Chemotherapy: Drugs A-D Policy

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 Policy and Chemotherapy: Drugs P-Z Policy 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

HCPCS 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 (Ryrevant)**

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 J9061, (injection, amivantamab-vmjw, 2 mg)>>

**Prescribing Restrictions**

Frequency of billing equals «1,400 mg/700» 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.

«Maximum billing unit(s) = 1,400 mg/700 units>>

Part 2 – Chemotherapy: Drugs A-D Policy
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 Chrysanthemi

Asparaginase Erwinia chrysanthemi contains an asparaginase specific enzyme derived from Erwinia chrysanthemi. Asparaginase Erwinia chrysanthemi 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 chrysanthemi 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 chrysanthemi 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)
Asparaginase Erwinia Chrysanthemi (recombinant)
Rywn (Rylaze™)

Asparaginase erwinia chrysanthemi (recombinant)-rywn is an enzyme that catalyzes the conversion of the amino acid L-asparagine into aspartic acid and ammonia. The pharmacological effect of Rylaze is based on the killing of leukemic cells due to depletion of plasma asparagine. Leukemic cells with low expression of asparagine synthetase have a reduced ability to synthesize asparagine, and therefore depend on an exogenous source of asparagine for survival.

Indications
All FDA-approved indications

Dosage
FDA-approved dosages

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

Billing
HCPCS code J9021, (injection, asparaginase, recombinant, [Rylaze], 0.1 mg)

Suggested ICD-10-CM Diagnosis Codes
C91.00, C91.01, C91.02
Atezolizumab (Tecentriq®)
Atezolizumab is a humanized monoclonal antibody immune checkpoint inhibitor that binds to programmed death ligand 1 (PD-L1) to selectively prevent the interaction between the programmed cell death-1 (PD-1) and B7.1 (also known as CD80) receptors, while still allowing interaction between PD-L2 and PD-1. PD-L1 is an immune checkpoint protein expressed on tumor cells and tumor infiltrating cells and down regulates anti-tumor T-cell function by binding to PD-1 and B7.1; blocking PD-1 and B7.1 interactions restores antitumor T-cell function. Immune checkpoint inhibition combined with the mitogen-activated protein kinase (MAPK) pathway increase antigen presentation and T-cell infiltration/activation to suppress tumor growth and improve tumor immunogenicity (when compared to targeted therapy alone).

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 J9022 (injection, atezolizumab, 10 mg)

Suggested ICD-10 Diagnosis Codes
Breast Cancer
C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119 C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229 C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419 C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529 C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819 C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929
Hepatocellular Carcinoma
C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8, C22.9

Lung Cancer
C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.2

Melanoma
C43.0, C43.10, C43.11, C43.12, C43.20, C43.21, C43.22, C43.30
C43.31, C43.39, C43.4, C43.51, C43.52, C43.59, C43.60, C43.61, C43.62, C43.70, C43.71
C43.72, C43.8, C43.9

Urothelial Carcinoma
C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0, C67.1, C67.2, C67.3, C67.4, C67.5,
C67.6, C67.7, C67.8, C67.9, C68.0

Prescribing Restrictions
Maximum billing unit (s) equals 1680mg/168 units.

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 (Yescarta®)
YESCARTA, 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 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
Yescarta is considered medically necessary when all of the following criteria are met:

Universal criteria:
- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with an oncologist or hematologist
- Patient has an ECOG performance status of 0 or 1
- Patient does not have the following:
  - Primary central nervous system lymphoma
  - Active or serious infection or inflammatory disorders
  - Prior allogeneic hematopoietic stem cell transplant (HSCT)
- Patient must have adequate bone marrow, cardiac, pulmonary, renal hepatic and organ functions
- Healthcare facility is enrolled in the Yescarta and Tecartus REMS Program
- The provider facility is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) for Immune Effector Cell Therapy (IECT)
- Outpatient administration is restricted to Hospital Outpatient Services only
- Patient has not previously received treatment with a CAR T-cell immunotherapy
Relapsed or refractory large B-cell lymphoma:

