PAYMENT POLICY

Genetic Testing

Policy

CommunityCare reimburses medically necessary genetic testing, genetic counseling, and human leukocyte antigen testing when it meets established coverage criteria and is performed by an approved provider.

Definition

Genetic testing involves molecular analysis of human DNA, RNA, genes, and chromosomes to detect whether or not a person has an inherited trait or disorder, an acquired genetic alteration, a spontaneous genetic mutation, or is a carrier of a gene that could lead to a particular disorder or disease.

Genetic counseling is a process of communication between patients and trained professionals intended to educate individuals or families about a genetic disease or the risk of a predisposition for genetic disease to facilitate informed reproductive or medical decisions. Genetic counselors also provide supportive counseling and anticipatory guidance when a hereditary disorder or birth defect has occurred.

Human leukocyte antigens (HLA) are a group of protein molecules located on bone marrow cells that can provoke an immune response. HLA testing, also known as tissue typing or histocompatibility testing, may be determined by serology or by DNA analysis.

Prerequisite(s)

CommunityCare's Referral, Notification, Pre-Certification and Authorization policy apply.

Member Cost-Sharing

Covered services subject to applicable member out-of-pocket costs (e.g., co-payment, coinsurance, deductible).

CommunityCare Reimburses

Genetic testing and related genetic counseling are considered eligible for reimbursement only when used to establish the diagnosis or character of a disease process if:

- The member displays clinical features or is at direct risk of inheriting a particular mutation, or
- The result of the test directly impacts either the treatment or future diagnostic testing needed by the member, or
- After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain.
- Genetic counseling is eligible for reimbursement for the same conditions as genetic testing.

The following list of genetic tests / assays is eligible for reimbursement when medical necessity criteria are met. This list is not all-inclusive.

- Inherited BRCA-1 or BRCA-2 mutations for breast and ovarian cancer
- Germline mutations of the *RET* proto-oncogene in medullary carcinoma of the thyroid (MTC)
- Inherited susceptibility to colon cancer
- Cystic fibrosis (CFTR)
- Hemochromatosis (HFE)
- Retinoblastoma (Rb)
- Von Hippel-Lindau disease (VHL)
- Alpha-thalassemia (alpha globin)
- Hemoglobin E beta thalassemia
- Tay-Sachs disease (HXA (hexosaminidase A))
- Gaucher disease (GBA (acid beta glucosidase))
- Niemann-Pick disease (NPC1, NPC2 (sphingomyelin phosphodiesterase))
- Sickle cell anemia (SCA)
- Canavan disease (ASPA (aspartoacylase A))
- Multiple endocrine neoplasia type 2
- Factor V Leiden thrombophilia (F5 (Factor V))
- Congenital profound deafness (GJB2)
- Myotonic muscular dystrophy (DMPK, ANF-9)
- Hypertonic cardiomyopathy (HCM)
- Fragile X syndrome (FXS)
- Amyotrophic lateral sclerosis (ALS)
- Long QT Syndrome (LQTS)
- Acute Myelogenous Leukemia (AML)
- Multiple Myeloma (MM)
- Hodgkin Lymphoma (HL)

CommunityCare Does *Not* Reimburse

Genetic testing is not covered specifically for the following or any other indication that does not meet medical necessity guidelines:

- Genetic testing for the purposes of screening except as medically indicated for certain cancers and heritable diseases listed under "Community Care Reimburses"
- Genetic testing for family planning, to determine the sex of a fetus, or paternity.
- Genetic testing for diagnosis or risk assessment of Alzheimer's Disease
- Genetic testing for mutations associated with Malignant Melanoma susceptibility
- Genetic testing for Developmental Delay, Autism Spectrum Disorders and/or Mental Retardation.
- Genetic testing primarily for the medical management of other family members who are not covered under a CommunityCare benefit plan.
- Direct to consumer genetic testing (mail order, internet ordering, over-the-counter kits, etc.)
- Genetic counseling performed in conjunction with non-covered genetic testing.
- Genetic testing related to infertility, pre-implantation testing of embryos, previous unexplained stillbirth or recurrent first trimester miscarriages.
- Genetic testing that is not a covered benefit of the member contract.

In addition, the following tests are not eligible for reimbursement due to the lack of scientific evidence to support any positive affect on clinical outcomes:

- OncoVue Testing
- ResponseDX: Lung, ResponseDX: Colon, ResponseDX: Gastric
- TZAM Diagnostics Multiplex PCR for detection of H. pylori.
- Oncotype DX Colon Cancer Test
- Genotyping for Cytochrome P450 polymorphisms (tests to identify specific genetic variations that may be linked to reduced/enhanced effect or severe side effects of drugs including, but not limited to, Warfarin, tamoxifen, proton pump inhibitors, clopidogrel, selective serotonin reuptake inhibitors and other antidepressants or antipsychotics.)

Provider Billing Guidelines

CommunityCare expects the appropriate CPT or HCPCS code(s) specific to the service(s) provided to be reported. . If no specific code exists for the lab service provided, the appropriate unlisted or unspecified code should be reported. CPT codes and modifiers should be used in accordance with CPT coding guidelines. CommunityCare does not expect to receive HCPCS "S" codes reported for these services. All services may be subject to coding or medical necessity review.

For verification of services, CommunityCare requires providers to identify genetic lab services reported with unlisted or unspecified codes by one of the following methods:

- Identification of the test / assay name in the description field of the claim form, and/or
- Medical records and/or lab reports

Related Policies

CPT & HCPCS Level II Modifiers Policy
Authorization Policy
Coding Overview Policy