
Chemotherapy: Drugs A-D Policy

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This section contains policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Chemotherapy: An Overview* section in this manual. Additional policy information for chemotherapy drug services can be found in the *Chemotherapy: Drugs E-O* and *Chemotherapy: P-Z* sections in this manual.

Ado-Trastuzumab Emtansine

Ado-trastuzumab emtansine is a Human Epidermal Growth Factor Receptor 2 (HER2)-targeted antibody-drug conjugate which contains the humanized anti-HER2 IgG1, trastuzumab, covalently linked to the microtubule inhibitory drug DM1 (a maytansine derivative) via the stable thioether linker MCC (4-[N- maleimidomethyl] cyclohexane-1-carboxylate). Emtansine refers to the MCC- DM1 complex. Upon binding to sub-domain IV of the HER2 receptor, ado- trastuzumab emtansine undergoes receptor-mediated internalization and subsequent lysosomal degradation, resulting in intracellular release of DM1- containing cytotoxic catabolites. Binding of DM1 to tubulin disrupts microtubule networks in the cell, which results in cell cycle arrest and apoptotic cell death.

Indications

For the treatment of patients with HER2 positive metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. They should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. Documentation must be submitted with the TAR to establish medical necessity.

Dosage

The recommended dose of ado-trastuzumab emtansine is 3.6 mg/kg given as an intravenous infusion every three weeks (21-day cycle) until disease progression or unacceptable toxicity. Ado-trastuzumab emtansine should not be administered at doses greater than 3.6 mg/kg nor should it be substituted for or used with trastuzumab.

Billing

HPCS code J9354 (injection, ado-trastuzumab emtansine, 1 mg)

Aldesleukin

Aldesleukin is a lymphokine that stimulates growth of T-lymphocytes. Aldesleukin is used to treat metastatic renal cell carcinoma and metastatic malignant melanoma. It is a “biologic response modifier” that promotes anti-tumor activity mediated through the immune system.

Required Codes

Aldesleukin is reimbursable when billed in conjunction with ICD-10-CM diagnosis codes C43.0 thru C43.9 (malignant melanoma of skin), C64.1 thru C65.9 (malignant neoplasm of kidney and renal pelvis).

Dosage

Adult patients diagnosed with metastatic renal cell carcinoma or metastatic malignant melanoma may be treated with a dosage schedule consisting of two five-day treatment cycles separated by a rest period of nine days. Patients receive a dose of 600,000 IU/kg of aldesleukin administered every eight hours through a 15-minute intravenous infusion, for a total of 14 doses. Following the rest period, the schedule is repeated for another 14 doses, to a maximum of 28 doses per course.

Billing

HCPCS code J9015 (injection, aldesleukin, per single use vial)

Aldesleukin may be billed in conjunction with CPT® code 96413 (chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug).

«Amivantamab-vmjw (Rybrevant)

Amivantamab-vmjw is a bispecific antibody that binds to the extracellular domains of epidermal growth factor receptor (EGFR) and mesenchymal-epithelial transition (MET). In in vitro and in vivo studies amivantamab-vmjw was able to disrupt EGFR and MET signaling functions through blocking ligand binding and, in exon 20 insertion mutation models, degradation of EGFR and MET. The presence of EGFR and MET on the surface of tumor cells also allows for targeting of these cells for destruction by immune effector cells, such as natural killer cells and macrophages, through antibody-dependent cellular cytotoxicity (ADCC) and trogocytosis mechanisms, respectively.

Indications

All FDA-approved indications

Age Limit

Must be 18 years of age or older

Dosage

FDA-approved dosages

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS code C9083, (injection, amivantamab-vmjw, 10 mg)

Prescribing Restrictions

Frequency of billing = 1400 mg/140 units weekly for 4 weeks, then every 2 weeks thereafter. Note that the initial dose is administered as a split infusion in week 1 on days 1 and 2.»

Aprepitant

Aprepitant injection is a substance P/neurokinin-1 (NK-1) receptor antagonist anti-emetic drug for intravenous (I.V.) administration.

Indications

Aprepitant is used in combination with dexamethasone and a 5-HT₃ receptor antagonist to prevent nausea and vomiting symptoms associated with initial and repeat courses of highly-emetic cancer chemotherapy (HEC) or moderately-emetic cancer chemotherapy (MEC).

Age

18 years and older

Dosage

Single Dose Regimen for HEC:

- 130 mg I.V. given as a single dose approximately 30 minutes before initiation of a chemotherapy cycle.

Multiple Dose Regimen for MEC

- 100 mg I.V. given approximately 30 minutes before initiation of a chemotherapy cycle on Day 1, followed by an 80 mg aprepitant oral capsule given once daily on Days 2 and 3.

Authorization

No *Treatment Authorization Request* (TAR) is generally required for reimbursement, unless the claim exceeds the recommended maximum dose or frequency.

Required Codes

The following ICD-10-CM diagnosis code is required for reimbursement:

- Z51.11 (Encounter for anti-neoplastic chemotherapy)

Billing

HCPCS code J0185 (injection, aprepitant, 1 mg)

One (1) unit of J0185 = 1 mg of aprepitant emulsion

Arsenic Trioxide

The mechanism of action of arsenic trioxide is not completely understood. Arsenic trioxide causes morphological changes and DNA fragmentation characteristic of apoptosis in NB4 human promyelocytic leukemia cells in vitro.

Indications

For the induction of remission and consolidation in patients 4 years of age and older with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR alpha gene expression.

Dosage

Recommended induction treatment schedule:

Intravenously at a dose of 0.15 mg/kg daily until bone marrow remission. Total induction dose should not exceed 60 doses.

Recommended consolidation treatment schedule:

Intravenously at a dose of 0.15 mg/kg daily for 25 doses over a period of five weeks.