- Patient must meet the general criteria above
- Patient has one of the following historically confirmed diagnosis of relapsed or refractory large B-cell lymphoma:
  - Diffuse large B-cell (DLBCL) not otherwise specified
  - Primary mediastinal large B-cell lymphoma (PMBCL)
  - High grade B-cell lymphoma
  - DLBCL arising from follicular lymphoma
- Patient has relapsed or refractory disease after two or more line of systemic therapy which include at a minimum anti-CD20 monoclonal antibody unless the tumor is CD20-negative and anthracycline containing chemotherapy regimen
- Patient had chemotherapy-refractory disease defined as no response to the most recent therapy or relapse with 1 year after autologous hematopoietic stem cell transplantation (HSCT)

Relapsed or refractory follicular lymphoma

- Patient must meet the general criteria above
- Patient has a histologically confirmed diagnosis or follicular lymphoma
- Patient has relapsed or refractory disease, defined as progression after two or more lines of systemic therapy
- Patient does not have transformed lymphoma or other aggressive lymphomas

Initial approval is for three months (one treatment only).

Reauthorization
Repeat treatment is not approvable.

YESCARTA and TECARTUS REMS:
The goals of the Yescarta and Tecartus Rems are to mitigate the risks of cytokine release syndrome (CRS) and neurological toxicities by:

1. Ensuring that hospitals and their associated clinics that dispense Yescarta and/or Tecartus are specially certified and have on-site, immediate access to tocilizumab
2. Ensuring those who prescribe, dispense, or administer Yescarta and/or Tecartus are aware of how to manage the risks of CRS and neurological toxicities}
**Age Limit**

Must be 18 years of age or older.

**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 unit of Q2041 equals a single infusion of up to 200 million autologous anti-CD19 CAR-positive viable T cells.

Administration code: CPT code 96413 (Chemo administration, intravenous infusion; up to 1 hour, single or initial substance or drug).

**Important Instructions for Billing**

Due to system limitations, providers are to take the following steps when submitting claims for Yescarta:

1. Submit and receive back an approved TAR/Service Authorization Request (SAR)
2. Bill using Q2041 (Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures per therapeutic dose).
3. Completion of claim forms:
   - Claims are restricted to hospital outpatient services. Note that claims from pharmacies and clinics will be denied.
   - Outpatient claims may be billed by paper claim using UB-04 or electronically using 837I.
   - Providers must submit one service line on the TAR/SAR request and enter “4” in the Units box.
   - On the 837I or UB-04 claim form, providers must submit one claim line to represent one service.
     - Claims submitted with more than one claim will be denied.
   - Providers must submit an invoice for reimbursement.
   - This process will ensure that the total reimbursement paid for the quantity of four is no more than the paid price on the provider submitted invoice.
   - Yescarta must be billed on its own with no other drug or biological.
4. «For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website for completion of 837I and UB-04 claim forms.

5. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 96413

Suggested ICD-10-CM Diagnosis Codes

C82.00 thru C82.49, C82.50 thru C82.59, C82.60 thru C82.69, C82.80 thru C82.89, C82.90 thru C82.99, C83.30 thru C83.39, C85.20 thru C85.29.

Prescribing Restrictions

Frequency of billing is once in a lifetime.»»

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 equals 1 mg of BCG live colony-forming units (CFU)
Belantamab mafodotin-blimf (BLENREP®)
Belantamab mafodotin-blimf 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-blimf 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-blimf 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-blimf 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-blimf 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-blimf
- Wholesalers and distributors must only distribute belantamab mafodotin-blimf to certified healthcare facilities

Further information is available at http://www.blenreprems.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 Restrictions
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 fluorouracil-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:

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</tbody>
</table>
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

Bevacizumab-maly (Alymsys®)
Bevacizumab products bind vascular endothelial growth factor (VEGF) and prevent the interaction of VEGF to its receptors Flt-1 and KDR (fms-like tyrosine kinase receptor 1 [Flt-1] and Kinase insert domain receptor [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 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**
An approved Treatment Authorization Request (TAR) is required for reimbursement.

