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## Proposed Local Coverage Determination (LCD): MoIDX: GUARDANT360® Plasma-Based Comprehensive Genomic Profiling in Solid Tumors (DL38043)

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Section Navigation

# Proposed LCD

### Please Note: This is a Proposed policy.

Proposed LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed LCDs are not necessarily a reflection of the current policies or practices of the contractor.

### - Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=391&amp;ver=1)</a>	A and B MAC	10111 - MAC A	J - J	Alabama
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=394&amp;ver=1)</a>	A and B MAC	10112 - MAC B	J - J	Alabama
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=392&amp;ver=1)</a>	A and B MAC	10211 - MAC A	J - J	Georgia
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=395&amp;ver=1)</a>	A and B MAC	10212 - MAC B	J - J	Georgia
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=393&amp;ver=1)</a>	A and B MAC	10311 - MAC A	J - J	Tennessee
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=396&amp;ver=1)</a>	A and B MAC	10312 - MAC B	J - J	Tennessee
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=374&amp;ver=1)</a>	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=378&amp;ver=1)</a>	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=375&amp;ver=1)</a>	A and B and HHH MAC	11301 - MAC A	J - M	Virginia

<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=379&amp;ver=1)</a>	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=376&amp;ver=1)</a>	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=380&amp;ver=1)</a>	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=377&amp;ver=1)</a>	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
<a href="#">Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=381&amp;ver=1)</a>	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

## – **Proposed LCD Information**

### Document Information

# Proposed LCD

#### Source LCD ID

N/A

#### Proposed LCD ID

DL38043

#### Proposed LCD Title

MoIDX: **GUARDANT360®** Plasma-Based Comprehensive Genomic Profiling in Solid Tumors

#### AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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#### CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

**Coverage Guidance**

**Coverage Indications, Limitations, and/or Medical Necessity**

Guardant360 is covered for patients with non-CNS originated solid tumors who meet the criteria of NCD 90.2 only when the following conditions are met:

- Tissue-based CGP is infeasible or (i.e., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) **or** specifically in NSCLC Tissue-based CGP has shown no actionable mutations;
- The patient is a candidate for further treatment with a drug that is either FDA-approved for that patient's cancer, or has an NCCN 1 or NCCN 2A recommendation for that patient's cancer, and
- The FDA-approved indication or NCCN recommendation requires information about the presence or absence of a genetic biomarker tested for in the Guardant360 assay

A wide array of cancer treatments have developed ranging from surgery to medications. One of the newer approaches to the medical treatment of cancer has been to use drugs based on genetic features of a malignancy. While many patients will not benefit from genetic testing to select treatment, for those whose cancers have select biomarkers, the treatment of choice often includes therapy targeting that specific biomarker or therapy being avoided because of a biomarker.<sup>1-13</sup>

In spite of the importance of actionable biomarker identification in cancer, research has shown that many patients do not receive genetic testing for the presence of actionable mutations in their cancers, and there are geographic disparities in testing with patients in rural areas and those receiving care at community treatment centers being less likely to receive testing.<sup>14-16</sup> In addition, logistical challenges to testing such as adequate tissue and the availability of any tissue have been identified as barriers to tissue-based genomic testing.<sup>15</sup> Additionally, even among patients whose cancers were genomically profiled at diagnosis and found to have a mutation for which they are receiving targeted treatment, resistance to the initial targeted treatment may emerge. For some patients, the identification of a new mutation, not present in the original tissue sample and found in the blood, may allow the selection of a new targeted life-prolonging therapy.<sup>17</sup>