Required Codes

Arsenic trioxide is reimbursable when billed with one of the following ICD-10-CM diagnosis codes:

- C92.40
- C92.41
- C92.42

Billing

HCPCS code J9017 (injection, arsenic trioxide, 1 mg)

Asparaginase *Erwinia Chrysanthemii*

Asparaginase *Erwinia chrysanthemii* contains an asparaginase specific enzyme derived from *Erwinia chrysanthemii*. Asparaginase *Erwinia chrysanthemii* catalyzes the deamidation of asparagine to aspartic acid and ammonia, resulting in a reduction in circulating levels of asparagine. The mechanism of action of asparaginase *Erwinia chrysanthemii* is thought to be based on the inability of leukemic cells to synthesize asparagine due to lack of asparagine synthetase activity, resulting in cytotoxicity specific for leukemic cells that depend on an exogenous source of the amino acid asparagine for their protein metabolism and survival.

Indications

For the treatment of patients with acute lymphoblastic leukemia who have developed hypersensitivity to *E. coli*-derived asparaginase.

Dosage

To substitute for a dose of pegaspargase:

The recommended dose is 25,000 International Units/m² administered intramuscularly three times a week (Monday/Wednesday/Friday) for six doses for each planned dose of pegaspargase.

To substitute for a dose of native *E. coli* asparaginase:

The recommended dose is 25,000 International Units/m² administered intramuscularly for each scheduled dose of native *E. coli* asparaginase within a treatment.

Maximum dose of 50,000 units unless there is documentation that patient's body surface area (BSA) is greater than 2.6 m².

Required Codes

Asparaginase *Erwinia chrysanthemii* is reimbursable when billed with one of the following ICD-10-CM diagnosis codes:

C91.00 or C91.02

Billing

HCPCS code J9019 (injection asparaginase [erwinaze], 1,000 IU)

Atezolizumab

Atezolizumab is an Fc-engineered, humanized, monoclonal antibody that binds to PD-L1 and blocks interactions with the PD-1 and B7.1 receptors. Atezolizumab is a non-glycosylated IgG1 kappa immunoglobulin that has a calculated molecular mass of 145 kDa. PD-L1 may be expressed on tumor cells and/or tumor-infiltrating immune cells and can contribute to the inhibition of the anti-tumor immune response in the tumor microenvironment. Binding of PD-L1 to the PD-1 and B7.1 receptors found on T cells and antigen presenting cells suppresses cytotoxic T-cell activity, T-cell proliferation and cytokine production.

Atezolizumab is a monoclonal antibody that binds to PD-L1 and blocks its interactions with both PD-1 and B7.1 receptors. This releases the PD-L1/PD-1 mediated inhibition of the immune response, including activation of the anti-tumor immune response without inducing antibody-dependent cellular cytotoxicity.

Indications

Atezolizumab is indicated for the treatment of patients 18 years of age or older with:

- Locally advanced or metastatic urothelial carcinoma who:
 - Have disease progression during or following platinum-containing chemotherapy
 - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- Metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Atezolizumab.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. Documentation must indicate that the patient has one of the following diagnoses:

- Locally advanced or metastatic urothelial carcinoma
- Metastatic non-small cell lung cancer

Dosage

Administer 1,200 mg as an intravenous infusion over 60 minutes every three weeks. Dilute prior to intravenous infusion.

Required Codes

For the treatment of bladder cancer, use ICD-10-CM diagnosis codes: C67.0, C67.1, C67.2, C67.3, C67.4, C67.5, C67.6, C67.7, C67.8 and C67.9.

For the treatment of lung cancer, use ICD-10-CM diagnosis codes: C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.30, C34.31, C34.32, C34.80, C34.81, C34.82, C34.90, C34.91 and C34.92.

Billing

HCPCS code J9022 (injection, atezolizumab, 10 mg)

Avelumab (Bravencio®)

Avelumab is a programmed death ligand-1 (PD-L1) blocking antibody. PD-L1 may be expressed on tumor cells and tumor-infiltrating immune cells and can contribute to the inhibition of the anti-tumor immune response in the tumor microenvironment. Binding of PD-L1 to the PD-1 and B7.1 receptors found on T cells and antigen presenting cells suppresses cytotoxic T-cell activity, T-cell proliferation and cytokine production. Avelumab binds PD-L1 and blocks the interaction between PD-L1 and its receptors PD-1 and B7.1. This interaction releases the inhibitory effects of PD-L1 on the immune response resulting in the restoration of immune responses, including anti-tumor immune responses.

Indications

FDA approved indications

Dosage

FDA approved dosages

Authorization

No *Treatment Authorization Request* (TAR) is required for reimbursement

Age Limits

Must be 12 years of age or older

Billing

HCPCS code J9023 (injection, avelumab, 10 mg)

One (1) unit of J9023 equals 10 mg of avelumab

Prescribing Restrictions

Frequency of billing equals 800 mg/80 units every 2 weeks

Maximum billing unit(s) equals 800 mg/80 units

Axicabtagene ciloleucel

Axicabtagene ciloleucel suspension is a CD19-directed genetically modified autologous T-cell immunotherapy for intravenous (I.V.) infusion.

Indications

Axicabtagene ciloleucel is indicated for the treatment of adults with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including the following:

- Diffuse large B-cell lymphoma (DLBCL) not otherwise specified,
- Primary mediastinal large B-cell lymphoma,
- High grade B-cell lymphoma, or
- DLBCL arising from Follicular lymphoma.

Axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

Age

18 years and older

Dosage

A single infusion bag contains a suspension of chimeric antigen receptor (CAR)-positive T cells of 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells in approximately 68 mL.

Required Codes

Axicabtagene ciloleucel is reimbursable when billed with one of the following ICD-10-CM diagnosis codes:

- C83.30 thru C83.39
- C85.20 thru C85.29

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates all of the following:

- The service is medically necessary to treat an adult with relapsed or refractory large B-cell Lymphoma after two or more lines of systemic therapy;
- A clinician's written order and treatment plan for the service has been requested;
- The provider facility is certified by the Yescarta™ REMS (Risk Evaluation and Management Strategy) Program for Axicabtagene ciloleucel administration; and
- The provider facility is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) for Immune Effector Cell Therapy (IECT).

