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Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Genetic Testing

Appropriate Use Criteria: Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer

Proprietary

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer

Clinical Indications

General Requirements

Repeated testing of the same individual for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing of the same tumor site with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same individual and the same tumor by different providers over a short period of time

Cell-free DNA (ctDNA, Liquid Biopsy) Testing

Individuals with invasive malignancy for whom liquid biopsy is a companion diagnostic test

Liquid (ctDNA) based testing is considered **medically necessary** for individuals with invasive malignancy for whom the liquid biopsy test is a companion diagnostic test described by the U.S. Food and Drug Administration (FDA) as necessary for patient selection, and **BOTH** of the following criteria are met:

- Specific cancer treatment is being considered to correspond with the FDA companion diagnostic indication
- Other somatic tumor testing results do not already provide support for the specific cancer therapy being considered that corresponds to the FDA companion diagnostic indication

Individuals with locally advanced (stage IIIb), recurrent, or metastatic non-small cell lung cancer

Liquid (ctDNA) based testing is considered **medically necessary** for individuals with pathologically confirmed locally advanced (stage IIIb), recurrent, or metastatic non-small cell lung cancer (NSCLC), and **ALL** of the following criteria are met:

- There is insufficient tumor tissue available for NGS-based somatic profiling or for whom tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition
- No prior NGS-based somatic profiling test has previously been performed for this pathological diagnosis of NSCLC
- The test is being used to provide genetic information related to the current set of actionable mutations recognized by ASCO guidelines to inform management at diagnosis or treatment progression on or after chemotherapy or immunotherapy

Individuals with metastatic breast cancer who may benefit from PIK3CA or ESR1-targeted therapy

Liquid (ctDNA) based testing, to include PIK3CA and/or ESR1 somatic tumor testing, is considered **medically necessary** to identify individuals who may benefit from the use of alpelisib or elacestrant, respectively (or other FDA-approved targeted agent) when **ALL** of the following criteria are met:

- The individual is either an adult man OR postmenopausal woman
- The individual has ER-positive and HER2-negative metastatic breast cancer
- The individual is a candidate for an applicable FDA-approved targeted agent
- The individual has not had prior testing for the targeted gene of interest in the metastatic setting
- There is insufficient tumor tissue available for NGS-based somatic profiling or tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition

Individuals with metastatic adenocarcinoma of the prostate who may benefit from a PARP inhibitor or PD-1 inhibitor

Liquid (ctDNA) based testing is considered **medically necessary** for individuals with metastatic adenocarcinoma when **ALL** of the following criteria are met:

- The individual has biopsy-proven adenocarcinoma of the prostate
- The individual has not had prior NGS testing in the metastatic setting
- The individual is a candidate for **ONE** of the following therapies:
    - FDA-approved PARP inhibitor (olaparib, rucaparib, or other approved PARP inhibitor)
    - FDA-approved PD-1 inhibitor (pembrolizumab, or other approved checkpoint inhibitor)
- There is insufficient tumor tissue available for NGS-based somatic profiling or tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition

Rationale

Liquid biopsy refers to diagnostic tests obtained from a blood sample used to inform the management of individuals with cancer. Given that intra-tumoral heterogeneity and tumor evolution contribute to treatment failure in patients with cancer, there has been interest in exploring liquid biopsy for use as an alternative to tissue biopsy in the diagnosis of cancer, for clinical response to targeted agents of cancer treatment, for early cancer detection (i.e., screening) and for cancer surveillance. Cell-free DNA (cfDNA) is defined as DNA that is circulating freely in body fluids, such as blood plasma, and is released from all types of cells. Circulating tumor DNA (ctDNA) refers to fragments of DNA that are released from a tumor and migrate into bodily fluids, such as blood plasma. A liquid biopsy panel is defined as five or more ctDNA genes or gene mutation variants being tested. There are more than a dozen commercially available liquid biopsy panel tests, and the turnaround time varies for this testing but is typically 7-10 days.

