

Camptosar® (Irinotecan)

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[Terms and Conditions](#)

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Policy Summary

Overview

Irinotecan hydrochloride (HCL) is an antineoplastic drug that is a semisynthetic derivative of camptothecin, an alkaloid extract from plants. The drug works by causing strand breaks in DNA that the cell cannot repair leading to cell death.

Guidelines

As published in [CMS Program Integrity Manual, Section 13.5.1](#), in order to be covered under Medicare, a service shall be reasonable and necessary.

Drugs and biologicals must be determined to meet the statutory definition under the statute [§1861\(t\) \(1\)](#).

[Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50](#), describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals;
- They are of the type that are not usually self-administered by the patients who take them;
- They meet all the general requirements for coverage of items as incident to a physician's services;
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- They are not excluded as immunizations; and
- They have not been determined by the FDA to be less than effective.

Coverage for medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia listed below.

- National Comprehensive Cancer Network (NCCN) Drugs and Biologies Compendium
- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Thomson Micromedex DrugDex

- Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

The compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium.

Note: It is not appropriate to bill for services that are not covered (as described by this entire policy guideline) as if they are covered. When billing for non-covered services, use the appropriate modifier.

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge will be excluded (i.e., for both the drug and its administration). Also excluded from payment is any charge for other services (such as office visits) which are primarily for the purpose of administering a non-covered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals and cancer chemotherapeutic agents approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling.

Therefore, payment may be made for an FDA-approved chemotherapeutic drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the contractor determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

There are many reasons to consider an unlabeled use for a cancer chemotherapy agent. Some of these are:

- Drugs may be effective for many other cancers in addition to the ones that were considered in the primary drug labeling.
- Many chemotherapeutic agents are given in combinations. Any one of the drugs in the combination may not have been approved in the initial labeling of the products. In addition the combination of effective chemotherapeutic agents changes over time.
- Cancer chemotherapeutic agents are always changing and improving over time.
- Oncologists are often left with few approved treatment options if initial treatment regimens have failed.

Coverage

Irinotecan (Camptosar®) is FDA approved for the following indications:

- First-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum.
- Patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-based therapy.

Refer also to the NCCN Compendium® for additional off- label indications.

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this policy guideline. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

The medical record must include the following information:

- The name of the drug or biological administered;
- The route of administration;
- The dosage (e.g., mgs, mcgs, cc's or IU's); and
- The duration of the administration (for CPT codes that are time based).

Applicable Codes

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J9206	Injection, Irinotecan, 20 mg

Modifier	Description
KX	Requirements specified in the medical policy have been met

Diagnosis Code	Description
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
C15.9	Malignant neoplasm of esophagus, unspecified
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
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant (Deleted 09/09/2020)
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
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
C18.9	Malignant neoplasm of colon, unspecified

Diagnosis Code	Description
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified (Deleted 09/09/2020)
C21.1	Malignant neoplasm of anal canal (Deleted 09/09/2020)
C21.2	Malignant neoplasm of cloacogenic zone (Deleted 09/09/2020)
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas (Deleted 09/09/2020)
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb

Diagnosis Code	Description
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C45.1	Mesothelioma of peritoneum (Deleted 09/09/2020)
C45.9	Mesothelioma, unspecified (Deleted 09/09/2020)
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified (Deleted 09/09/2020)
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C50.011	Malignant neoplasm of nipple and areola, right female breast (Deleted 09/09/2020)
C50.012	Malignant neoplasm of nipple and areola, left female breast (Deleted 09/09/2020)
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast (Deleted 09/09/2020)
C50.111	Malignant neoplasm of central portion of right female breast (Deleted 09/09/2020)
C50.112	Malignant neoplasm of central portion of left female breast (Deleted 09/09/2020)
C50.119	Malignant neoplasm of central portion of unspecified female breast (Deleted 09/09/2020)
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast (Deleted 09/09/2020)
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast (Deleted 09/09/2020)