Billing

HCPCS code Q2041 (Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR T cells, including leukapheresis and dose preparation procedures, per therapeutic dose)

One (1) unit of Q2041 = a single infusion of up to 200 million autologous anti-CD19 CAR-positive viable T cells

Azacitidine

Azacitidine is a pyrimidine nucleoside analog of cytidine and is believed to exert its antineoplastic effects by causing hypomethylation of DNA and direct cytotoxicity on abnormal hematopoietic cells in the bone marrow.

Indications

Azacitidine is indicated for treatment of patients with:

- Refractory anemia
- Refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions)
- Refractory anemia with excess blasts or excess blasts in transformation
- Chronic myelomonocytic leukemia
- Acute myeloid leukemia

Dosage

The recommended starting dosage of azacitidine is 75 mg/m², given subcutaneously or intravenously once a day for seven days. This is usually repeated every four weeks for at least four cycles, and then continued as long as the patient continues to improve. The dosage may be increased to a maximum of 100 mg/m² if there is no initial response to treatment.

Billing

HCPCS code J9025 (injection, azacitidine, 1 mg)

Azacitidine is reimbursable for either intravenous or subcutaneous administration. Azacitidine may be billed either as an I.V. push or I.V. infusion over 40 minutes.

Note: Refer to the *Chemotherapy: An Overview* section of this manual for both subcutaneous injection and I.V. infusion administration billing codes.

BCG Live Intravesical

BCG Live is an attenuated, live culture preparation of the Bacillus of Calmette and Guerin (BCG) strain of *Mycobacterium bovis* for intravesical instillation.

Indications

BCG Live intravesical is used for the following indications:

- Carcinoma *in situ* (CIS) of the urinary bladder
- Primary or recurrent state Ta and/or T1 papillary tumors following transurethral resection (TUR)

BCG Live is not indicated for treatment of papillary tumors of stages higher than T1.

Age

18 years and older

Dosage

The recommended dose for the intravesical treatment of CIS and for the prophylaxis of recurrent papillary tumors consists of one vial of BCG Live suspended in 50 mL of preservative-free saline.

Authorization

No *Treatment Authorization Request* (TAR) is generally required for reimbursement.

Required Codes

Do not report in conjunction with CPT code 90586.

Billing

HCPCS code J9030 (injection, BCG live intravesical instillation, 1 mg)

One (1) unit of J9030 = 1 mg of BCG live colony-forming units (CFU)

Belantamab mafodotin-blmf (BLENREP®)

Belantamab mafodotin-blmf is an antibody-drug conjugate (ADC). The antibody component is an afucosylated IgG1 directed against BCMA, a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is MMAF, a microtubule inhibitor. Upon binding to BCMA, belantamab mafodotin-blmf is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis. Belantamab mafodotin-blmf had antitumor activity in multiple myeloma cells and mediated killing of tumor cells through MMAF-induced apoptosis, as well as by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Authorization

No *Treatment Authorization Request* (TAR) is required for reimbursement.

REMS Program

Belantamab mafodotin-blmf is available only through a restricted program under a Risk Evaluation and Management Strategy (REMS) called the Blenrep REMS because of the risks of ocular toxicity.

Notable requirements of the Blenrep REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training in the Blenrep REMS
- Prescribers must counsel patients receiving belantamab mafodotin-blmf about the risk of ocular toxicity and the need for ophthalmic examinations prior to each dose
- Patients must be enrolled in the Blenrep REMS and comply with monitoring
- Healthcare facilities must be certified with the program and verify that patients are authorized to receive belantamab mafodotin-blmf
- Wholesalers and distributors must only distribute belantamab mafodotin-blmf to certified healthcare facilities

Further information is available at <http://www.blenrepregs.com> and 1-855-209-9188.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J9037 (injection, belantamab mafodotin-blmf, 0.5 mg)

Suggested ICD-10-CM Diagnosis Codes

C90.00, C90.02

Prescribing Restriction(s)

Frequency of billing = 2.5 mg/kg once every 21 days

Belinostat

Belinostat is a histone deacetylase inhibitor and catalyzes the removal of acetyl groups from the lysine residues of histones and some non-histone proteins. In vitro, belinostat caused the accumulation of acetylated histones and other proteins, inducing cell cycle arrest and/or apoptosis of some transformed cells with preferential cytotoxicity towards tumor cells compared to normal cells.

Indications

For the treatment of patients 18 years of age and older with relapsed or refractory peripheral T-cell lymphoma.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Dosage

The recommended dose is 1,000 mg/m² once daily on days 1 through 5 of a 21-day cycle.

Billing

HCPCS code J9032 (injection, belinostat, 10 mg)

Bendamustine HCl

Bendamustine hydrochloride (HCl) is an alkylating agent for intravenous (I.V.) administration.

Indications

Bendamustine HCl is used to treat the following conditions:

- Chronic lymphocytic leukemia (CLL)
- Indolent B-cell non-Hodgkin's lymphoma (NHL)
 - Disease refractory to rituximab or relapsed within six months of a rituximab-containing treatment regimen.

Age

18 years and older

Dosage

The recommended dosage varies based on the treatment condition and subsequent level of organ system toxicity.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates all of the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for bendamustine HCl.

Billing

HCPCS code J9033 = (injection, bendamustine HCl (treanda), 1 mg)

One (1) unit of J9033 = 1 mg of bendamustine HCl (treanda)

HCPCS code J9034 = (injection, bendamustine HCl (bendeka), 1 mg)

One (1) unit of J9034 = 1 mg of bendamustine HCl (bendeka)

Bevacizumab

Policy for intravitreal bevacizumab (HCPCS code J9035) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Bevacizumab is a vascular endothelial growth factor-specific angiogenesis inhibitor and is reimbursable for the treatment of:

- Metastatic breast cancer, with paclitaxel for treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer
- Unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer, with carboplatin and paclitaxel for first line treatment
- Metastatic colorectal cancer, with intravenous five fluorouacil-based chemotherapy for first- or second-line treatment
- Glioblastoma multiforme, as a single agent for patients with progressive disease following prior therapy
- Metastatic renal cell carcinoma with interferon alpha
- Cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan in persistent, recurrent, or metastatic disease
- Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan

Dosage

The recommended dosage for bevacizumab varies depending upon the disease being treated.

