebraska is proud to work with our provider network to serve your patients, our members. We are updating several medical policies. Please review the changes and effective dates outlined here:

Medical Policy V.59 Genetic Testing: Hereditary Cancer Susceptibility
Effective Date: 07/01/2024
Preauthorization Required: YES

Updating

Hereditary Neuroendocrine Cancer Susceptibility Panel

A hereditary neuroendocrine cancer susceptibility panel is one that includes genes that are associated with inherited susceptibility to a neuroendocrine cancer.

I. Genetic testing using a hereditary neuroendocrine cancer susceptibility panel (81437, 81438) is considered **medically necessary** when:
   A. The member has at least one of the following:
      1. Adrenocortical carcinoma, **OR**
      2. Paraganglioma/pheochromocytoma, **OR**
      3. Parathyroid adenoma or primary hyperparathyroidism before age 30, **OR**
      4. Multiple parathyroid adenomas, **OR**
      5. Multi-gland hyperplasia without obvious secondary cause, **OR**
      6. Recurrent primary hyperparathyroidism, **OR**
   B. The member meets criteria for *MEN1* sequencing and/or deletion/duplication analysis, **OR**
   C. The member meets criteria for *RET* sequencing and/or deletion duplication analysis, **AND**
   D. The panel does not include genes without a known association with a neuroendocrine cancer by ClinGen.

II. Genetic testing using a hereditary neuroendocrine cancer susceptibility panel (81437, 81438) is considered **investigational** for all other indications.

Medical Policy V.61 Oncology: Circulating Tumor DNA and Circulating Tumor
Effective Date: 07/01/2024
Preauthorization Required: YES

Updating

Broad Molecular Profiling Panel Tests via Circulating Tumor DNA (ctDNA)

I. Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) (0239U, 0242U, 0326U, 0409U, 81445, 81455, 81462, 81463, 81464) are considered **medically necessary** when:
   A. The member has a diagnosis, progression, or recurrence of one of the following:
      1. Stage IV or metastatic lung adenocarcinoma, **OR**
      2. Stage IV or metastatic large cell lung carcinoma, **OR**
      3. Stage IV or metastatic squamous cell lung carcinoma, **OR**
      4. Stage IV or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **OR**
      5. Locally advanced/metastatic pancreatic adenocarcinoma, **OR**
      6. Metastatic or advanced gastric cancer, **OR**

7. Metastatic or advanced esophageal or esophagogastric junction cancer, **OR**
8. Metastatic prostate cancer, **OR**
9. Stage III or higher cutaneous melanoma**, OR**
10. Metastatic colorectal cancer, **OR**
11. Locally advanced or metastatic ampullary adenocarcinoma, **OR**
12. Persistent or recurrent cervical cancer**, OR**
13. Unresectable or metastatic biliary tract cancer**, OR**
14. Suspected or confirmed histiocytic neoplasm, **OR**
15. Locoregional unresectable or metastatic extrapulmonary poorly differentiated neuroendocrine carcinoma or large or small cell carcinoma or mixed neuroendocrine-non-neuroendocrine neoplasm**, OR**
16. Suspected metastatic malignancy of unknown primary with initial determination of histology, **OR**
17. Recurrent ovarian, fallopian tube or primary peritoneal cancer**, OR**
18. Recurrent or stage IV breast cancer.

II. Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) (0239U, 0242U, 0326U, 81445, 81455, 81462, 81463, 81464) are considered **investigational** for all other indications.

III. Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) (0239U, 0242U, 0326U, 81445, 81455, 81462, 81463, 81464) performed simultaneously with solid tumor tissue testing are considered **investigational**.

Lung Cancer Focused Panel Tests via Circulating Tumor DNA (ctDNA)

I. Lung cancer focused panel tests via circulating tumor DNA (ctDNA) (0179U, 81210, 81235, 81275, 81462, 81479, 0388U) are considered **medically necessary** when:
   A. The member has a diagnosis or progression of any of the following:
      1. Stage IV or metastatic lung adenocarcinoma, **OR**
      2. Stage IV or metastatic large cell lung carcinoma, **OR**
      3. Stage IV or metastatic squamous cell lung carcinoma, **OR**
      4. Stage IV or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS).

II. Lung cancer focused panel tests via circulating tumor DNA (ctDNA) (0179U, 81210, 81235, 81275, 81462, 81479, 0388U) are considered **investigational** for all other indications.

Medical Policy V.65 Genetic Testing: Epilepsy, Neurodegenerative and Neuromuscular Disorders
Effective Date: 07/01/2024
Preauthorization Required: YES

Updating

***HTT* Repeat Analysis**

I. *HTT* repeat analysis to establish a diagnosis or for predictive testing of Huntington's disease (HD) (81271, 81274) is considered **medically necessary** when:
   A. The member displays clinical features of Huntington's disease (i.e., progressive motor disability featuring chorea, where voluntary movement may also be affected), **OR**
   B. The member has a clinical diagnosis of Huntington's Disease, **OR**
   C. The member is undergoing predictive testing*, **AND**
      1. The member is presymptomatic/asymptomatic, **AND**

2. The member is 18 years of age or older**, AND**
    a) The member has a close relative with CAG trinucleotide repeat expansion of 27 or more in *HTT*, **OR**
    b) The member has a first-degree relative with a clinical diagnosis of HD without prior genetic testing.

