DECISIONDx BIOMARKER TESTS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

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Description:

DecisionDx tests by Castle Biosciences, Inc. are proprietary biomarker based molecular diagnostic assays that are being investigated to assist in risk stratification for individuals with orphan cancers.

DecisionDx biomarkers under investigation to predict response to treatment include DecisionDx-UM for uveal melanoma, DecisionDx-LGG and DecisionDx-G-CIMP for gliomas, DecisionDx-Thymoma, DecisionDx-EC for esophageal LGG, DecisionDx-LEA for esophageal adenocarcinoma, DecisionDx-GBM for glioblastoma multiforme and DecisionDx-Melanoma. These tests have been investigated to predict which individuals are most likely to respond to first line standard of care treatment and have best overall survival. Studies are underway to identify and develop optional therapies for those least likely to respond to therapy.
DECISIONDx BIOMARKER TESTS (cont.)

Criteria:

- DecisionDx biomarkers to predict outcomes to treatment are considered experimental or investigational based upon:
  
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These biomarkers include, but are not limited to:

- DecisionDx-EC
- DecisionDx-GBM
- DecisionDx-G-CIMP
- DecisionDx-LEA
- DecisionDx-LGG
- DecisionDx-Melanoma
- DecisionDx-Thymoma
- DecisionDx-UM

Resources:


DECISIONDx BIOMARKER TESTS (cont.)

**Resources:** (cont.)