Required Codes

Bevacizumab is reimbursable only with one of the following ICD-10-CM diagnosis codes:

C18.0 thru C20	C64.1 thru C64.9
C21.2	C71.0 thru C71.9
C21.8	E08.311
C34.00 thru C34.92	E08.3211 thru E08.3213
C48.1 thru C48.2	E08.3219
C50.011 thru C50.929	E08.3311 thru E08.3313
C53.0 thru C53.9	E08.3319
C56.1 thru C57.4	E08.3411 thru E08.3413

Required Codes (continued)

E08.3419	E11.3419
E08.3511 thru E08.3513	E11.3511 thru E11.3513
E08.3519	E11.3519
E09.311	E13.311
E09.3211 thru E09.3213	E13.3211 thru E13.3213
E09.3219	E13.3219
E09.3311 thru E09.3313	E13.3311 thru E13.3313
E09.3319	E13.3319
E09.3411 thru E09.3413	E13.3411 thru E13.3413
E10.311	E13.3419
E10.3211 thru E10.3213	E13.3511 thru E13.3513
E10.3219	E13.3519
E09.3419	H34.8110 thru H34.8112
E09.3511 thru E09.3513	H34.8120 thru H34.8122
E09.3519	H34.8130 thru H34.8132
E10.3311 thru E10.3313	H34.8190 thru H34.8192
E10.3319	H34.8310 thru H34.8312
E10.3411 thru E10.3413	H34.8320 thru H34.8322
E10.3419	H34.8330 thru H34.8332
E10.3511 thru E10.3513	H34.8390 thru H34.8392
E10.3519	H35.3210 thru H35.3213
E11.311	H35.3220 thru H35.3223
E11.3211 thru E11.3213	H35.3230 thru H35.3233
E11.3219	H35.3290 thru H35.3293
E11.3311 thru E3313	H35.351 thru H35.353
E11.3319	H35.359
E11.3411 thru E11.3413	H35.81

Billing

HCPCS code J9035 (injection, bevacizumab, 10 mg)

One (1) unit equals 10 mg

Bevacizumab is packaged in 100 mg and 400 mg vials, and it may be necessary to discard the unused portion of a vial. Providers may bill for a quantity equal to the amount given to the patient plus the amount wasted. Providers must specify the amount wasted in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim.

Bevacizumab-awwb (Mvasi)

Bevacizumab products bind human vascular endothelial growth factor (VEGF) and prevent the interaction of VEGF to its receptors (Flt-1 and KDR) on the surface of endothelial cells. The interaction of VEGF with its receptors leads to endothelial cell proliferation and new blood vessel formation in in vitro models of angiogenesis. Administration of bevacizumab products to xenotransplant models of colon cancer in nude (athymic) mice caused reduction of microvascular growth and inhibition of metastatic disease progression.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code Q5107 (injection, bevacizumab-awwb, biosimilar, [mvasi] 10 mg)

One (1) unit of Q5107 equals 10 mg of bevacizumab-awwb

Bevacizumab-bvzr (Zirabev)

Bevacizumab-bvzr, a recombinant humanized monoclonal IgG1 antibody, binds to vascular endothelial growth factor (VEGF) and inhibits the interaction of VEGF to Flt1 and KDR receptors on the surface of endothelial cells. In the process, it leads to the proliferation of endothelial cells and formation of new blood vessels.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code Q5118 (injection, bevacizumab-bvcr, biosimilar [Zirabev], 10 mg)

Prescribing Restrictions

Frequency of billing equals every 14 days

Maximum billing units equals 2,280 mg equals 228 units

«Blinatumomab (Blincyto®)

Blinatumomab is a bispecific CD19-directed CD3 T-cell engager that binds to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T-cells. It activates endogenous T-cells and mediates the formation of a synapse between the T-cell and the tumor cell, upregulation of cell adhesion molecules, production of cytolytic proteins, release of inflammatory cytokines and proliferation of T-cells, which results in redirected lysis of CD19-positive cells.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Blincyto REMS:

Blincyto must be prepared and administered based on the Risk Evaluation and Mitigation Strategy (REMS) requirements defined by the FDA. The goals of the Blincyto REMS are to mitigate the risk of cytokine release syndrome which may be life-threatening or fatal; the risk of neurological toxicities which may be severe, life-threatening, or fatal; and the risk of preparation and administration errors associated with use of Blincyto by:

- Informing healthcare providers about the risk of cytokine release syndrome which may be life-threatening or fatal
- Informing healthcare providers about the risk of neurological toxicities which may be severe, life-threatening, or fatal
- Informing pharmacists, who will prepare and dispense Blincyto, and nurses, who will administer Blincyto, about the risk of preparation and administration errors associated with use of Blincyto»

Billing

HCPCS code J9039 (injection, blinatumomab, 1 microgram)

Bortezomib

Bortezomib is approved for the treatment of multiple myeloma and mantle cell lymphoma.

Dosage

The recommended initial dose for bortezomib is 1.3 mg/m² and may be administered intravenously at a concentration of 1 mg/ml or subcutaneously at a concentration of 2.5 mg/ml. Bortezomib is for intravenous or subcutaneous use only and should not be administered by any other route.

Required Codes

Bortezomib is reimbursable only with one of the following ICD-10-CM diagnosis codes:

C83.10 thru C83.19

C90.00 thru C90.02

Billing

HCPCS code J9041 (injection, bortezomib [velcade], 0.1 mg)

Reimbursement for any dosage in excess of 35 units requires documentation of body surface area greater than 2.7 m² or with an approved *Treatment Authorization Request* (TAR).

Brentuximab Vedotin

Brentuximab vedotin is a CD30-directed antibody-drug conjugate (ADC) consisting of three components: (1) the chimeric IgG1 antibody cAC10, specific for human CD30, (2) the microtubule disrupting agent monomethyl auristatin E (MMAE), and (3) a protease-cleavable linker that covalently attaches MMAE to cAC10. Nonclinical data suggest that the anticancer activity of brentuximab vedotin is due to the binding of the ADC to CD30-expressing cells, followed by internalization of the ADC-CD30 complex, and the release of MMAE via proteolytic cleavage. Binding of MMAE to tubulin disrupts the microtubule network within the cell, subsequently inducing cell cycle arrest and apoptotic death of the cells.