**Summary of Evidence**

Traditionally, tumor genotyping has been conducted by direct interrogation of tumor tissue obtained through invasive tissue sampling procedures. This diagnostic approach, however, is limited by the availability of sufficient tumor tissue and the ability of patients to undergo invasive procedures. In a recent study of over 100 community-based oncologists, nearly one-third of NSCLC patients were not tested for EGFR or ALK, over 75% were not tested for ROS1 fusions, and fewer than 10% were tested for all guideline-recommended alterations.<sup>15</sup> These results were similar to a study in a single academic center where only 58% of non-squamous NSCLC were tested for EGFR and 40% for ALK fusions, despite 13% of patients undergoing repeat invasive biopsies to obtain sufficient tissue for genomic testing.<sup>18</sup> Tissue availability was similarly limited in several recent series, some of which reported that more than 50% of NSCLC patients had insufficient or unobtainable material for tissue-based CGP.<sup>19-21</sup> Even when successful, tissue acquisition procedures pose a significant morbidity and mortality risk to Medicare patients. In a recent report, 19% of all lung tissue acquisition procedures resulted in a serious adverse event,<sup>22</sup> while the National Lung Cancer Screening Trial reported 1-2% mortality rates in their cohorts.<sup>23</sup> The FDA has also specifically approved a medication for patients who have cancer (cancer type unspecified on the label) for which there is a high risk associated with surgical resection.<sup>24</sup> Given the high rates of inadequate genotyping described above, plasma-based CGP can provide an opportunity for non- and under-genotyped patients to benefit from therapy matched to a genetic biomarker. Early studies suggested that plasma-based CGP can identify potential genomic targets in both the first and second lines, with response rates similar to those of patients identified using tissue-based CGP and tissue-based CoDX.<sup>20,21,25-27</sup> It has been shown that the region of DNA sequenced is important, since alterations may occur outside the sequenced region or involve complex alterations (e.g. indels, copy number alterations, or rearrangements) that are not detectable by certain tests.<sup>28</sup> Newer techniques such as next-generation sequencing (NGS), offer the possibility of not only increased analytical sensitivity but also the ability to detect a broader range of genomic alterations.<sup>29</sup> While the evidence appears most developed for clinically actionable targets in NSCLC, targeted therapy for cancer has been recommended for a number of other cancers as well. Genetic biomarkers associated with specific guideline recommended targeted therapies for a number of conditions is summarized below in Table 1. These guidelines are updated frequently, so new genes not listed in the table may also become part of guideline-consensus recommendations.

Non-small cell lung cancers	EGFR BRAF MET HER2 / ERBB2 ALK ROS1 RET MET KRAS
Colorectal <sup>3,10</sup>	KRAS NRAS BRAF
Breast <sup>2</sup>	HER2 / ERBB2 BRCA1 BRCA2
Endometrial <sup>13</sup>	HER2 / ERBB2
Gastric and Gastroesophageal <sup>4</sup>	HER2 / ERBB2

Gastrointestinal Stromal Tumor <sup>11</sup>	KIT PDGFRA BRAF
Melanomas	BRAF KIT
Ovarian <sup>7</sup>	BRCA1 BRCA2
Pancreatic <sup>8</sup>	BRCA1 BRCA2
Prostate <sup>9</sup>	BRCA1 BRCA2
Thyroid <sup>12</sup>	BRAF RET
Chordoma <sup>1</sup>	EGFR

Additionally, there are now medications, which are FDA approved for cancers based on the presence of genetic mutations in the cancer, regardless of the tissue of origin.

**Microsatellite instability**

Microsatellite instability structures are composed of a repeated nucleotide sequences that emerge due to defects in mismatch repair during DNA replication.<sup>30</sup> The importance of them in cancer, is that Microsatellite Instability High (MSI-H) tumors have been found to respond to immunotherapy,<sup>31</sup> and one immunotherapy drug, pembrolizumab, now has an FDA indication for the treatment of patients with unresectable or metastatic, MSI-H solid tumors.<sup>32</sup>

**NTRK**

The tropomyosin receptor kinase (TRK) receptor family is family of transmembrane proteins, some of which are encoded by the NTRK1, NTRK, and NTRK3 genes. Of these Guardant360 tests for NTRK1 mutations, including fusions. Fusions in the NTRK genes lead to chimeric TRK proteins, which have oncogenic potential, and have been viewed as a potential therapeutic target for cancer.<sup>33</sup>

Larotrectinib, a TRK inhibitor, has received FDA approval for NTRK positive (without a known resistance mutation) tumors in patients with metastatic disease or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or that have progressed following treatment.<sup>24</sup>

**Guardant360**

Guardant360 is a comprehensive genomic profiling test that identifies mutations in 73 genetic mutations. It has demonstrated targeted therapy response rates similar to tissue-detected genomic targets in numerous published NSCLC studies. <sup>20,21,25-28</sup> In addition to sequencing accuracy, research has been done evaluating the ability of the test to identify actionable mutations across cancers originating in a number of organ systems.