For liquid biopsy, preanalytical issues, such as the type of specimen analyzed, procedures of sample collection, handling, processing and storage, and certain patient factors.[1] Use of plasma (rather than serum) is preferred and the type of collection tubes, preservatives in those tubes, and temperature of those tubes for 3-7 days after specimen collection are also important. Moreover, liquid biopsy performance of liquid biopsy varies by patient setting. For example, ctDNA levels are often low or undetectable in patients with a low tumor burden, cancer at specific sites and specific histologies, or tumors that have low levels of proliferation, apoptosis and/or vascularization.[2] Of crucial importance to liquid biopsy is that clonal hematopoiesis of indeterminate potential (CHIP), a phenomenon associated with increasing age, can affect the interpretation of cfDNA results, particularly when low variant-associated fraction (VAF) ctDNAs are identified.[2] Overall, limited data are available regarding the effect of blood draw procedures and potentially confounding patient related factors that may contribute to the release of cell-free DNA.[1] Like other tests for clinical use, the stages of development for liquid biopsy tests include demonstration of analytical validity, clinical validity, and clinical utility. Importantly, clinical utility refers to evidence of clinically meaningful improvements in clinical outcomes (clinical efficacy or reduced toxicity) compared with standard testing methods used to direct patient management.

The most common clinical scenario where use of ctDNA analysis is pursued is for patients with advanced or metastatic non-small cell lung cancer. In the past, ctDNA analysis in advanced/metastatic NSCLC was reserved for the assessment of epidermal growth factor receptor (EGFR) mutational status, either in treatment-naïve patients with insufficient tissue for tumor genotyping or after acquired resistance to 1st/2nd generation EGFR tyrosine-kinase inhibitor treatments. However, there is now evidence to support the clinical use of broad-based platform such as next-generation sequencing (NGS) in genotyping for multiple other actionable oncogene drivers (such as aberrations in EGFR, ALK, ROS1, RET, MET, HER2, KRAS, NTRK, and/or BRAF) in newly diagnosed patients with tumor tissue available for initial genotyping.[3,4] Prospective studies have shown that positive finding on plasma NGS testing are highly concordant with tissue-based NGS test findings, although negative findings in plasma requires further testing.[5, 6] Some guidelines suggest that liquid biopsy can be used in certain clinical settings when tissue testing proves inadequate[7], although the ASCO guidelines found that there is currently insufficient evidence to support the use of this test method routinely for the diagnosis of primary lung adenocarcinoma.[3] More recent data indicate that use of osimertinib (a targeted agent used to treat EGFR mutated NSCLC) in the adjuvant setting for patients with resected stage IB-IIIA NSCLC is associated with clinically significant improvements in overall survival.[8] In this scenario, EGFR testing of tissue specimens can be obtained before surgery or at the time of surgery. While neoadjuvant treatment targeted at EGFR mutations is being explored, it has not been established as effective with major pathological response rates of 15%, which is below the threshold expected.[9]

Another area of keen interest in the application of ctDNA testing is in colorectal cancer where there is exploration of ctDNA in several potential applications to inform clinical decision-making. Prospective studies such as CIRCULATE, COBRA, Dynamic II/III, and ACT3 are underway in the MRD setting to further understand how ctDNA may be used.[10] Data from the Dynamic study, a non-inferiority study featuring use of circulating tumor DNA (ctDNA) to guide adjuvant therapy for stage II colon cancer, have now been published.[11] This is a phase II biomarker-driven multicenter trial that enrolled 455 patients in Australia and New Zealand who were randomly assigned to either ctDNA-guided chemotherapy or standard management, which was clinician-guided based on conventional criteria. The primary endpoint was recurrence-free survival (RFS) at 2 years with a non-inferiority design that involved a large 8.5% margin to still be considered non-inferior. Predictably, the relapse-free survival rate was low and non-inferior in both study arms. The putative advantage to the ctDNA guided therapy was that the proportion of patients who needed to be treated with adjuvant chemotherapy compared to standard management decreased (15.3% vs. 27.9%). But the most striking caveat is that the risk of getting exposed to oxaliplatin-containing adjuvant chemotherapy (with its risk of chemotherapy-related peripheral neuropathy) tripled. There is a 2.7% risk of oxaliplatin exposure in the standard arm vs. 9.5% risk in the ctDNA arm. Therefore, this innovation does not produce better cancer treatment outcomes, and it increases the exposure to the drug most worthy of avoiding in this setting. The predictable early reaction of oncologists to this data was that ctDNA positive patients should be treated but that also ctDNA negative patients with T4 tumors who mismatch-repair proficient should also still be treated (consistent with ASCO guidelines Accounting for this likely set of actions, the net result of adding ctDNA testing for stage II colon cancer patients will be increased exposure to oxaliplatin-containing chemotherapy and little or no real world decrease in total use of adjuvant chemotherapy. Thus, it remains unclear whether use of ctDNA testing will produce net clinical benefit for this patient population.

