BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual

Approved Revised: Do Not Implement Until 7/31/25

Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies

DESCRIPTION

Expanded molecular or genetic panel testing has been proposed as a method to evaluate many genetic markers at a single time to identify chemotherapeutic agents that target specific pathways when the individual has failed to respond to standard therapy. For instance, comprehensive genomic profiling is recommended for individuals with non-small cell lung cancer to identify rare driver mutations to ensure these individuals receive the most appropriate treatment. There are a wide variety of commercially available expanded panel kits available. The following list contains examples of expanded genetic panels:

- FoundationOne®CDx analyzes 236 cancer-related solid tumor genes (e.g., lung, breast, colon, gastrointestinal, pancreatic, head and neck, ovarian, or thyroid cancers)
- FoundationOne® Heme test analyzes 406 hematologic cancer-related genes
- OnkoMatch™ detects 68 genetic mutations associated with solid tumors
- GeneTrails™ Solid Tumor Panel analyses 37 genes mutations in solid tumors
- SmartGenomics™ analysis of 62 cancer-associated genes for hematologic cancers and solid tumors
- Guardant360® panel analyzes 68 genes associated with solid tumors
- Caris Life Sciences offers individual tumor profiling services that analyzes of up to 56 tumor-associated genes
- Paradigm Cancer Diagnostic (PcDx™) Panel

POLICY

- The use of expanded cancer mutation panels or broad molecular profiling for selecting targeted cancer treatment is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- The use of expanded cancer mutation panels or broad molecular profiling for selecting targeted cancer treatment for all other indications is considered ***investigational***.

MEDICAL APPROPRIATENESS

- Molecular testing using expanded cancer mutation panels or broad molecular profiling is considered **medically appropriate** if **ANY ONE** the following are met:

    - Individual has a diagnosis of non-small cell lung cancer and **ALL** of the following:
        - The expanded panel test must include the EGFR, ALK, ROS1, KRAS, MET, NTRK, RET, ERBB2 and BRAF mutation testing
    - Individual has a diagnosis of colon and/or rectal cancer with suspected or proven metastasis and **ALL** of the following:
        - The expanded panel test must include the KRAS, NRAS, BRAF V600E, HER2 amplifications, and MMR or MSI status (if not previously done) mutation testing

IMPORTANT REMINDERS

This document has been classified as public information.

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits, or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

SOURCES

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