In a study by Rozenblum et al., tissue biopsies from 101 advanced NSCLC patients were tested locally for EGFR mutations and ALK fusions.<sup>34</sup> Tissue-based CGP identified 15 EGFR and ALK alterations missed locally, but could only be performed in 82 of the 101 (81%) patients because of tissue exhaustion. Guardant360 was used in the 19 remaining patients and two (11%) additional sensitizing EGFR mutations were found that had been missed with local tissue genotyping. In addition, alterations including MET amplification, ERBB2 (HER2) mutation, and two RET fusions were also identified (missed with local non-CGP genotyping), for a total of 6 driver alterations in 19 patients (32%). Thus, Guardant360 changed treatment in 32% of patients with insufficient samples for tissue-based CGP, with five receiving matched therapy. These five patients achieved a 60% objective response rate and 100% disease control rate.

A more recent study examined the clinical implications of using plasma-based testing in addition to tissue-based testing in 128 patients with NSCLC.<sup>35</sup> Of these 55 were found to have a therapeutically targetable mutation. Of these 55, only 31 had this mutation found in tissue and plasma, though not necessarily the same actionable mutation(s) in each testing method. For 16 patients, the mutation was found in tissue only, and for 8 it was found in plasma only. To further assess whether the selection of targeted therapy based on the detection of low allele frequency mutations that Guardant360 is able to identify has a clinical benefit, the authors assessed the depth of response to targeted mutations identified in plasma-based testing. A total of 42 patients received a targeted therapy consistent with the plasma-based testing, 12 of whom had that mutation also detectable in tissue-based testing as well. Of this 42, there were 36 (85.7%) who achieved a response of stable disease, partial response, or complete response.

The ability of Guardant 360 to identify actionable mutations in multiple types of cancer, including NSCLC, gastric cancer, and melanoma, was examined in 194 patients with metastatic cancer but no availability of tissue for NGS-based genotyping.<sup>25</sup> Actionable mutations were found in the majority of patients, but the study also evaluated treatment response when the patients were given therapy matching a genetic mutation in the test. In the group with NSCLC, 15 received matched therapy, and 13 of them responded to the therapy. Among those with gastric cancer, a total of nine received matched therapy, and 6 responded to treatment, with one of those six have a complete response (a patient with an ERBB2 amplification). Only 2 patients with melanoma received matched therapy, and one responded to this treatment.

Guardant360 has been validated recently across genetic mutation types (single nucleotide variants, indels, fusions, and copy number amplifications) and a range of specific actionable mutations in a study using orthogonal tissue and plasma-based methods.<sup>36,37</sup> Analytical performance of Guardant360 is summarized in the table below.

Mutation Type	LOD95	Sensitivity	Positive Predictive Value
<b>SNVs</b>	>0.25% 0.05 - 0.25%	100% 63.8%	99.2% 96.3%
<b>Indels</b>	>0.20% 0.05 -0.20%	100% 67.8%	98.2% 98.2%

<b>Fusions</b>	>0.20% 0.05-0.20%	95% 83%	100% 100%
<b>CNAs</b>	2.24-2.76 copies	95%	100%

Additionally, the study assessed the detection rate of tumor DNA using Guardant360 from 10,585 patients with more than 20 different cancers. Detection rate was >60% for nearly all cancers and around 80-90% for NSCLC, breast cancer, colorectal cancer, prostate cancer, gastroesophageal cancer, and gynecologic cancer. For primary CNS malignancies the detection rate was less 50%.

While MoIDX initially covered the Guardant360 assay for the selection of targeted therapy in NSCLC, the assay tests for the presence of mutations in over 70 genes and Microsatellite Instability (MSI). More recent research looking beyond NSCLC has shown that the analytical and clinical performance of the Guardant360 assay varies little between mutation type and tissue origin, with the exception of malignancies arising in the central nervous system.<sup>36,37</sup>

**Guardant360 Test Description and Intended Use** Guardant360 analyzes tumor-derived cell-free DNA (also known as ctDNA) to detect somatic alterations, though it also reports germline alterations.

Guardant360 detects the following classes of alterations:

- Base pair substitutions (also known as SNVs);
- Small (≤20 bp) and large (>20 bp) indels;
- Copy number amplifications (CNAs); and
- Fusions
- Microsatellite Instability

The analytical performance characteristics of Guardant360 are similar across mutation types, specific actionable mutations, and tissue types, except primary CNS cancers.