Indications

Brentuximab vedotin is indicated for adults 18 years of age and older for the following:

- The treatment of patients with Hodgkin lymphoma (HL) after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates.
- The treatment of patients with HL at high risk of relapse or progression as post ASCT consolidation.
- The treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Dosage

The recommended dose is 1.8 mg/kg administered only as an intravenous infusion over 30 minutes every 21 days. Treatment may be continued until the earliest of a maximum of 16 cycles, disease progression or unacceptable toxicity. The maximum dose is 180 mg every 21 days; however, this dose may be exceeded if justification for the higher dose is submitted with the claim. The maximum daily dosage is 180 mg.

Billing

HCPCS code J9042 (injection, brentuximab vedotin, 1 mg)

Brexucabtagene autoleucel (Tecartus™)

Brexucabtagene autoleucel, a CD19 (Cluster of Differentiation 19)-directed genetically modified autologous T cell immunotherapy, binds to CD19-expressing cancer cells and normal B cells. Studies demonstrated that following anti-CD19 CAR T cell engagement with CD19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T cell activation, proliferation, acquisition of effector functions, and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement

TAR Criteria

Tecartus is considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages
- Must be administered in a health care facility registered with the Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program
- Patient must be 18 years of age or older
- Patient must have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)
- Patient previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody (for example, rituximab), and a Bruton tyrosine kinase inhibitor (BTKi) (for example, acalabrutinib, ibrutinib, zanubrutinib)
- Patient had disease progression after their last regimen or refractory disease to their most recent therapy
- Patient must have adequate bone marrow, cardiac, pulmonary, renal, and organ functions

- Patient does not have the following:
 - Active or serious infections
 - Prior allogeneic hematopoietic stem cell transplant (HSCT)
 - Detectable cerebrospinal fluid malignant cells or brain metastases
 - History of central nervous system (CNS) lymphoma or CNS disorders
- TECARTUS is not prescribed concurrently with other CAR T-cell immunotherapy (for example, Kymriah, YESCARTA)

Initial Authorization is for three months (1 dose only)

Reauthorization

Continued therapy is not approvable.

REMS Program

TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program. This is due to Cytokine Release Syndrome and Neurologic Toxicities. TECARTUS must be administered in a certified health care facility.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code Q2053, Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

Providers are to take the following steps when submitting claims for TECARTUS:

- Submit and receive back an approved *Treatment Authorization Request* (TAR)

- Completion of claim forms:
 - Outpatient claims may be billed by paper claim using *CMS-1500* or electronically using ASC X12N 837P v.5010.
 - Providers must submit one (1) service line on the TAR request, and enter “4” in the Units box
 - On the 837P or *CMS-1500* claim form, provider must submit one claim line to represent one (1) service.
 - ❖ Claims submitted with more than one claim line will be denied
 - Provider must submit an invoice for reimbursement.
 - This process will ensure that the total reimbursement paid for the quantity of four (4) is no more than the paid price on the provider submitted invoice
 - Tecartus must be billed on its own with no other drug or biological
 - For instructions regarding physician claim form completion, refer to the Medi-Cal website, forms section for completion of [837P](#) and [CMS-1500 claim forms](#).

Suggested ICD-10-CM Diagnosis Codes

C83.10, C83.11, C83.12, C83.13, C83.14, C83.15, C83.16, C83.17, C83.18, C83.19

Prescribing Restrictions

Frequency of billing equals one dose only. No repeat authorization.

Cabazitaxel

Cabazitaxel is an antineoplastic agent belonging to the taxane class. Cabazitaxel is a microtubule inhibitor that binds to tubulin and promotes its assembly into microtubules while simultaneously inhibiting disassembly. This leads to the stabilization of microtubules, which results in the inhibition of mitotic and interphase cellular functions.

Indications

Cabazitaxel is indicated in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Restrictions

Restricted to males ages 18 and older.

Diagnosis Restrictions

Restricted to ICD-10-CM diagnosis code C61.

Dosage

The recommended dose is 25 mg/m² administered as a one-hour intravenous infusion every three weeks in combination with oral prednisone 10 mg administered daily throughout cabazitaxel treatment.

When billing for more than 62 mg per dose, providers must document body surface area exceeds 2.5 meters squared.

Billing

HCPCS code J9043 (injection, cabazitaxel, 1 mg)

One billing unit = 1 mg

Carboplatin

Carboplatin, 50 mg (HCPCS code J9045), a platinum-containing chemotherapeutic agent, is reimbursable to treat the following:

Testicular cancer	Breast cancer
Ovarian cancer	Cancer of the esophagus
Bladder cancer	Cancer of the nasal cavity
Adrenal gland cancer	Wilms' tumor
Lung cancer (small-cell and non-small cell)	Cancer without specification of the primary site
Cancer of the cervix	Retinoblastoma
Endometrial cancer	Brain cancer
Neuroblastoma	Cancer of the skin
Osteogenic sarcoma	Hodgkin lymphoma
Head, face and neck cancer	Non-Hodgkin lymphoma

CPT code 96413 (chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug) may be billed in conjunction with carboplatin code J9045.

Place of Service: Outpatient

Carboplatin is used as an alternative to cisplatin in the outpatient setting due to its lower gastrointestinal toxicity and short infusion time. No pre or post-treatment hydration or forced diuresis is required, as with cisplatin.

Dosage

The maximum dose is for carboplatin is 20 units. Doses in excess of 20 units will be allowed when medically justified, such as dose based on age, sex, renal function, weight, height, etc., Carboplatin Area Under Curve (AUC) Calculation.

Billing

HCPCS code J9045 (injection, carboplatin, 50 mg)

Carfilzomib

Carfilzomib is a tetrapeptide epoxyketone proteasome inhibitor that irreversibly binds to the N-terminal threonine-containing active sites of the 20S proteasome, the proteolytic core particle within the 26S proteasome. Carfilzomib had antiproliferative and proapoptotic activities *in vitro* in solid and hematologic tumor cells.

