

Anal Cancer

Medical Oncology

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Anal Cancer Guideline

Anal cancer treatment is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- I. Anal cancer-specific chemotherapy for **ANY** of the following: [9] [26] [18]
 - A. Metastatic anal cancer chemotherapy with **ANY** of the following:
 1. 5-Fluorouracil (5-FU) + cisplatin [2] [3] [19]
 2. Paclitaxel + carboplatin [6] [1]
 - B. Anal cancer chemotherapy with 5-FU + cisplatin [2] [3]
- II. Anal cancer chemotherapy is considered medically appropriate when the documentation demonstrates **ALL** of the following: [9] [19] [26] [18]
 - A. Associated-cancer chemotherapy medication regimens per the *National Comprehensive Cancer Network (NCCN) Guidelines*, approved by the United States (US) Food and Drug Administration (FDA), clinically prescribed and as authorized by the payor.
 - B. Physical ability and clinical status of **ANY** of the following:
 1. Eastern Cooperative Oncology Group (ECOG) Performance Status Grade of 2 or less
 2. Karnofsky Performance Status (KPS) Grade of 70 or more
 - C. Treatment is for **ANY** of the following:
 1. Inguinal node recurrence
 2. Localized therapy
 3. Locally recurrent prior to abdominoperineal resection (APR)
 4. Metastatic local control
 5. Metastatic subsequent therapy
 6. Metastatic therapy



LCD 33394

See also, **LCD 33394**: Drugs and Biologicals, Coverage of, for Label and Off-Label Uses at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



LCD 34026

See also, **LCD 34026**: Trastuzumab - Trastuzumab Biologics [LCD title] at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.



LCD 37205

See also, **LCD 37205**: Chemotherapy Drugs and their Adjuncts at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

Gastrointestinal Cancer Summary of Changes

GI Cancer clinical guidelines from 2023 to 2024 had the following version changes:

- Citations updated, evidence review completed with no major change in criteria.
- Medications added to each indication.

GI Cancer Procedure Codes

Table 1. Associated Procedure Codes

CODE	DESCRIPTION
J8999	PRESCRIPTION DRUG, ORAL, CHEMOTHERAPEUTIC, NOS
J9228	INJECTION, IPILIMUMAB, 1 MG
J9190	INJECTION, FLUOROURACIL, 500 MG
J9060	INJECTION, CISPLATIN, POWDER OR SOLUTION, 10 MG
J0640	INJECTION, LEUCOVORIN CALCIUM, PER 50 MG
J9263	INJECTION, OXALIPLATIN, 0.5 MG
J9299	INJECTION, NIVOLUMAB, 1 MG
J9267	INJECTION, PACLITAXEL, 1 MG
J9045	INJECTION, CARBOPLATIN, 50 MG
J9271	INJECTION, PEMBROLIZUMAB, 1 MG
J8520	CAPECITABINE, ORAL, 150 MG
J8521	CAPECITABINE, ORAL, 500 MG
J9280	INJECTION, MITOMYCIN, 5 MG
J9035	INJECTION, BEVACIZUMAB, 10 MG
C9257	INJECTION, BEVACIZUMAB, 0.25 MG