**Criteria for Coverage** Guardant360 is covered only when **all** of the following conditions are met:

- Patient has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system. Patients who would meet all of the indications on the FDA label for larotrectinib if they are found to have an NTRK mutation may be considered to have advanced cancer. **and**
- Patient has not previously been tested with the Guardant360 test for the same primary cancer. For a patient who has been tested previously using Guardant360 for a cancer, that patient may not be tested again unless he or she has a new primary cancer diagnosis. In a patient with previously tested primary cancer, who has evidence of new malignant growth, that growth may be considered to be a different primary cancer if it does not originate from the same cell line or it is physiologically different enough that it responds differently to treatment than the previously tested cancer. **and**
- Patient is untreated for the primary cancer being tested or the patient is not responding to treatment (e.g. progression or new lesions on treatment), **and**
- The patient has decided to seek further cancer treatment with the following conditions:  
The patient is a candidate for further treatment with a drug that is either FDA-approved for that patient's cancer, or has an NCCN 1 or NCCN 2A recommendation for that patient's 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 assay. **and**  
Tissue-based CGP is infeasible (i.e., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) **or** specifically in NSLC Tissue-based CGP has shown no actionable mutations.

If no alteration is detected by Guardant360 or if ctDNA is insufficient/not detected, tissue-based genotyping should be considered.

**Analysis of Evidence  
(Rationale for Determination)**

Level of Evidence

Quality: Moderate  
Strength: Limited  
Weight: Limited

The clinical utility of Guardant360 testing for patients with advanced cancer at diagnosis or at progression, as defined in the intended use above, is quite promising. At present, the assay appears to have similar performance to detect mutations regardless of the tissue of origin or mutation type.

While tissue-based testing remains the preferred tool to test for actionable mutations in cancer, for patients in whom obtaining this tissue is not feasible, liquid biopsy with Guardant360 represents an alternative which may allow more patients to get potentially effective cancer treatment.

**- Proposed Process Information**

**Synopsis of Changes**

CHANGES	FIELDS CHANGED
Not Applicable	N/A

**Associated Information**  
N/A

**Sources of Information**  
N/A

**Bibliography**  
 1. NCCN Bone Cancer Panel. *Bone Cancer Version 1.2019*. August 3 2018.  
 2. NCCN Breast Cancer Panel. *Breast Cancer Version 4.2018*. February 8 2019.  
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**Open Meetings/Contractor Advisory Committee (CAC) Meetings**

MEETING DATE	MEETING TYPE	MEETING STATE(S)	MEETING INFORMATION
05/06/2019	Open Meeting	South Carolina	Columbia, SC

**MAC Meeting Information URL(s)**

N/A

**Proposed LCD Posting Date**

03/28/2019

**Comment Period Start Date**

05/06/2019

**Comment Period End Date**

06/20/2019

**Released to Final LCD Date****Please Note: This is not the LCD Effective Date.**

N/A

**Reason for Proposed LCD**

- Provider Education/Guidance

**Proposed Contact**

Part B Policy  
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## - Coding Information

# Proposed LCD

### Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

### Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

### CPT/HCPCS Codes

#### Group 1 Paragraph:

N/A

#### Group 1 Codes:

CODE	DESCRIPTION
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

### ICD-10 Codes that Support Medical Necessity

#### Group 1 Paragraph:

N/A

#### Group 1 Codes:

ICD-10 CODE	DESCRIPTION
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip
C00.2	Malignant neoplasm of external lip, unspecified
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified

ICD-10 CODE	DESCRIPTION
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.2	Malignant neoplasm of uvula
C05.8	Malignant neoplasm of overlapping sites of palate
C06.0	Malignant neoplasm of cheek mucosa
C06.1	Malignant neoplasm of vestibule of mouth
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C07	Malignant neoplasm of parotid gland
C08.0	Malignant neoplasm of submandibular gland
C08.1	Malignant neoplasm of sublingual gland
C08.9	Malignant neoplasm of major salivary gland, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect



ICD-10 CODE	DESCRIPTION
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma

ICD-10 CODE	DESCRIPTION
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas

Showing 1 to 100 of 467 entries in Group 1

[First](#) [Prev](#) [1](#) [2](#) [3](#) [4](#) [5](#) [Next](#) [Last](#)

#### ICD-10 Codes that DO NOT Support Medical Necessity

N/A

#### Additional ICD-10 Information

N/A

#### - **Associated Documents**

##### Attachments

N/A

##### Related Local Coverage Documents

N/A

##### Related National Coverage Documents

N/A

#### - **Keywords**

N/A

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30

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[HHS.gov/Open](https://www.hhs.gov/open/) - Opens in a new window (https://www.hhs.gov/open/)

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