


MEDICAL POLICY	Circulating Tumor Cell and DNA Assays For Cancer Management (Medicare Only)
Effective Date: 6/1/2021  6/1/2021	Medical Policy Number: 306 Medical Policy Committee Approved Date: 5/2021
Medical Officer Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Notes:

- This policy does not addresses cell-free DNA tests (also known as circulating tumor DNA tests or liquid biopsies) for non-small cell lung cancer. (See [Cross References](#) section below)

Service	Medicare Guidelines
<i>Next-generation sequencing assays performed on solid tumor cell-free DNA in plasma (i.e. liquid biopsies)</i>	<ul style="list-style-type: none"> National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2)¹ Local Coverage Determination (LCD): MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (L38168)² Local Coverage Article: Billing and Coding: Guardant360® (A58214)³ Local Coverage Article: Billing and Coding: MoIDX: Circulating Tumor Cell Marker Assays (A57816)⁴
<i>PIK3CA Gene Tests</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): MoIDX: Molecular Diagnostic Tests (MDT) (L36807)⁵ Local Coverage Article: Billing and Coding: MoIDX: PIK3CA Gene Tests (A55200)⁶

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CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
0229U	BCAT1(Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis
0155U	PIK3CA (phosphatidylinositol-hyphen4,5-hyphenbisphosphate 3-hyphenkinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y)
0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-hyphen4,5-hyphenbisphosphate 3-hyphenkinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status
81309	PIK3CA (phosphatidylinositol-hyphen4, 5-hyphenbiphosphate 3-hyphenkinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)
86152	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)
86153	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.	
81479	Unlisted Molecular Pathology

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

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REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

Medical Policies

- Circulating Tumor Cell and DNA Assays For Cancer Management (All Lines of Business Except Medicare)
- Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (All Lines of Business Except Medicare)
- Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (Medicare Only)
- Genetic Testing: Non-Covered Genetic Panel Tests (Medicare Only)
- Genetic Studies and Counseling

Pharmacy Policies

- Injectable ANTI-Cancer Medications. Antineoplastics, ORPTCONC102
- Oral ANTI-Cancer Medications. Antineoplastics, ORPTCONC103

REFERENCES

1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2). <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372>. Published 2020. Accessed 3/24/2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (L38168). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=38168>. Published 2020. Accessed 3/24/2021.
3. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Guardant360® (A58214). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=58214>. Published 2020. Accessed 3/24/2021.
4. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: Circulating Tumor Cell Marker Assays (A57816). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=57816>. Published 2019. Accessed 3/24/2021.
5. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): MoIDX: Molecular Diagnostic Tests (MDT) (L36807). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36807>. Published 2020. Accessed 4/20/2021.

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6. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: PIK3CA Gene Tests (A55200). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55200>. Published 2020. Accessed 4/20/2021.