CODE	DESCRIPTION
J9206	INJECTION, IRINOTECAN, 20 MG
J9303	INJECTION, PANITUMUMAB, 10 MG
J9308	INJECTION, RAMUCIRUMAB, 5 MG
J9055	INJECTION, CETUXIMAB, 10 MG
J9400	INJECTION, ZIV-AFLIBERCEPT, 1 MG
J9171	INJECTION, DOCETAXEL, 1 MG
J9355	INJECTION, TRASTUZUMAB, EXCLUDES BIOSIMILAR, 10 MG
J9178	INJECTION, EPIRUBICIN HCL, 2 MG
Q5112	INJECTION, TRASTUZUMAB-DTTB, BIOSIMILAR, (ONTRUZANT), 10 MG
Q5113	INJECTION, TRASTUZUMAB-PKRB, BIOSIMILAR, (HERZUMA), 10 MG
Q5114	INJECTION, TRASTUZUMAB-DKST, BIOSIMILAR, (OGIVRI), 10 MG
Q5116	INJECTION, TRASTUZUMAB-QYYP, BIOSIMILAR, (TRAZIMERA), 10 MG
Q5117	INJECTION, TRASTUZUMAB-ANNS, BIOSIMILAR, (KANJINTI), 10 MG
Q5107	INJECTION, BEVACIZUMAB-AWWB, BIOSIMILAR, (MVASI), 10 MG
Q5118	INJECTION, BEVACIZUMAB-BVZR, BIOSIMILAR, (ZIRABEV), 10 MG
Q5126	INJECTION, BEVACIZUMAB-MALY, BIOSIMILAR (ALYMSYS), 10 MG

GI Cancer Definitions

Abdominoperineal resection is a surgical procedure in which the anus, rectum, and part of the sigmoid colon are removed to treat certain types of cancer, such as rectal cancer. This procedure involves creating a permanent opening (colostomy) in the abdominal wall for the elimination of waste.

Adenocarcinoma is a malignant tumor originating in glandular epithelium.

Adjuvant refers to enhancing the effectiveness of medical treatment.

Advanced disease is also called end-stage or terminal cancer. Advanced disease can occur when there are few signs that remission is possible.

BRAF V600E mutation is a specific mutation (change) in the BRAF gene (a gene that provides instructions for making a protein that helps transmit chemical signals from outside the cell to the cell's nucleus), which makes a protein that is involved in sending signals in cells and in cell growth. This BRAF gene mutation may be found in some types of cancer, including melanoma and colorectal cancer. It may increase the growth and spread of cancer cells.

Chemotherapy is a treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Chemotherapy may be given by mouth, injection, infusion or on the skin depending on the type and stage of the cancer being treated. It may be given alone or with other treatments, such as surgery, radiation therapy or biologic therapy.

Combined positive score is a robust, reproducible PD-L1 scoring method that predicts response to pembrolizumab in patients with G/GEJ cancer.

Deficient mismatched repair (dMMR) can be due to germline mutations in DNA mismatch repair genes (MLH1, MSH2, MSH6, or PMS2) or somatic epigenetic silencing of MLH1, which result in unrepaired repetitive DNA sequences. These altered sequences increase the risk of multiple cancers, but are most commonly associated with colorectal cancer.

Definitive treatment is the treatment plan for a disease or disorder that has been chosen as the best one for a patient after all other choices have been considered.

Eastern Cooperative Oncology Group (ECOG) scale describes a patient's level of functioning in terms of the ability to care for one's self, daily activity and physical ability (eg, walking, working).

Esophageal cancer is cancer that forms in tissues lining the esophagus (the muscular tube through which food passes from the throat to the stomach).

First-line treatment is the first treatment given for a disease, and is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation. When used by itself, first-line therapy is the one accepted as the best treatment.

Gastric cardia is the part of the stomach that is closest to the esophagus.

HER-2 positive describes cells that have a protein called HER2 on their surface. In normal cells, HER2 helps control cell growth. Cancer cells that make too much HER2 may grow more quickly and are more likely to spread to other parts of the body.

Indeterminate findings are inconclusive or insufficient for treatment planning.

Inguinal is situated in the region of the groin or in either of the lowest lateral regions of the abdomen.

Karnofsky performance status (KPS) is an assessment tool for functional impairment. It can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. In most serious illnesses, the lower the Karnofsky score, the worse the likelihood of survival.

Kirsten rat sarcoma viral oncogene homolog (KRAS) mutation is an error in a protein in normal cells. It is called KRAS because it was first identified as causing cancer in Kirsten RAT Sarcoma virus. Normally, KRAS serves as an information hub for signals in the cell that lead to cell growth.

