Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP323

Section: Medical Benefit Policy

Subject: Molecular Profiling of Malignant Tumors to Identify Targeted Therapies

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Molecular Profiling of Malignant Tumors to Identify Targeted Therapies

II. Purpose/Objective:

To provide a policy of coverage regarding Molecular Profiling of Malignant Tumors to Identify Targeted Therapies

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for

Members of the same age

DESCRIPTION:
Molecular profiling is a method for identifying multiple biomarkers in the malignant tumors of persons who have cancer. The biomarker information can be used to identify treatment options.

INDICATIONS:

REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

FoundationOne, Foundation One CDx, Memorial Sloan Kettering Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT), or Target Now Molecular Profiling Service Caris Diagnostics) - (Commercial and Medicare Business Segments), Guardant 360 TissueNext

Molecular profiling to identify targeted therapies utilizing one of the following tests: **FoundationOne, Foundation One CDx, Guardant 360 TissueNext, Memorial Sloan Kettering Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT), or MI Profile and MI Tumor Seek (Caris Diagnostics)** will be considered medically necessary when **all of the following** criteria are met:

- A diagnosis of recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer has been established; **and**
- A decision has been made to seek further cancer treatment, such as therapeutic chemotherapy; **and**
- The member has not been previously tested using the same NGS test for the same primary diagnosis of cancer without evidence of progression;
- The test is being used:
    - To establish eligibility for checkpoint inhibition immunotherapy including but not limited to Bavencio (avelumab), Imfinzi (durvalumab), Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab), Yervoy (ipilimumab); **and/or**
    - As a companion diagnostic for drugs including but not limited to: Alecensa (alectinib), Cotellic (cobimetinib) in combination with Zelboraf (vemurafenib), Erbitux (cetuximab), Gilotrif (afatinib), Herceptin (trastuzumab), Iressa (gefitinib), Kadcyla (ado-trastuzumabemtansine), Mekinist (trametinib), Perjeta (pertuzumab), Rubraca (rucaparib), Tarceva (erlotinib), Tafinlar (dabrafenib), Tafinlar (dabrafenib) in combination with Mekinist (trametinib), Tagrisso (osimertinib), Vectibix (panitumumab), Xalkori (crizotinib), Zelboraf (vemurafenib), Zykadia (ceritinib)

FoundationOne Liquid CDx: (Commercial and Medicare Business Segments)

FoundationOne Liquid CDx circulating tumor cell free DNA (cfDNA) molecular profiling testing is considered to be medically necessary at diagnosis or progression for the following indications when the criteria are met:

1. FoundationOne Liquid CDx is considered to be medically necessary to identify single gene alterations, rearrangements and copy-number alterations including all NTRK fusions, in all solid tumors; or.

2. A diagnosis of non-small cell lung cancer is suspected but the member's physical condition poses unacceptable risk for invasive biopsy; **or**
   A diagnosis of non-small cell lung cancer has been confirmed on pathology, but insufficient tumor sample is available for molecular testing;

   and

   The treating physician will use the results to guide therapy

   or
3. FoundationOne Liquid CDx is considered to be medically necessary as a companion diagnostic test for the PARP inhibitor rucaparib (Rubraca) in metastatic castration-resistant prostate cancer patients with BRCA mutations, and three EGFR inhibitors for the first-line treatment of non-small cell lung cancer (NSCLC) in patients with certain EGFR mutations -- gefitinib (Iressa), osimertinib (Tagrisso), and erlotinib (Tarceva).

FoundationOne Heme: (Commercial and Medicare Business Segments)

- The member has a diagnosis of AML, MDS or MPN. AML, MDS and MPN are herein classified as refractory and/or metastatic cancers and fulfil the NCD 90.2 criteria.

- The test has satisfactorily completed a TA by MolDX® for the stated indications of the test.
- The assay performed includes at least the minimum genes and positions indicated for its intended use, as described in an associated coverage Article or found in the TA forms.
- For members that do not have a diagnosis of a myeloid malignancy, where one is suspected, the member must have an undefined cytopenia for greater than 4 months, other possible causes have been reasonably excluded.
- Testing is performed on bone marrow biopsies, bone marrow aspirates, bone marrow clots, peripheral blood samples, or extramedullary sites suspected of harboring a myeloid malignancy.