Indications

Carfilzomib is indicated for the treatment of multiple myeloma.

Combination Therapy:

- In combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy

Monotherapy:

- As a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy

Limited to patients 18 years of age and older.

Dosage

The recommended dosing regimens for monotherapy and combination therapy differ. Please refer to the appropriate literature for the regimens.

Required Codes

Carfilzomib is reimbursable when billed with one of the following ICD-10-CM diagnosis codes:

C90.00	C90.20
C90.02	C90.22
C90.10	C90.30
C90.12	C90.32

Billing

HPCS code J9047 (injection, carfilzomib, 1 mg)

Cemiplimab-rwlc (Libtayo)

Cemiplimab-rwlc is a monoclonal antibody that targets checkpoint inhibitor PD-1 (programmed death 1) and blocks its interaction with PD-L1 and PD-L2, releasing the PD-1 pathway-mediated inhibition of the immune response, including antitumor response, thereby decreasing tumor growth. Binding of the PD-1 ligands and PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J9119 (injection, cemiplimab-rwlc, 1 mg)

Prescribing Restrictions

Frequency of billing = Every 21 days

Maximum billing unit(s) = 350 mg = 350 units

Cetuximab

Cetuximab is reimbursable for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck, and metastatic colorectal carcinoma.

Dosage

The recommended dosing schedule for intravenous infusion of cetuximab is an initial dose of 400 mg/m², followed by 250 mg/m² every week or 500 mg/m² every two weeks.

See additional billing information for cetuximab under panitumumab in the *Chemotherapy: Drugs P-Z Policy* section of this manual.

Required Codes

Cetuximab is reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes:

C00.0 thru C14.8

C30.0 thru C31.9

C18.0 thru C20

C32.0 thru C32.9

C21.2

C76.0

C21.8

Note: A California Children's Services/Genetically Handicapped Persons Program (CCS/GHPP) Service Authorization Request (SAR) overrides the preceding diagnostic restrictions.

Billing

HCPCS code J9055 (injection, cetuximab, 10 mg)

Cisplatin

Cisplatin is reimbursable when used as treatment of the following:

- Testicular and ovarian tumors
- Transitional cell bladder cancer
- Malignancies of the head and neck
- Small cell lung cancer
 - Undifferentiated
 - Lymphocyte-like
 - Oat cell type carcinomas
- Cervical carcinomas
 - Squamous cell
 - Metastatic
- Solid tumors in children where radiation or other chemotherapeutic agents are not appropriate
 - Osteosarcomas
 - Neuroblastomas
 - Germ cell tumors

Dosage

Maximum dosage is 250 mg (25 billing units); greater dosage allowed if documentation shows body surface area (BSA) is greater than 2.5 m².

Inpatient Services Requirements

This type of chemotherapy requires adequate hydration of the patient. If it is not possible to maintain hydration in an outpatient setting or if the patient has previously had severe reactions (such as nausea and vomiting), inpatient treatment may be required. If administration of cisplatin is the only reason for hospital admission, the Medi-Cal consultant may approve a short hospitalization (less than 24 hours) up to three times in a 30-day period.

Intraperitoneal Cisplatin Therapy for Ovarian Malignancy

Intraperitoneal cisplatin therapy for ovarian malignancy is reimbursable when re-exploration has shown that systemic therapy has failed, as indicated by persistence and/or recurrence of the disease. In most cases, the Medi-Cal consultant will authorize a one-day inpatient admission to permit adequate hydration prior to administration of the agent.

Normally, intraperitoneal catheters and shunts are established to permit instillation of the medication over an extended period.

Billing

HCPCS code J9060 (cisplatin, 10 mg)

Cladribine

Cladribine is a synthetic antineoplastic agent for intravenous (I.V.) administration.

Indications

Cladribine is used to treat patients with neoplastic conditions such as hairy cell leukemia.

Age

All ages

Dosage

The dose and frequency of cladribine administration varies based on the patient's age, treatment condition, and response to therapy. The dose may range from 0.09-1.4 mg/kg/day given by I.V. infusion from between 1 to 7 days per cycle.

Authorization

No *Treatment Authorization Request* (TAR) is generally required for reimbursement.

Billing

HCPCS code J9065 (injection, cladribine, per 1 mg)

One (1) unit of J9065 = 1 mg of cladribine injection solution

Clofarabine

Clofarabine is indicated for the treatment of pediatric patients 1 to 21 years of age with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens.

Authorization

A *Treatment Authorization Request* (TAR) is required for reimbursement.

Dosage

The recommended pediatric dosage and schedule for clofarabine is 52 mg/m² administered by intravenous infusion over two hours daily for five consecutive days. Treatment cycles are repeated approximately every two to six weeks.

Billing

HCPCS code J9027 (injection, clofarabine, 1 mg)

Clofarabine may be billed in conjunction with CPT code 96415 (chemotherapy administration, intravenous infusion technique; one to eight hours).

Copanlisib

Copanlisib is a kinase inhibitor for intravenous (I.V.) administration.

Indications

Copanlisib is used to treat relapsed follicular lymphoma in adult patients who have received at least two prior systemic therapies.

Dosage

The recommended dose is 60 mg I.V. administered on treatment days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (three weeks on and one week off).

Age

18 years and older

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation of the following:

- The service is medically necessary;
- The patient has follicular lymphoma in relapse despite having received at least two systemic chemotherapy treatment regimens;
- The physician's legible, complete, and signed treatment plan/order for copanlisib.

Billing

HCPCS code J9057 (injection, copanlisib, 1 mg)

One (1) unit of J9057 = 1 mg of copanlisib injection solution

Cyclophosphamide

Cyclophosphamide, 100 mg (HCPCS code J9070) has a maximum dosage of 6.8 Gm. However, a dose in excess of 6.8 Gm is allowed with documentation of patient weight exceeding 136 kg.

Daratumumab

Daratumumab is an IgG1k human monoclonal antibody (mAb) that binds to CD38 and inhibits the growth of CD38-expressing tumor cells by inducing apoptosis directly through Fc-mediated cross linking and by immune-mediated tumor cell lysis through complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). Myeloid-derived suppressor cells (MDSCs) and a subset of regulatory T-cells (CD38+Tregs) express CD38 and are susceptible to daratumumab-mediated cell lysis.