Diagnosis Code	Description
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast (Deleted 09/09/2020)
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast (Deleted 09/09/2020)
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast (Deleted 09/09/2020)
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast (Deleted 09/09/2020)
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast (Deleted 09/09/2020)
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast (Deleted 09/09/2020)
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast (Deleted 09/09/2020)
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast (Deleted 09/09/2020)
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast (Deleted 09/09/2020)
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast (Deleted 09/09/2020)
C50.611	Malignant neoplasm of axillary tail of right female breast (Deleted 09/09/2020)
C50.612	Malignant neoplasm of axillary tail of left female breast (Deleted 09/09/2020)
C50.619	Malignant neoplasm of axillary tail of unspecified female breast (Deleted 09/09/2020)
C50.811	Malignant neoplasm of overlapping sites of right female breast (Deleted 09/09/2020)
C50.812	Malignant neoplasm of overlapping sites of left female breast (Deleted 09/09/2020)
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast (Deleted 09/09/2020)
C50.911	Malignant neoplasm of unspecified site of right female breast (Deleted 09/09/2020)
C50.912	Malignant neoplasm of unspecified site of left female breast (Deleted 09/09/2020)
C50.919	Malignant neoplasm of unspecified site of unspecified female breast (Deleted 09/09/2020)
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles (Deleted 09/09/2020)
C71.1	Malignant neoplasm of frontal lobe (Deleted 09/09/2020)

Diagnosis Code	Description
C71.2	Malignant neoplasm of temporal lobe (Deleted 09/09/2020)
C71.3	Malignant neoplasm of parietal lobe (Deleted 09/09/2020)
C71.4	Malignant neoplasm of occipital lobe (Deleted 09/09/2020)
C71.5	Malignant neoplasm of cerebral ventricle (Deleted 09/09/2020)
C71.6	Malignant neoplasm of cerebellum (Deleted 09/09/2020)
C71.7	Malignant neoplasm of brain stem (Deleted 09/09/2020)
C71.8	Malignant neoplasm of overlapping sites of brain (Deleted 09/09/2020)
C71.9	Malignant neoplasm of brain, unspecified (Deleted 09/09/2020)
C72.9	Malignant neoplasm of central nervous system, unspecified (Deleted 09/09/2020)
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck (Deleted 09/09/2020)
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes (Deleted 09/09/2020)
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes (Deleted 09/09/2020)
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes (Deleted 09/09/2020)
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes (Deleted 09/09/2020)
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes (Deleted 09/09/2020)
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions (Deleted 09/09/2020)
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified (Deleted 09/09/2020)
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum (Deleted 09/09/2020)
C78.2	Secondary malignant neoplasm of pleura (Deleted 09/09/2020)
C78.30	Secondary malignant neoplasm of unspecified respiratory organ (Deleted 09/09/2020)
C78.39	Secondary malignant neoplasm of other respiratory organs (Deleted 09/09/2020)
C78.4	Secondary malignant neoplasm of small intestine (Deleted 09/09/2020)
C78.5	Secondary malignant neoplasm of large intestine and rectum (Deleted 09/09/2020)
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.80	Secondary malignant neoplasm of unspecified digestive organ (Deleted 09/09/2020)
C78.89	Secondary malignant neoplasm of other digestive organs (Deleted 09/09/2020)
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis (Deleted 09/09/2020)
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis (Deleted 09/09/2020)
C79.11	Secondary malignant neoplasm of bladder (Deleted 09/09/2020)
C79.19	Secondary malignant neoplasm of other urinary organs (Deleted 09/09/2020)
C79.2	Secondary malignant neoplasm of skin (Deleted 09/09/2020)
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges (Deleted 09/09/2020)
C79.40	Secondary malignant neoplasm of unspecified part of nervous system (Deleted 09/09/2020)
C79.49	Secondary malignant neoplasm of other parts of nervous system (Deleted 09/09/2020)

Diagnosis Code	Description
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.61	Secondary malignant neoplasm of right ovary (Deleted 09/09/2020)
C79.62	Secondary malignant neoplasm of left ovary (Deleted 09/09/2020)
C79.71	Secondary malignant neoplasm of right adrenal gland (Deleted 09/09/2020)
C79.72	Secondary malignant neoplasm of left adrenal gland (Deleted 09/09/2020)
C79.81	Secondary malignant neoplasm of breast (Deleted 09/09/2020)
C79.82	Secondary malignant neoplasm of genital organs (Deleted 09/09/2020)
C79.89	Secondary malignant neoplasm of other specified sites (Deleted 09/09/2020)
C79.9	Secondary malignant neoplasm of unspecified site (Deleted 09/09/2020)
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.8	Other secondary neuroendocrine tumors
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C80.2	Malignant neoplasm associated with transplanted organ (Deleted 09/09/2020)
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z80.49	Family history of malignant neoplasm of other genital organs (Deleted 09/09/2020)
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.43	Personal history of malignant neoplasm of ovary
Z85.830	Personal history of malignant neoplasm of bone
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.841	Personal history of malignant neoplasm of brain (Deleted 09/09/2020)
Z85.858	Personal history of malignant neoplasm of other endocrine glands

