TRICARE Policy Manual 6010.63-M, April 2021

Pathology And Laboratory

Chapter 6

Section 3.1

Genetic Testing And Counseling

Issue Date: March 10, 2000

Authority: 32 CFR 199.4(a)(1)(i)

Revision: C-24, October 31, 2024

1.0 DESCRIPTION

Genetic testing includes tests that are intended to be confirmatory of a clinical diagnosis which is already suspected based on the patient's symptoms or risk status. Additionally, genetic tests may be performed to aid in the treatment of a disease or they may influence the medical management of the individual or pregnancy. Under the family planning benefit, genetic testing may also be performed in certain high risk individuals and pregnancies.

2.0 POLICY

2.1 Genetic counseling provided by an otherwise authorized provider is covered.

2.2 Genetic tests that have received United States (US) Food and Drug Administration (FDA) medical device 510(k) clearance or premarket approval that are medically necessary for the diagnosis and treatment of an illness or injury and have demonstrated clinical utility are a TRICARE benefit.

Note: Non-FDA approved genetic tests that are covered under the Defense Health Agency (DHA) Evaluation of Non-FDA Approved Laboratory Developed Tests (LDTs) Demonstration Project may be found in the TRICARE Operations Manual (TOM), Chapter 18, Section 3 .

- For preconception and prenatal carrier screening tests, see Chapter 6, Section 3.2 .

2.3 Coverage of FDA approved genetic tests that represent a preventive service (e.g., Cologuard™) must be based on recommendations from the US Department of Health and Human Services (HHS). This includes recommendations from the United States Preventive Services Task Force (USPSTF) and the Health Resources and Services Administration (HRSA). (See Chapter 7, Sections 2.1 and 2.2 .)

2.4 Genetic counseling services shall be billed using the appropriate Evaluation and Management (E/M) codes.

2.5 FDA-approved tests used for an on-label indication as a companion diagnostic may be cost-shared under this paragraph when the companion diagnostic test is required prior to, or during, otherwise-covered pharmacologic therapy.

3.0 EXCLUSIONS

3.1 Genetic testing that is not medically necessary and does not influence the beneficiary's medical management including, but not limited to: the Agendia® Breast Cancer Test Suite (MammaPrint®, TargetPrint® and BluePrint® tests) and, the 23andMe Personal Genome Service (PGS) test.

3.2 Current Procedural Terminology (CPT) code 96040 medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family, as this code is limited to genetic counselors that are not recognized as TRICARE authorized providers.

3.3 FDA approved tests that represent preventive services that are not recommended by HHS.

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