II. *HTT* repeat analysis to establish a diagnosis or for predictive testing of Huntington's disease (HD) (81271, 81274) is considered **investigational** for all other indications.

Medical Policy V.67 Genetic Testing: Gastroenterology (Non-Cancerous)
Effective Date: 07/01/2024
Preauthorization Required: YES

Adding

Non-invasive Liver Fibrosis Serum Tests

I. Non-invasive liver fibrosis serum tests (0002M, 0003M, 84450, 84460, 85049) to rule out liver fibrosis are considered **medically necessary** when:
    A. The member has one of the following:
        1. Nonalcoholic fatty liver disease (NAFLD), **OR**
        2. Nonalcoholic steatohepatitis (NASH), **OR**
        3. Type 2 diabetes, **OR**
        4. Obesity (BMI >25), **OR**
        5. Abnormal liver function tests, **OR**
        6. A history of alcohol use, **AND**
    B. The member had previous fibrosis-4 index (FIB-4) testing with a score of greater than 1.3.

II. Non-invasive liver fibrosis serum tests (0002M, 0003M, 84450, 84460, 85049) to rule out liver fibrosis are considered **investigational** for all other indications.

Updating

***HLA-DQ* Genotyping Analysis**

I. *HLA-DQ2* and *HLA-DQ8* variant analysis (81370, 81375, 81376, 81377, 81382, 81383) to rule out celiac disease (CD) is considered **medically necessary** when the member meets one of the following:
    A. The member is being evaluated for celiac disease, **AND**
        1. Had an inconclusive serology (antibody) result, **OR**
        2. Had an inconclusive histology (biopsy) result, **OR**
        3. Started a gluten-free diet before evaluation for celiac disease.

HLA-DQ2 and *HLA-DQ8* variant analysis (81370, 81375, 81376, 81377, 81382, 81383) to rule out celiac disease is considered **investigational** for all other indications.

Hereditary Inflammatory Bowel Disease / Crohn's Disease Panel Tests

I. Genetic testing for inflammatory bowel disease (81479, 81321, 81406, 81407), including Crohn's disease, via a multigene panel is considered **medically necessary** when:
    A. The member was diagnosed with infantile-onset inflammatory bowel disease (Infantile-IBD) before age 2 years, **OR**
    B. The member was diagnosed with very early onset inflammatory bowel disease (VEO-IBD) before age 6 years, **AND**

1. At least one of the following:
    a) The member has congenital multiple intestinal atresias, **OR**
    b) The member has congenital diarrhea, **OR**
    c) The member has a diagnosis of malignancy under age 25, **OR**
    d) The member has features of an inborn error of immunity such as susceptibility to infections, **OR**
    e) The member has complex autoimmune features, **OR**
    f) The member has a close relative meeting any of the above criteria, **OR**
2. The member is undergoing stem cell transplant, **OR**
3. The member has a history of multiple intestinal resections.

II. Genetic testing for inflammatory bowel disease (81479, 81321, 81406, 81407), including Crohn's disease, via a multigene panel is considered **investigational** for all other indications.

Removing

Known Familial Variant Analysis for Cardiac Disorders
Left Ventricular Non Compaction Cardiomyopathy (LVNC)

Medical Policy V.71 Genetic Testing: Eye Disorders
Effective Date: 07/01/2024
Preauthorization Required: YES

Updating

Inherited Retinal Dystrophies Multigene Panel Analysis

I. Genetic testing for inherited retinal dystrophies via a multigene panel (81404, 81406, 81408, 81434, 81479) is considered **medically necessary** when:
    A. The member has findings consistent with one of the following:
        1. Rod-cone degeneration (e.g., retinitis pigmentosa), **OR**
        2. Cone-rod degeneration (e.g., achromatopsia), **OR**
        3. Chorioretinal degeneration**, OR**
        4. Macular dystrophy, **AND**
    B. The test includes, at a minimum, the *RPE65* gene.

II. Genetic testing for inherited retinal dystrophies via a multigene panel (81404, 81406, 81408, 81434, 81479) is considered **investigational** for all other indications.