Indications

Daratumumab is indicated for the treatment of patients 18 years of age or older with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.

Authorization

An approved TAR is required for reimbursement. The TAR must state that the treatment is for a patient with multiple myeloma.

Required Codes

ICD-10-CM diagnosis codes C90.00, C90.01, C90.10 and C90.30.

Dosage

Dilute and administer daratumumab as an intravenous infusion. The recommended dose is 16 mg/kg of body weight:

«Dosage Table»

Frequency	Stage of Treatment
Weekly	Weeks 1-8
Every two weeks	Weeks 9-24
Weekly	Weeks 25 onwards until disease progression

Billing

HCPCS code J9145 (injection, daratumumab, 10 mg)

Daratumumab and Hyaluronidase-fihj (Darzalex Faspro™)

Darzalex Faspro is a subcutaneous CD38-directed antibody. Daratumumab is an IgG1κ human monoclonal antibody directed against CD38. CD38 is a cell surface glycoprotein which is highly expressed on myeloma cells. By binding to CD38, daratumumab inhibits the growth of CD38-expressing tumor cells by inducing apoptosis directly through Fc mediated cross linking as well as by immune-mediated tumor cell lysis through complement dependent cytotoxicity, antibody dependent cell mediated cytotoxicity, and antibody dependent cellular phagocytosis. Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. At the recommended dose, hyaluronidase acts locally and the effects are reversible; permeability of subcutaneous tissue is restored within 24 to 48 hours.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J9144 (injection, daratumumab 10 mg and hyaluronidase-fihj)

Suggested ICD-10-CM Diagnosis Codes

C90.00, C90.01, C90.02

Prescribing Restrictions

Frequency of billing = 1,800 mg/ 180 units every week

Maximum billing unit(s) = 1,800 mg/ 180 units

Daunorubicin

Daunorubicin has antimitotic and cytotoxic activity through a number of proposed mechanisms of action. Daunorubicin forms complexes with DNA by intercalation between base pairs. It inhibits topoisomerase II activity by stabilizing the DNA-topoisomerase II complex, preventing the relegation portion of the ligation-relegation reaction that topoisomerase II catalyzes. Single strand and double strand DNA breaks result. Daunorubicin may also inhibit polymerase activity, affect regulation of gene expression, and produce free radical damage to DNA.

Indications

Daunorubicin is administered for the treatment of remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) in adults and remission induction in acute lymphocytic leukemia in children and adults.

Dosage

The usual dose of daunorubicin is 45 mg/m² (90 mg or 9 units) and requires no authorization. If the dose administered is greater than 90 mg, an approved *Treatment Authorization Request* (TAR) documenting that the patient's body surface area is greater than 2.0 m² is required for reimbursement.

Billing

HCPCS code J9150 (injection, daunorubicin, 10 mg)

Daunorubicin/Cytarabine Liposome (Vyxeos)

Vyxeos (daunorubicin and cytarabine) liposome for injection is a liposomal formulation of daunorubicin and cytarabine at a fixed 1:5 molar ratio. The 1:5 molar ratio of daunorubicin:cytarabine has been shown to have synergistic effects at killing leukemia cells in vitro and in murine models. Daunorubicin has antimitotic and cytotoxic activity, which is achieved by forming complexes with DNA, inhibiting topoisomerase II activity, inhibiting DNA polymerase activity, affecting regulation of gene expression, and producing DNA-damaging free radicals. Cytarabine is a cell cycle phase-specific antineoplastic agent, affecting cells only during the S-phase of cell division. Cytarabine acts primarily through inhibition of DNA polymerase. Based on animal data, the liposomes enter and persist in the bone marrow, where they are taken up intact by bone marrow cells. In leukemia-bearing mice, the liposomes are taken up by leukemia cells to a greater extent than by normal bone marrow cells. After cellular internalization, liposomes undergo degradation releasing cytarabine and daunorubicin within the intracellular environment.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J9153 (injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine)

One (1) unit of J9153 equals 1 mg of daunorubicin and 2.27 mg of cytarabine

Decitabine

Decitabine is used in the treatment of myelodysplastic syndrome and acute myeloid leukemia.

Dosage

Maximum dosage is 122 mg per day unless documented that the body surface area (BSA) is greater than 2.7 m².

Billing

HCPCS code J0894 (injection, decitabine, 1 mg).

Degarelix

Degarelix is reimbursable for treatment of advanced prostate cancer in males.

Dosage

Maximum dosage is 240 mg (quantity equals 240); frequency is limited to once every rolling 28 days.

Required Codes

Degarelix is reimbursable when billed in conjunction with ICD-10-CM diagnosis code C61.

Billing

HCPCS code J9155 (injection, degarelix, 1 mg)

One unit = 1 mg

Denileukin Diftitox

Denileukin diftitox is reimbursable for patients with persistent cutaneous T-cell lymphoma.

Authorization

A TAR must be submitted with the following documentation that the patient has:

- A diagnosis of recurrent or persistent cutaneous T-cell lymphoma; and
- Stage IB, IIA, IIB, IIIA, IIIB or IVA (denileukin diftitox is not covered for patients in stage IA or IVB); and
- Failed or been intolerant of other U.S. Food and Drug Administration approved medications such as topical chemotherapeutic agents, and/or electron beam therapy, and/or phototherapy, and/or interferon, and/or topical retinoids, and/or systemic retinoids, and/or extracorporeal photopheresis, and/or single agent chemotherapy, and/or combination chemotherapy; and
- At least 20 percent of the malignant cells in any tissue sample expressing the CD25 component of the Interleukin-2 receptor

The initial TAR is valid only for three cycles. Subsequent authorization should be based upon patient response and the documentation submitted with the TAR.

Dosage

The usual dosage is 9 or 18 mcg/kg/day, administered intravenously for five consecutive days, every 21 days. Optimal duration of therapy has not been determined.

