PriorityHealth

MEDICAL POLICY
No. 91609-R2

MULTI-MARKER TUMOR PANELS

Effective Date: July 1, 2018	**Review Dates: 11/14, 11/15, 11/16, 5/18, 2/19**
Date Of Origin: November 12, 2014	**Status: Current**

Summary of Changes

Clarification

- Pg. 5, Section VI: CPT code 0037U is covered for all products except for Medicaid.

I. POLICY/CRITERIA

Coverage of multi-marker tumor panels using next generation sequencing in the diagnosis and treatment of cancer requires prior authorization by eviCore with criteria A, B, and C as follows:

A. Patients with one or more of the following conditions may be eligible for multi-marker tumor panel testing via next-generation sequencing (NGS):

1. Patients with a new diagnosis of stage IV non-small cell lung cancer (NSCLC).
2. Patients with a new diagnosis of cancer of unknown primary (CUP).
3. Patients with a new diagnosis of a hematologic malignancy associated with a high frequency of actionable mutations.
4. Patients with a new diagnosis of Stage IV rare solid tumors for whom very limited or no systemic treatment exists in clinical care guidelines and/or pathways.
5. Patients with a new diagnosis of Stage IV solid tumor types having poor prognosis, very limited benefit from standard of care chemotherapies and actionable mutations.
6. Patients with stage IV solid tumors who have exhausted the established guideline-driven systemic therapy and requisite molecular testing but who desire further treatment.
7. Patients with one of the above diagnosis (A1-A6) for whom tissue to perform evidence-based tumor genome mutation analysis is not available.

B. General requirements

All of the following conditions are met:

1. Pathologic diagnosis consistent with categories A1-A7 above
2. ECOG performance status 0-2

3. Submission by the treating physician of all pathology, imaging, and treatment notes as well as ACP consultation notes (if applicable per criteria C1).
4. Service is requested from a contracted provider.

C. Both of the following specific requirements must be met for conditions A4-A6:
   1. Advance care planning (ACP) completed with a trained facilitator or a palliative care physician.
   2. Patients must attest that they would be willing to consider participation in a clinical trial if the analysis identifies relevant clinical trials.

Definitions for purposes of this policy:

New diagnosis: identified within the last two months or a new primary site

Rare cancer: as documented by the National Institutes of Health, Genetic and Rare Diseases @ https://rarediseases.info.nih.gov/diseases/diseases-by-category/1/rare-cancers

Actionable mutation: a targeted therapy is available for the mutation

II. COVERAGE FOR DRUG THERAPY RECOMMENDED BY NEXT GENERATION SEQUENCING TESTS

Multi-marker tumor panels using next-generation sequencing analyses are intended to link actionable mutations with specific drugs to personalize therapy. While some mutations have known corresponding drug therapies in specific tumor types or may identify relevant clinical trials for which the patient may be eligible, these analyses will identify mutations for which there is insufficient evidence to confer coverage for a specific drug.

For example, targeted therapy for patients with melanoma who have a V600E BRAF mutation, several drugs have been shown to improve outcomes. However, for the same mutation in colon cancer, no benefit is realized and there are no FDA approved or NCCN recommended therapies.

Coverage for drug therapy recommended by next-gen sequencing results will be consistent with existing pharmacy coverage policy as outlined below.

A. To be covered, the prescribed drug(s) must meet one of the following three criteria:
   1. FDA approved indication
   2. Listing in one of the following drug compendium
      a. The American Hospital Formulary Service Drug Information

   b. Thomson Micromedex DrugDex or DrugPoints
   c. The National Comprehensive Cancer Network (NCCN) Guidelines.
   d. Clinical Pharmacology
3. Provider submission of at least two peer-reviewed journal articles
   a. whose primary purpose is to evaluate the use of the drug for the off-label diagnosis for which it is requested, and
   b. that support the proposed off-label use as generally safe and effective for the patient's diagnosis. *(Policy 11-0022 Documentation Required for Off-Label Use of Drugs)*

B. In circumstances where the patient is eligible for a clinical trial, Priority Health will cover the cost of the clinical trial as outlined in the coverage policy *Clinical Trials - 91606*.

C. In all other circumstances, therapies recommended by next-generation sequencing testing either alone or in combination would not be covered, even under coverage policy *Experimental/Investigational/Unproven Care/Benefit Exceptions - 91117*, This coverage decision is consistent with The State of Michigan "Right to Try Act."

Exception: For commercial members only, Priority Health would cover ongoing drug therapy with an experimental agent outside of a clinical trial if the patient:
1. successfully completes three months of drug therapy, ***AND***
2. maintains performance status, ***AND***
3. demonstrates either
   a. a clinically significant reduction in a relevant tumor biomarker during that time, ***OR***
   b. at least partial tumor regression by RECIST criteria (http://www.recist.com/index.html) or by Immune-Related Response Criteria http://clincancerres.aacrjournals.org/content/15/23/7412.long)

There are no exceptions for Medicare beneficiaries. However, beneficiaries have the right to appeal any denial.

III. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required ☐ Not Applicable

☒ All tests performed at non-participating laboratories will require prior authorization for all products.

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

V. BACKGROUND

Next-generation sequencing of patient tumors to personalize cancer treatment has been endorsed by the National Comprehensive Cancer Network (NCCN) for non-small cell lung cancer. However, several factors warrant consideration of this standard in selected patients and selected tumor types outlined in this policy. First, the Accountable Care Act requires health plans to cover phase 1 through phase 4 clinical trials. Second, the NCCN recommends clinical trials as the standard of care even when other options exist. Third, as noted above, eligibility for ACA-eligible cancer clinical trials is often determined by emerging biomarkers. Fourth and most importantly, for certain malignancies, there remains a high unmet need and limited therapeutic options. In the circumstances outlined in this policy, Priority Health will cover next generation sequencing to provide additional insights into the therapeutic options available to patients and their physicians.

VI. CODING INFORMATION

ICD-10 Codes: *not specified*

CPT/HCPCS Codes:

81445 Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis and RNA analysis when performed, 5-50 genes (e.g., ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed

81450 Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis and RNA analysis when performed, 5-50 genes (e.g., BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed *(Not covered for Medicaid)*

81455 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed *(Not covered for Medicaid)*

0037U Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, and microsatellite instability and tumor mutational burden (Not *covered for Priority Medicaid)*

-- Applies to proprietary test: FoundationOne CDx™ (F1CDx) by Foundation Medicine, Inc.

For full coverage information of molecular diagnostic test codes see policy:
91540 Genetics Counseling Testing Screening

VII. REFERENCES

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National Comprehensive Cancer Network guidelines for non-small cell lung cancer. (http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf version 4.2014

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