Guardant360 and Guardant360CDx: (Commercial)

Molecular profiling to identify targeted therapies utilizing Guardant360 CDx will be considered medically necessary for any the following indications when criteria are met:

1. Guardant360 and Guardant360CDx is considered medically necessary to provide information biomarkers in all solid tumors
    - The member is a candidate for further treatment with a drug that is either FDA-approved for that cancer, or has an NCCN 1 or NCCN 2A recommendation for that cancer, or
    - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360 or Guardant360 CDx assay

For the MEDICARE BUSINESS SEGMENT:

Guardant360 and Guardant360 CDx is covered when the member:
- has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system, **and**
- is untreated for the primary cancer being tested, or is not responding to treatment, **and**
- has decided to seek further cancer treatment with the following conditions:
    - The member is a candidate for further treatment with a drug that is either FDA-approved for that cancer, or has an NCCN 1 or NCCN 2A recommendation for that cancer, **and**
    - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360 CDx assay

OncoExTra (Commercial and Medicare)

OncoExTra is considered medically necessary for any the following indications when criteria are met:
- The member is diagnosed with an unresectable or metastatic solid tumor(s); and
- The test is used to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy;

  and
- The member has progressed following prior treatment

EXCLUSIONS:
The Plan currently considers the use of molecular profiling tests such as, but not limited to EXaCT-1 Whole Exome Sequencing, GeneKey, GeneTrails Solid Tumor Panel, MatePair, MyAML, OmniSeq, OnkoMatch, OncInsights, and SmartGenomics to be **experimental, investigational or unproven** and **NOT COVERED.** At this time, published, peer-reviewed, medical literature to support the use of these tests is limited and insufficient to establish their analytical validity or clinical utility.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Molecular Profiling of Malignant Tumors
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS

Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

81445 Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, 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 *[Signatera]*

81449 targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements,

81450 Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis *[NeoTYPE Myeloid Disorders Profile, OncoHeme Next-Generation Sequencing for Myeloid Neoplasms, Onkosight Myeloid Disorder Panel]*

81455 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis *[FoundationOne Heme, MI Profile, OmniSeq, OnkoSight, Tempus|xT, FoundationOne Heme]*

81456 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis

0013U Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s) [*MatePair Targeted Rearrangements*]

0014U Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s) [*MatePair Targeted Rearrangements*]

0334U Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden (Guardant360 TissueNext™)

0036U Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses [*EXaCT-1 Whole Exome Testing*]

0037U Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden [*FoundationOne CDx (F1CDx)]*

0048U Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s) *[MSK-IMPACT (Memorial Sloan Kettering Integrated Mutation Profiling of Actionable Cancer Targets*)]

0050U Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements [*MyAML NGS Panel*]

0056U Hematology (acute myelogenous leukemia), DNA, whole genome next generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s) [*MatePair Acute Myeloid Leukemia Panel*]

0179U Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s) **(Non-covered for Medicare per A57867)**

0211U Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association *[MI Cancer Seek- Caris]*

0239U Targeted genomic sequence analysis panel 311 genes [*FoundationOne® Liquid CDx*]

0242U Targeted genomic sequence analysis panel 55-74 genes [*Guardant360® CDx*]

0326U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden [*Guardant360 LDT panel*]

0329U Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor mutational burden and microsatellite instability, utilizing formalin-fixed paraffin embedded tumor tissue [*OncoExTra*]
0334U Oncology (solid organ) targeted genomic sequence analysis, formalin-fixed paraffin embedded (FFEP) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden *[Guardant360 Tissue Next]*
0409U Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
Centers for Medicare and Medicaid Services (CMS). Decision memo for next-generation sequencing (NGS) for Medicare beneficiaries with advanced cancer. CAG-00450N. March 16, 2018.

MolDx LCD L37649 Guardant360® Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLC)

NCCN Clinical Practice Guidelines in Oncology. Colon cancer v1.2022

NCCN Clinical Practice Guidelines in Oncology. Non-small cell lung cancer v3.2022

U.S. Food & Drug Administration. FoundationOne CDx - P170019

Dhir M, Choudry HA, Holtzman MP, et al. Impact of genomic profiling on the treatment and outcomes of patients with advanced gastrointestinal malignancies. Cancer Med. 2017; 6(1):195-206

Gong J, Cho M, Sy M, et al. Molecular profiling of metastatic colorectal tumors using next-generation sequencing: a single-institution experience. Oncotarget. 2017; 8(26):42198-42213

Cheng DT, Mitchell TN, Zehir A, et al. Memorial Sloan Kettering-Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT): a hybridization capture-based next-generation sequencing clinical assay for solid tumor molecular oncology. J Mol Diagn. 2015; 17(3):251-264.

