Medical Coverage Policy
Policy Number – MP24-040E
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Companion diagnostics

Background

Companion diagnostics tests are genomic tests that use an individual's specific genetic makeup, or tumor genetic profile, to help determine response to a specific medication. These tests might analyze a specific gene or have a multi-panel approach to look at several genetic markers at the same time. The multi-panel tests can be targeted (specific types of genes or a genetic pathway) or open.

Companion diagnostic tests are typically FDA approved.

Policy statement

Disclaimer: This policy is applicable to TRICARE Prime and Select beneficiaries and may not apply to Active Duty Service Members (ADSM) under Supplemental Health Care Program (SHCP) or TRICARE Prime Remote (TPR) in accordance with TRICARE Operations Manual (TOM) Chapter 17, Section 3. Please review TOM Chapter 17, Section 3, Paragraph 2.0 onwards, regarding SHCP coverage and any TRICARE-specific exclusions included in this coverage policy to accurately determine the benefit for ADSMs.

Nucleic acid tests designated as companion diagnostics, may be approved if all the following criteria are met:

I. Test is listed as a designated FDA-approved companion diagnostic test on the following list: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) | FDA
II. Test is being done to determine eligibility for specific medication only
III. Pharmacologic therapy being considered is eligible for cost-share
IV. Pharmacologic therapy being considered will be used for an on-label indication only

Limitations of coverage

I. Multi-gene panel testing may not be covered for any other indications as there is insufficient evidence of clinical efficacy
II. Certain tests and codes may be excluded from coverage based on government payment restrictions

TRICARE Policy Chapter 6, Section 3.1
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.

References

1. FDA fda.gov
2. TRICARE Policy Manual Chapter 6, Section 3.1 TRICARE Manuals - Display Chap 6 Sect 3.1 (Change 135, Sep 26, 2024) (health.mil)

Approved by:

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