Definitions

Off-Label Drug Use: An off-label/unlabeled use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information. An indication is defined as a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration and frequency of administration, and population to whom the drug would be administered. Drugs used for indications other than those in the approved labeling may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice. Determinations as to whether medication is reasonable and necessary for an individual patient are made on appeal on the same basis as all other such determinations (i.e.,

with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

References

CMS National Coverage Determinations (NCD)

[NCD 110.7 Anti-Cancer Chemotherapy for Colorectal Cancer](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses	A52855 Billing and Coding: Drugs and Biologicals	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L37205 Chemotherapy Drugs and their Adjuncts	N/A	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
N/A	A53049 Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
N/A	A58113 Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen	CGS	KY, OH	KY, OH
N/A	A52953 Chemotherapy Administration	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A52991 Billing and Coding: Chemotherapy Administration	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L34093 Chemotherapy and Biologicals Retired 06/07/2020	A57254 Billing and Coding: Irinotecan-J9206 Retired 06/07/2020	CGS	KY, OH	KY, OH
L33727 Irinotecan Retired 11/15/2019	N/A	First Coast	FL, PR, VI	FL, PR, VI

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none"> Reformatted policy; transferred content to new template

Date	Summary of Changes
09/09/2020	<p>Policy Summary</p> <p><i>Overview</i></p> <ul style="list-style-type: none"> Relocated language pertaining to FDA approved and off-label indications (see <i>Coverage</i> section) <p><i>Guidelines</i></p> <ul style="list-style-type: none"> Removed content addressed in the referenced <i>Medicare Benefit Policy Manual – Pub. 100-02, Chapter 15, Section 50</i> <p><i>Chemotherapy Administration</i></p> <ul style="list-style-type: none"> Removed content addressed in the Local Coverage Article (LCA) titled <i>Chemotherapy Administration (A52953)</i>; refer to the <i>References</i> section of the policy <p><i>Coding Guidelines</i></p> <ul style="list-style-type: none"> Removed instruction on appropriate code reporting <p><i>Coverage</i></p> <ul style="list-style-type: none"> Added language (relocated from the <i>Overview</i> section) to indicate irinotecan (Camptosar®) is FDA approved for the following indications: <ul style="list-style-type: none"> First-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum Patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-based therapy Refer also to the NCCN Compendium® for additional off-label indications <p><i>Documentation Requirements</i></p> <ul style="list-style-type: none"> Revised language to indicate: <ul style="list-style-type: none"> The patient’s medical record must contain documentation that fully supports the medical necessity for services included within this policy guideline This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures The medical record must include the following information: <ul style="list-style-type: none"> The name of the drug or biological administered; The route of administration; The dosage (e.g., mgs, mcgs, cc's or IU's); and The duration of the administration (for CPT codes that are time based) <p><i>Applicable Codes</i></p> <ul style="list-style-type: none"> Removed Modifier code GZ Added notation to indicate ICD-10 diagnosis codes C17.3, C21.0, C21.1, C21.2, C25.4, C45.1, C45.9, C47.9, C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, C71.0, C71.1, C71.2, C71.3, C71.4, C71.5, C71.6, C71.7, C71.8, C71.9, C72.9, C77.0, C77.1, C77.2, C77.3, C77.4, C77.5, C77.8, C77.9, C78.1, C78.2, C78.30, C78.39, C78.4, C78.5, C78.80, C78.89, C79.01, C79.02, C79.11, C79.19, C79.2, C79.32, C79.40, C79.49, C79.61, C79.62, C79.71, C79.72, C79.81, C79.82, C79.89, C79.9, C80.2, Z80.49, and Z85.841 were “deleted Sep. 9, 2020” <p><i>Supporting Information</i></p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information Archived previous policy version MPG035.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).