Le Tourneau C, Delord JP, Gonçalves A, et al.; SHIVA Investigators. Molecularly targeted therapy based on tumour molecular profiling versus conventional therapy for advanced cancer (SHIVA): a multicentre, open-label, proof-of-concept, randomised, controlled phase 2 trial. Lancet Oncol. 2015; 16(13):1324-1334

Presley CJ, Tang D, Soulos PR, et al. Association of broad-based genomic sequencing with survival among patients with advanced non–small cell lung cancer in the community oncology setting. JAMA. 2018; 320(5):469–477.

Hilal T, et al. Comprehensive genomic profiling in routine clinical practice leads to a low rate of benefit from genotype-directed therapy. BMC Cancer 2017 Aug 30;17(1):602.

Hellmann MD, Ciuleanu TE, Pluzanski A, et al. Nivolumab plus ipilimumab in lung cancer with a high tumor mutational burden. N Engl J Med. 2018; 378(22):2093-2104

Mandelker D, Zhang L, Kemel Y, et al. Mutation detection in patients with advanced cancer by universal sequencing of cancer-related genes in tumor and normal DNA vs guideline-based germline testing. JAMA. 2017; 318(9):825-835

Lanman RB, Mortimer SA, Zill OA, et al. Analytical and clinical validation of a digital sequencing panel for quantitative, highly accurate evaluation of cell-free circulating tumor DNA. PloS One. 2015;10(10):e0140712

Rozenblum AB, Ilouze M, Dudnik E, et al. Clinical impact of hybrid capture-based next-generation sequencing on changes in treatment decisions in lung cancer. J Thorac Oncol Off Publ Int Assoc Study Lung Cancer. 2017;12(2):258-268.

Coyne G, et al. Defining precision: the precision medicine initiative trials NCI-IMPACT and NCI-MATCH. Curr Probl Cancer 2017; 41(3):182-194.

Vivot A, et al. Pharmacogenomic biomarkers as inclusion criteria in clinical trials of oncology-targeted drugs: a mapping of ClinicalTrials.gov. Genet Med. 2016 Aug;18(8):796-805.

Tsimberidou AM. Initiative for molecular profiling and advanced cancer therapy and challenges in the implementation of precision medicine. Curr Probl Cancer 2017 May - Jun;41(3):176-181.

Thompson JC, Yee SS, Troxel AB, et al. Detection of therapeutically targetable driver and resistance mutations in lung cancer patients by next-generation sequencing of cell-free circulating tumor DNA. Clin Cancer Res Off J Am Assoc Cancer Res. 2016;22(23):5772-5782

Aggarwal C, Thompson JC, et al. Clinical Implications of Plasma-Based Genotyping With the Delivery of Personalized Therapy in Metastatic Non–Small Cell Lung Cancer. JAMA Oncol. doi:10.1001/jamaoncol.2018.4305

Lindeman NI, Cagle PT, Aisner DL, et al. Updated molecular testing guideline for the selection of lung cancer patients for treatment with targeted tyrosine kinase inhibitors: Guideline from the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. Arch Pathol Lab Med. 2018; 142(3):321-346

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)

McCoach CE, Blakely CM, Banks KC, et al. Clinical utility of cell-free DNA for the detection of ALK fusions and genomic mechanisms of ALK inhibitor resistance in non-small cell lung cancer. Clin Cancer Res. 2018;24(12):2758-2770.

Villaflor V, Won B, Nagy R, et al. Biopsy-free circulating tumor DNA assay identifies actionable mutations in lung cancer. Oncotarget. 2016;7(41):66880-66891.

Dagogo-Jack I, Fabrizio D, Lennerz J, et al. Circulating tumor DNA identifies EGFR coamplification as a mechanism of resistance to crizotinib in a patient with advanced MET-amplified lung adenocarcinoma. J Thorac Oncol. 2017;12(10):e155-e157.

Heerink WJ, de Bock GH, de Jonge GJ, Groen HJ, Vliegenthart R, Oudkerk M. Complication rates of CT-guided transthoracic lung biopsy: meta-analysis. Eur Radiol. 2017;27(1):138-148.