Lymphovascular invasion (LVI) indicates the presence or absence of tumor cells in lymphatic channels (not lymph nodes) or blood vessels within the primary tumor as noted microscopically by the pathologist.

Margin is the edge or border of the tissue removed in cancer surgery.

Metachronous describes something that is not functioning or occurring synchronously (at the same time).

Metastasis is the spread of a disease-producing agency (such as cancer cells) from the initial or primary site of disease to another part of the body.

Microsatellite instability-high (MSI-H) is a type of cancer cell that has a high number of mutations (changes) within microsatellites. For example, microsatellite testing that shows mutations in 30% or more microsatellites is called microsatellite instability-high.

Neoadjuvant treatment is treatment (such as chemotherapy or hormone therapy) administered before primary cancer treatment (such as surgery) to enhance the outcome of primary treatment.

Programmed cell death ligand 1 (PD-L1) expression is a protein that acts as a kind of “brake” to keep the body's immune responses under control. PD-L1 may be found on some normal cells and in higher-than-normal amounts on some types of cancer cells. Cancer cells that have a high amount of PDL1 may benefit from immunotherapy.

Perineural invasion (PNI) refers to the invasion of cancer to the space surrounding a nerve. It is common in head and neck cancer, prostate cancer and colorectal cancer.

Poorly differentiated histology describes tumor cells that don't look like normal cells. They're disorganized under the microscope and tend to describe high grade or grade III tumors that grow and spread faster than grade I tumors.

Progressive disease is cancer that is growing, spreading or getting worse.

Rat Sarcoma (RAS) wild-type is a term used to describe a gene called KRAS when it is found in its natural, non-mutated (unchanged) form. The KRAS gene makes a protein that is involved in cell signaling pathways that control cell growth, cell maturation and cell death. Mutated (changed) forms of the KRAS gene have been found in some types of cancer, including non-small cell lung cancer, colorectal cancer and pancreatic cancer. Knowing whether a patient's tumor has a wild-type or mutated KRAS gene may help plan cancer treatment.

Second-line treatment is treatment for a disease or condition after the initial treatment (first-line treatment) has failed, stopped working or has side effects that are not tolerated.

Squamous cell carcinoma (SCC) is carcinoma that is made up of or arises from squamous cells (stratified epithelium that consists at least in its outer layers of small scale like cells) and usually occurs in areas of the body exposed to strong sunlight over many years.

Staging in cancer is the process of determining how much cancer is within the body (tumor size) and if it has metastasized (spread).

Subsequent treatment is treatment given after the main treatment to reduce the chance of cancer coming back by destroying any remaining cancer cells. It usually refers to chemotherapy, radiation therapy, hormone therapy and/or immunotherapy given after surgery.

Third-line treatment is treatment that is given when both initial treatment (first-line therapy) and subsequent treatment (second-line therapy) don't work, or stop working.

TNM staging system is a system to describe the amount and spread of cancer in a person's body. T describes the size of the tumor and any spread of cancer into nearby tissue; N describes the spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).

Table 1. TNM Staging System

T describes the original Primary Tumor	N category describes whether or not the cancer has reached nearby lymph nodes	M category tells whether there are distant meta-stases (spread of cancer to other parts of the body).
TX Primary tumor cannot be evaluated	NX Regional lymph nodes cannot be evaluated	
T0 No evidence of primary tumor	N0 No regional lymph node involvement (no cancer found in the lymph nodes)	M0 No distant metastasis (cancer has not spread to other parts of the body)
Tis Carcinoma in situ (early cancer that has not spread to neighboring tissue)		
T1 to T4 Size and/or extent of the primary tumor	N1 to N3 Involvement of regional lymph nodes (number and/or extent of spread)	M1 Distant metastasis (cancer has spread to distant parts of the body)

Unresectable initial disease is cancer that is not capable of being surgically removed.

GI Cancer (ALL) References

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