Finally, there is also interest in the use of ctDNA testing for cancer screening. For example, use of the Galleri test (a type of circulating cell-free DNA test) has been studied in the Pathfinder study, a prospective interventional trial.[12] The premise is that a methylation assay applied to the cfDNA samples is highly informative as a signal for cancer detection and tissue of origin localization. The primary objectives (intermediate endpoints) of the Pathfinder study are the per participant count of the number and types of diagnostic tests required to achieve diagnostic resolution following a "signal detected" multi-cancer early detection test result, and also the per participant time required to achieve diagnostic resolution following a "signal detected" multi-cancer early detection test result.[12] These data have not yet been presented. Cancer screening studies require data to show that the benefits in terms of deaths avoided outweigh various harms of overdiagnosis and overtreatment that can occur based on the screening.[13]

References

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Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

May Be Medically Necessary When Criteria are Met

Code	May Be Medically Necessary When Criteria are Met
81462	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements
81463	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability
81464	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements
81479	Unlisted molecular pathology procedure
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)
0239U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations
0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements
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

Not Medically Necessary

Code	Not Medically Necessary
0007M	Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index
0229U	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis

Code	Not Medically Necessary
0285U	Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score - RadTox™ cfDNA test
0306U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient-specific panel for future comparisons to evaluate for MRD
0307U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD
0333U	Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in high-risk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gammacarboxy-prothrombin (DCP), algorithm reported as normal or abnormal result
0340U	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate
0388U	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection.
0405U	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected
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
0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected
0422U	Oncology (pan-solid tumor), analysis of DNA biomarker response to anti-cancer therapy using cell-free circulating DNA, biomarker comparison to a previous baseline pre-treatment cell-free circulating DNA analysis using next-generation sequencing, algorithm reported as a quantitative change from baseline, including specific alterations, if appropriate
0428U	Oncology (breast), targeted hybrid-capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden
0453U	Oncology (colorectal cancer), cell free DNA (cfDNA), methylation-based quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

History

Status	Review Date	Effective Date	Action
Updated codes 07/01/2024	n/a	Unchanged	Added CPT code 0453U (NMN).
Revised	07/18/2023	03/17/2024	Independent Multispecialty Physician Panel (IMPP) review. Replaced "contraindicated" with "unsafe or infeasible" for clarification of tissue biopsy. Added references. Removed CPT codes 81327 (NMN) and 0397U (MNWCM). Moved 0326U to MNWCM list. Added required language per new Medicare regulations.
Updated	n/a	01/01/2024	Annual CPT code update: Added 81462, 81463, and 81464. NMN codes: Added 0422U, 0428U; Removed 0011M, 0356U, 0368U.
Revised	04/12/2023	11/05/2023	IMPP review. Expanded on ESR1 ctDNA testing, per the FDA. Specified FDA approval of PARP and PD-1 inhibitors for treating individuals with metastatic prostate adenocarcinoma. Additional edits for clarity.
Updated	n/a	10/01/2023	Added new CPT codes 0368U, 0405U, 0409U, and 0410U. Added CPT codes 81327, 0007M, 0011M, 0229U, 0285U, 0333U, 0340U (moved from Somatic Tumor Testing guidelines).
Created	09/21/2022	02/12/2023	IMPP review. Original effective date.