Kim SB, Dent R, Wongchenko MJ, Singel SM, Baselga J. Concordance between plasma-based and tissue-based next-generation sequencing in LOTUS. Lancet Oncol. 2017;18(11):e638.

Young L, Ali S, Schrock A, et al. Kinase fusions in non-small cell lung carcinoma identified by hybrid capture based ctDNA assay. J Thorac Oncol. 2017;12(1):S524-S525.

Tran HT, Elamin Y, Simon GR, et al. Clinical utilization of a CLIA-certified cell-free DNA (cfDNA) blood test for identification of targetable molecular alterations in patients with non-small cell lung cancer (NSCLC). J Clin Oncol. 2016;34(15 Suppl):e23064.

McGregor BA, Chung J, Bergerot PG, et al. Correlation of circulating tumor DNA (ctDNA) assessment with tissue-based comprehensive genomic profiling (CGP) in metastatic urothelial cancer (mUC). J Clin Oncol. 2018;36(6 Suppl):453.

Rolfo C, Mack PC, Scagliotti GV, et al. Liquid biopsy for advanced non-small cell lung cancer (NSCLC): A statement paper from the IASLC. J Thorac Oncol. 2018;13(9):1248-1268.

Schrock AB, Welsh A, Chung JH, et al. Hybrid capture-based genomic profiling of circulating tumor DNA from patients with advanced non-small cell lung cancer. J Thorac Oncol. 2018;doi:10.1016/

Paik PK, Felip E, et al. Tepotinib in Non–Small-Cell Lung Cancer with MET Exon 14 Skipping Mutations. N Engl J Med 2020 Sep 3;383(10):931-943.

Odegaard JI, Vincent JJ, et al. Validation of a Plasma-Based Comprehensive Cancer Genotyping Assay Utilizing Orthogonal Tissue- and Plasma-Based Methodologies. Clin Cancer Res. 2018 Aug 1;24(15):3539-3549.

Makarem M, Leighl NB. Molecular Testing for Lung Adenocarcinoma: Is It Time to Adopt a “Plasma-First” Approach? Cancer O 2020

Aggerwal C, Thompson JC, et al. Clinical Implications of Plasma-Based Genotyping With the Delivery of Personalized Therapy in Metastatic Non–Small Cell Lung Cancer. JAMA Oncol 2018

MolDX: Next-Generation Sequencing for Solid Tumors (L38119)

MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38043)

MolDx: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047)

MolDx: Targeted and Comprehensive Genomic Profile Next-Generation sequencing Testing in Cancer (A56518)

NCCN Clinical Practice Guidelines in Oncology. Pancreatic Adenocarcinoma v1.2023

NCCN Clinical Practice Guidelines in Oncology. Gastric Cancer v1.2023

NCCN Clinical Practice Guidelines in Oncology. Breast cancer v4.2023

NCCN Clinical Practice Guidelines in Oncology. Esophageal and Esophagogastric Junction Cancers v2.2023

Massard C, Michiels S, Ferté C, et al. High-throughput genomics and clinical outcome in hard-to-treat advanced cancers: Results of the MOSCATO 01 trial. Cancer Discov. 2017 Jun;7(6):586-595.

Belin L, Kamal M, Mauborgne C, et al. Randomized phase II trial comparing molecularly targeted therapy based on tumor molecular profiling versus conventional therapy in patients with refractory cancer: Cross-over analysis from the SHIVA trial. Ann Oncol. 2017 Mar 1;28(3):590-596.

Dy GK, Nesline MK, Papanicolau-Sengos A, et al. Treatment recommendations to cancer patients in the context of FDA guidance for next generation sequencing. BMC Med Inform Decis Mak. 2019 Jan 18;19(1):14.

Seeber A, Chahine G, Nasr F, et al. Treatment according to a comprehensive molecular profiling can lead to a better outcome in heavily pretreated patients with metastatic cancer: Data of a pooled analysis. Cancer J. 2019;25(2):73-79.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/18

Revised: 12/19 (add FoundationOne Liquid); 2/20(Add Medicare Guardant360 indication); 9/20(add indications for Guardant 360CDx and FoundationOne CDx); 6/21 (add indications for Oncotype MAP Pan Cancer); 3/23 (add indications for FoundationOne Heme), 10/23 (revise Guardant360 criteria)

Reviewed: 6/22, 6/23