Medical Policy V.73 Genetic testing: Aortopathies and Connective Tissue Disorders
Effective Date: 07/01/2024
Preauthorization Required: YES

Updating

***FBN1* Sequencing and/or Deletion/Duplication Analysis**

I. *FBN1* sequencing and/or deletion/duplication analysis (81408, 81479) to confirm a diagnosis of Marfan syndrome is considered **medically necessary** when:
    A. The member has one of the following:
        1. Aortic root enlargement (Z-score of 2 or greater) or dissection, **OR**
        2. Ectopia lentis, **OR**
    B. The member has a systemic score of 7 or higher using the list of symptoms below (point values in parentheses):

1. Wrist AND thumb sign (3)
2. Wrist OR thumb sign (1)
3. Pectus carinatum deformity (2)
4. Pectus excavatum or chest asymmetry (1)
5. Hindfoot deformity (2)
6. Plain flat foot (pes planus) (1)
7. Pneumothorax (2)
8. Dural ectasia (2)
9. Protrusio acetabulae (2)
10. Reduced upper segment / lower segment AND increased arm span/height ratios (1)
11. Scoliosis or thoracolumbar kyphosis (1)
12. Reduced elbow extension (1)
13. 3 of 5 facial features (dolichocephaly, downward slanting palpebral fissures, enophthalmos, retrognathia, malar hypoplasia) (1)
14. Skin striae (1)
15. Myopia (1)
16. Mitral valve prolapse (1).

Medical Policy V.74 Genetic Testing: General Approach to Genetic and Molecular Testing
Effective Date: 07/01/2024
Preauthorization Required: YES

Adding

General Criteria for Targeted Carrier Screening

The criteria below is intended for the evaluation of genetic testing that has not been more specifically addressed by coverage criteria in another policy.

Targeted carrier screening is defined as a test that screens for a known mutation in one gene associated with a specific genetic condition.

I. Carrier screening for a genetic disorder may be considered **medically necessary** when:
   A. The member is considering pregnancy or is currently pregnant, **AND**
   B. The genetic disorder is a recessive condition with a childhood onset, **AND**
   C. One of the following:
      1. The member has a close relative with a known pathogenic or likely pathogenic variant associated with the disorder, **OR**
      2. The member's reproductive partner is a carrier for the genetic disorder, **OR**
      3. The member or the member's reproductive partner are members of a population known to have a carrier rate of 1% or higher for the genetic condition, **OR**
      4. The member or the member's reproductive partner has a first- or second-degree relative who is affected with the genetic disorder.

II. Carrier screening for a genetic disorder is considered **investigational** when the member does not meet any criteria above.

Updating:

General Criteria for Single Gene or Multigene Panel Analysis

The criteria below is intended for the evaluation of genetic testing that has not been more specifically addressed by coverage criteria in another policy.

I. Genetic testing for a genetic condition via single-gene or multigene panel analysis may be considered **medically necessary** when:
   A. The member displays clinical features of the suspected genetic condition, **AND**
   B. The diagnosis remains uncertain after appropriate clinical evaluation and other standard laboratory tests/imaging/etc. have been performed, **AND**
   C. The test has clinical validity, as demonstrated by accurately determining diagnostic, prognostic or clinical information for a disease, **AND**
   D. The test has clinical utility, as demonstrated by at least one of the following:
      1. The test will determine if a particular therapeutic intervention is effective (or ineffective) in the member, or if a particular intervention may be harmful, **OR**
      2. The test will directly impact the clinical management, **OR**
      3. The test will determine prognosis, **OR**
      4. The test will provide or refine estimates of the natural history, recurrence risk, or the predicted course of the genetic condition, **AND**
   E. There is no known pathogenic or likely pathogenic familial variant for the genetic condition for which targeted variant analysis would be more appropriate, **AND**
   F. Non-genetic causes for the member's clinical features have been ruled out (e.g., pathogens, drug toxicity, environmental factors, etc.), **AND**
   G. An association with the gene or multigene panel and disease has been established

II. Genetic testing in an individual under the age of 18 for an adult-onset condition is considered **not medically necessary**.

III. Genetic testing via single-gene or multigene panel analysis is considered **investigational** or **not medically necessary** when the above criteria are not met.

General Criteria for Oncology Algorithmic Tests

The criteria below is intended for the evaluation of genetic testing that has not been more specifically addressed by coverage criteria in another policy.

I. Oncology algorithmic testing* is considered **medically necessary** when:
   A. The member has a suspected or confirmed neoplasm and/or malignancy, **AND**
   B. The test has clinical validity, as demonstrated by accurately determining diagnostic, prognostic or clinical information for a disease, **AND**
   C. The test has clinical utility, as demonstrated by at least one of the following:
      1. The test will determine if a particular therapeutic intervention is effective (or ineffective) in the member, or if a particular intervention may be harmful, **OR**
      2. The test will directly impact the clinical management, **OR**
      3. The test will determine prognosis, **OR**
      4. The test will provide or refine estimates of the natural history, recurrence risk, or the predicted course of the genetic condition.

II. Oncology algorithmic testing is considered **investigational** for all other indications.

*See the Oncology: Algorithmic testing policy for criteria regarding common algorithmic tests

Medical Policy V.77 Genetic Testing: Dermatologic Conditions
Effective Date: 07/01/2024
Preauthorization Required: YES

Removing
Epidermolysis Bullosa Multigene Panels