Regence Oregon and Utah | Regence Idaho and select counties of Washington

Medical Policy Manual

Topic: Genetic and Molecular Diagnostic Testing

Date of Origin: September 15, 1999

Section: Genetic Testing

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Genetic testing is performed to detect changes in DNA, RNA, chromosomes, proteins, or certain metabolites. A number of molecular diagnostic techniques (described by the molecular diagnostic CPT code range) are used to conduct this analysis.

Genetic testing may be performed for several different purposes, including:

- Diagnosing or predicting susceptibility for inherited conditions
- Screening for common disorders
- Selecting appropriate treatments (also known as pharmacogenetic testing)

Genetic Counseling

Due to the complexity of interpreting genetic test results, patients should receive pre- and post-test genetic counseling from a qualified professional when testing is performed to diagnose or predict susceptibility for inherited diseases. The benefits and risks of genetic testing should be fully disclosed to individuals prior to testing, and counseling concerning the test results should be provided.

MEDICAL POLICY CRITERIA

The following general criteria are applied to genetic and molecular diagnostic testing.

I. Genetic Testing for Inherited Diseases

A. Genetic testing to establish a diagnosis or susceptibility for an inherited disease may be **medically necessary** when *all* of the following criteria are met:

1. There must be a reasonable expectation based on family history (pedigree analysis), risk factors, and symptomatology that a genetically inherited condition exists.

2. Diagnostic results from physical examination, pedigree analysis, and conventional testing are inconclusive and a definitive diagnosis is uncertain.

3. The clinical utility of the genetic test must be established. The clinical records must document:

a. How test results will guide decisions regarding: disease treatment, prevention, or management, such as averting treatment for other possible diagnoses, AND

b. These treatment decisions would not otherwise be made in the absence of the genetic test results.

B. Genetic testing to establish a diagnosis or susceptibility for an inherited disease is considered **not medically necessary** if any of criteria I.A.1- I.A.3.b above are not met.

C. Genetic testing of children to predict adult onset diseases is considered **not medically necessary** unless test results will guide current decisions concerning prevention and this benefit would be lost by waiting until the child has reached adulthood.

II. Genetic Testing Not Related to Inherited Conditions

Genetic testing for indications *other than* determining risk or establishing a diagnosis for a genetically inherited disease (e.g., genotyping for drug selection and dosing) may be considered **medically necessary** when *all* of the following criteria are met:

A. Diagnostic results from physical examination and conventional testing are inconclusive; and

B. The clinical records document how results of genetic testing are necessary to guide treatment decisions; and

C. There is reliable evidence in the peer-reviewed scientific literature that health outcomes are improved as a result of treatment decisions based on molecular genetic test results.

REFERENCES[1,2]

1. Williams, MS. Genetics and managed care: Policy statement of the American College of Medical Genetics. *Genet Med*. 2001 Nov-Dec;3(6):430-5. PMID: 11715009
2. Holtzman, NA, Watson, MS. Promoting safe and effective genetic testing in the United States. Final report of the Task Force on Genetic Testing. *J Child Fam Nurs*. 1999 Sep-Oct;2(5):388-90. PMID: 10795196

CROSS REFERENCES

None. See Genetic Testing section, for separate policies on specific genetic tests.

CODES	NUMBER	DESCRIPTION
CPT	81200 – 81479	Molecular pathology code range
HCPCS	G0452	Molecular pathology procedure; physician interpretation and report
	S3800	Genetic testing for amyotrophic lateral sclerosis (ALS)
	S3840	DNA analysis for germline mutations of the RET proto-oncogene for susceptibility to multiple endocrine neoplasia type 2
	S3841	Genetic testing for retinoblastoma
	S3842	Genetic testing for Von Hippel-Lindau disease
	S3844	DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound deafness
	S3845	Genetic testing for alpha thalassemia
	S3846	Genetic testing for hemoglobin E beta-thalassemia
	S3849	Genetic testing for Niemann-Pick disease
	S3850	Genetic testing for sickle cell anemia
	S3853	Genetic testing for muscular dystrophy
	S3861	Genetic testing, sodium channel, voltage-gated, type V, alpha subunit (SCN5A) and variants for suspected Brugada syndrome
	S3865	Comprehensive gene sequence analysis for hypertrophic cardiomyopathy
	S3866	Genetic analysis for a specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family