Billing

HCPCS code J9160 (injection, denileukin diftitox, 300 mcg)

Denosumab

Policy for the use of denosumab in the treatment of giant cell tumor of bone may be found in *Injections: Drugs A-D* Policy section in this manual.

Docetaxel

Docetaxel is an antineoplastic agent that acts by disrupting the microtubular network in cells that is essential for mitotic and interphase cellular functions. Docetaxel binds to free tubulin and promotes the assembly of tubulin into stable microtubules while simultaneously inhibiting their disassembly. This leads to the production of microtubule bundles without normal function and to the stabilization of microtubules, which results in the inhibition of mitosis in cells.

Indications

Docetaxel is indicated for the treatment of:

- Breast cancer
- Esophageal cancer
- Gastric cancer
- Head and neck cancer
- Non-small cell lung cancer
- Occult primary
- Ovarian cancer
- Prostate cancer
- Small cell lung cancer

Billing

HCPCS code J9171 (injection, docetaxel, 1 mg)

One (1) unit = 1 mg

CPT code 96413 (chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug) may be billed in conjunction with docetaxel and is separately reimbursable.

When billing for a quantity greater than 200 mg (200 units), providers must document that the patient's body surface area exceeds 2 m².

«Dostarlimab-gxly (Jemperli)

Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody. It is an anti-PD-1 humanized IgG4 monoclonal antibody, which inhibits programmed cell death-1 (PD-1) activity by binding to the PD-1 receptor on T-cells to block PD-1 ligands (PD-L1 and PD-L2) from binding. Blocking the PD-1 pathway inhibits the negative immune regulation caused by PD-1 receptor signaling (Hamid 2013).

Indications

All FDA-approved indications

Age Limits

Must be 18-years of age or older

Dosage

FDA-approved dosages

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS code C9082 (injection, dostarlimab-gxly, 100 mg)

Prescribing Restriction(s)

Frequency of billing = 500 mg/5 units every 3 weeks for 4 doses, then 3 weeks after dose 4, continue with 1,000 mg/10 units every 6 weeks.>>

Doxorubicin HCl

Doxorubicin is an anthracycline topoisomerase inhibitor isolated from *Streptomyces peucetius* var. *caesius*.

The mechanism of action of doxorubicin HCl is thought to be related to its ability to bind DNA and inhibit nucleic acid synthesis. Cell structure studies have demonstrated rapid cell penetration and perinuclear chromatin binding, rapid inhibition of mitotic activity and nucleic acid synthesis, and induction of mutagenesis and chromosomal aberrations.

Indications

Doxorubicin is indicated for the treatment of:

- Acute lymphoblastic leukemia
- Acute myeloblastic leukemia
- Wilms' tumor
- Soft tissue and bone sarcomas
- Ovarian carcinoma
- Transitional cell bladder carcinoma
- Thyroid carcinoma
- Gastric carcinoma
- Hodgkin lymphoma
- Non-Hodgkin lymphoma
- Small cell lung cancer
- Breast cancer

Dosage

The dose is variable depending upon the malignancy being treated. The maximum dose allowed is 200 mg, unless there is documentation that the patient's body surface is greater than 2.75 m².

Billing

HCPCS code J9000 (injection, doxorubicin hydrochloride, 10 mg)

Doxorubicin HCl Liposome

Doxorubicin is an anthracycline topoisomerase inhibitor isolated from *Streptomyces peucetius* var. *caesius*. Doxorubicin HCl liposome is doxorubicin hydrochloride encapsulated in liposomes for intravenous administration.

The mechanism of action of doxorubicin HCl is thought to be related to its ability to bind DNA and inhibit nucleic acid synthesis. Cell structure studies have demonstrated rapid cell penetration and perinuclear chromatin binding, rapid inhibition of mitotic activity and nucleic acid synthesis, and induction of mutagenesis and chromosomal aberrations.

The liposomes in doxorubicin HCl liposome are microscopic vesicles composed of a phospholipid bilayer that are capable of encapsulating active drugs. The liposomes are formulated with surface-bound methoxypolyethylene glycol, a process often referred to as pegylation, to protect liposomes from detection by the mononuclear phagocyte system and to increase blood circulation time.

Indications

Doxorubicin HCl liposome is indicated for the treatment of:

- Ovarian cancer after failure of platinum-based chemotherapy
- AIDS-related Kaposi's Sarcoma after failure of prior systemic chemotherapy or intolerance to such therapy
- Multiple myeloma in combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy
- Breast cancer

Dosage

The dosage is variable depending upon the malignancy being treated. Doses greater than 140 mg require documentation that the patient's body surface area (BSA) is greater than 2.5 m².

Required Codes

Doxorubicin HCl liposome is reimbursable when billed with any of the following ICD-10-CM diagnosis codes:

C46.0 thru C46.9

C88.2 thru C90.32

C50.011 thru C50.929

D47.Z9

C56.1 thru C57.4

Billing

HCPCS code Q2049 (injection doxorubicin hydrochloride, liposomal, imported Lipodox[®], 10 mg)

HCPCS code Q2050 (injection, doxorubicin hydrochloride, liposomal, not otherwise specified, 10 mg)

CPT code 96413 (chemotherapy administration intravenous infusion technique; up to one hour, single or initial substance/drug) is reimbursable when billed with HCPCS code Q2049 or Q2050.

Durvalumab

Durvalumab is a programmed death-ligand 1 (PD-L1) blocking antibody solution for intravenous (I.V.) administration.

Indications

Durvalumab is used to treat the following conditions:

- Urothelial Carcinoma
 - Locally advanced or metastatic disease that has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- Non-Small Cell Lung Cancer (NSCLC)
 - Unresectable Stage III NSCLC disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Age

18 years and older

Dosage

The recommended dosage varies based on the treatment condition:

- For Urothelial Carcinoma: 10 mg/kg I.V. every 14 days until disease progression or unacceptable toxicity.
- For Stage III NSCLC: 10 mg/kg I.V. every 14 days until disease progression, unacceptable toxicity or a maximum of 12 months.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for durvalumab.

Billing

HCPCS code J9173 (injection, durvalumab, 10 mg)

One (1) unit of J9173 = 10 mg of durvalumab

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.