Halaven® (Eribulin Mesylate)

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➲ Terms and Conditions

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- Coverage of Drugs and Biologicals for Label and Off-Label Uses

Related Medicare Advantage Reimbursement Policy

- Discarded Drugs and Biologicals Policy, Professional

Related Medicare Advantage Coverage Summaries

- Chemotherapy, and Associated Drugs and Treatments
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Policy Summary

➲ See Purpose

Overview

Halaven is an FDA-approved chemotherapy that offers an opportunity to live longer for women whose metastatic breast cancer (mBC) has progressed after at least 2 types of mBC therapy.

Halaven contains eribulin mesylate, a microtubule dynamics inhibitor. Eribulin mesylate is a synthetic analogue of halichondrin B, a product isolated from the marine sponge, Halichondria okadai.

Eribulin inhibits the growth phase of microtubules without affecting the shortening phase and sequesters tubulin into nonproductive aggregates. Eribulin exerts its effects via a tubulin-based antimitotic mechanism leading to G2/M cell-cycle block, disruption of mitotic spindles, and, ultimately, apoptotic cell death after prolonged mitotic blockage.

Guidelines

Eribulin Mesylate (Halaven) is a chemotherapeutic agent used in the treatment of:

- Metastatic breast cancer in patients who have received at least 2 prior chemotherapy regimens for the treatment of metastatic disease (prior treatment should have included an anthracycline and a taxane in either the adjuvant or metastatic setting).
- Liposarcoma, unresectable or metastatic: Treatment of unresectable or metastatic liposarcoma in patients who have received a prior anthracycline-containing regimen.

Halaven should be billed using chemotherapy administration codes and is payable in the following places of service: office (11), skilled nursing home for patients in a Part A stay (31) [if the drug is supplied by the facility, no claims for the drug should be submitted to the Part B carrier.], nursing facility for patients not in a Part A stay (32) and independent clinic (49) only when supplied as an “incident to” service by the physician.

As published in CMS IOM 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 statue 1861(t) (1) Drugs and Biologicals.

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 ratings listed below.

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

The compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as medically accepted if the:

- Indication is a Category 1 or 2A in NCCN
- Class I, Class IIa, or Class IIb in DrugDex; or,
- Narrative text in AHFS or Clinical Pharmacology is supportive.

Frequency is considered excessive when services are performed more frequently than listed in the package insert or generally accepted by peers and the reason for additional services is not justified by documentation. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

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

Chemotherapy Administration

This policy explains the coverage criteria for drugs and biologicals used in the treatment of cancer. The policy has been promulgated to establish the clinical conditions for which the included chemotherapeutic drug is considered to be medically reasonable and necessary and thus, covered by Medicare.

Chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients are not considered chemotherapy administration.

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 labeling of the drug.
- 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.

If a use is identified as not indicated by CMS or the FDA or if a use is specifically identified as not indicated (in one or more of the three compendia mentioned) or if it is determined (based on peer reviewed medical literature) that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered. In this instance, the administration is also not covered.

Several cancer chemotherapeutic agents and regimes have been developed and approved by the Food and Drug Administration (FDA) to treat various types of cancer. The intended mechanism of action is to interfere with or prevent the growth of malignant (cancerous) cells.

Generally, cancer chemotherapeutic agents are covered only if all of the following requirements are met:
- Documentation is present to support that the drug is safe and effective and is being administered for an approved indication.
- Documentation in the patient's medical record supports the medical necessity of administering the chemotherapy drug to that individual patient.
- Documentation in the patient's medical record supports that the chemotherapy drug was administered as billed.

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.

Refer to the Medicare Benefit Manual – Pub. 100-02, Chapter 15, Section 50.4.5

Applicable Codes

The following list(s) of procedure and/or diagnosis 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
J9179	Injection, Eribulin Mesylate, 0.1 MG

Diagnosis Code	Description
C22.3	Angiosarcoma of liver (Effective 09/09/2020)
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
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

Diagnosis Code	Description
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
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast

Diagnosis Code	Description
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of right left breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C53.0	Malignant neoplasm of endocervix (Deleted 09/09/2020)
C54.0	Malignant neoplasm of isthmus uteri (Deleted 09/09/2020)
C54.1	Malignant neoplasm of endometrium (Deleted 09/09/2020)
C54.2	Malignant neoplasm of myometrium (Deleted 09/09/2020)
C54.3	Malignant neoplasm of fundus uteri (Deleted 09/09/2020)
C54.8	Malignant neoplasm of overlapping sites of corpus uteri (Deleted 09/09/2020)
C54.9	Malignant neoplasm of corpus uteri, unspecified (Deleted 09/09/2020)
C55	Malignant neoplasm of uterus, part unspecified (Deleted 09/09/2020)
C78.00	Secondary malignant neoplasm of unspecified lung (Deleted 09/09/2020)
C78.01	Secondary malignant neoplasm of right lung (Deleted 09/09/2020)
C78.02	Secondary malignant neoplasm of left lung (Deleted 09/09/2020)
Z80.49	Family history of malignant neoplasm of other genital organ (Deleted 09/09/2020)
Z85.3	Personal history of malignant neoplasm of breast
Z85.831	Personal history of malignant neoplasm of soft tissue

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A56141 Billing and Coding: Chemotherapy	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
N/A	A52953 Billing and Coding: Chemotherapy Administration	Noridian	AS, CA (Northern and Southern), GU, HI, MP, NV	AS, CA (Entire State), 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

CMS Benefit Policy Manual

Chapter 15; § 50 Drugs and Biologicals

CMS Claims Processing Manual

Chapter 12; § 30.5 Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions
Chapter 17; § 40 Discarded Drugs and Biologicals
Chapter 32 Billing Requirements for Special Services

Other(s)

Prescribing information
NCCN Drugs & Biologics Compendium, National Comprehensive Cancer Network Website
Program Integrity Manual § 13.5.1 Reasonable and Necessary Provisions in LCDs, CMS Website
Social Security Act (Title XVIII) Standard References, Sections:

- 1862(a)(1)(A) Medically Reasonable & Necessary
- 1862(a)(1)(D) Investigational or Experimental
- 1833(e) Incomplete Claim
- 1861(t) (1) Drugs and Biologicals

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 • Reformatted policy; transferred content to new template
09/09/2020	Related Policies • Added reference link to the Medicare Advantage Reimbursement Policy titled *Discarded Drugs and Biologicals Policy, Professional* • Removed reference link to the Medicare Advantage Policy Guideline titled *Self-Administered Drug(s) (SAD)* Policy Summary *Guidelines* • Removed language pertaining to self-administered drugs Applicable Codes • Added ICD-10 diagnosis code C22.3

Date	Summary of Changes
	• Added notation to indicate ICD-10 diagnosis codes C53.0, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C78.00, C78.01, C78.02, and Z80.49 were "deleted Sep. 9, 2020" Supporting Information • Updated *References* section to reflect the most current information • Archived previous policy version MPG125.05

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.

*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.