**TAR Criteria**
Alymsys is considered medically necessary when all of the following criteria are met:
- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Alymsys will be used as a treatment for one of the following:
  - A. *Cervical cancer, persistent/recurrent/metastatic*
    - Treatment of persistent, recurrent, or metastatic cervical cancer (in combination with paclitaxel and either cisplatin or topotecan)
    - Treatment of persistent, recurrent, or metastatic cervical carcinoma (in combination with pembrolizumab, paclitaxel [conventional], and either cisplatin or carboplatin) – (plus or minus individualized radiation therapy and/or palliative care)
  - B. *Colorectal cancer, metastatic*
    - First- or second-line treatment of metastatic colorectal cancer (CRC) (in combination with fluorouracil-based chemotherapy)
    - Second-line treatment of metastatic CRC (in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy) after progression on a first-line treatment containing bevacizumab
    - Drug is not being used for the adjuvant treatment of colon cancer
  - C. *Glioblastoma, recurrent:*
    - Treatment of recurrent glioblastoma in adults
- **D. Non-small cell lung cancer, nonsquamous:**
  - First-line treatment of unresectable, locally advanced, recurrent or metastatic	nonsquamous non-small cell lung cancer (in combination with carboplatin and
paclitaxel)

- **E. Ovarian (epithelial), fallopian tube, or primary peritoneal cancer:**
  - **Stage III or IV disease, following initial surgical resection:** Treatment of stage
III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following
initial surgical resection (in combination with carboplatin and paclitaxel, followed
by single-agent bevacizumab)
  - **Platinum-resistant recurrent:** Treatment of platinum-resistant recurrent epithelial
ovarian, fallopian tube, or primary peritoneal cancer (in combination with
paclitaxel, doxorubicin [liposomal], or topotecan) in patients who received no
more than two prior chemotherapy regimens
  - **Platinum-sensitive recurrent:** Treatment of platinum-sensitive recurrent epithelial
ovarian, fallopian tube, or primary peritoneal cancer (in combination with
carboplatin and paclitaxel or with carboplatin and gemcitabine and then followed
by single-agent bevacizumab)

- **F. Renal cell carcinoma, metastatic:**
  - Treatment of metastatic renal cell carcinoma (in combination with interferon
alfa)

Initial authorization is for six months.
Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has experienced positive clinical response such as stabilization of disease or decrease in tumor size or spread.

Patient has absence of unacceptable toxicity such as gastrointestinal perforations and fistula, severe arterial thromboembolic events (ATE) grade four venous thromboembolic events (VTE), hypertensive crisis or hypertensive encephalopathy, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome (less than 2g of proteins in urine), severe infusion-related reactions, congestive heart failure (CHF), etc.

Reauthorization is for 12 months.

**Age Limits**

Must be 18 years of age or older.

**Billing**

HCPCS code C9142 (injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg).

**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 (Adcetris)

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

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA approved indications and dosing regimens
- Recipient must be 18 years of age or older
- Brentuximab Vedotin is being used for one of the following diagnoses and treatments:
  - **Anaplastic large cell lymphoma (primary cutaneous), relapsed**: Treatment of primary cutaneous anaplastic large cell lymphoma in recipients who have received prior systemic therapy
  - **Anaplastic large cell lymphoma (systemic), previously untreated**: Treatment of previously untreated systemic anaplastic large cell lymphoma (in combination with cyclophosphamide, doxorubicin, and prednisone)
- **Anaplastic large cell lymphoma (systemic), relapsed**: Treatment of systemic anaplastic large cell lymphoma after failure of at least one prior multiagent chemotherapy regimen

- **Hodgkin lymphoma, previously untreated**: Treatment of previously untreated stage III or IV classical Hodgkin lymphoma (in combination with doxorubicin, vinblastine, and dacarbazine)

- **Hodgkin lymphoma, relapsed or refractory**: Treatment of classical Hodgkin lymphoma after failure of at least 2 prior multiagent chemotherapy regimens (in recipients who are not autologous hematopoietic stem cell transplant [HSCT] candidates) or after failure of autologous HSCT

- **Hodgkin lymphoma, consolidation (post-autologous hematopoietic stem cell transplantation)**: Treatment of classical Hodgkin lymphoma in recipients at high risk of relapse or progression as post-autologous HSCT consolidation

- **Mycosis fungoides, relapsed**: Treatment of CD30-expressing mycosis fungoides in recipients who have received prior systemic therapy

- **Peripheral T-cell lymphoma, CD30-expressing, previously untreated**: Treatment of previously untreated CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified (in combination with cyclophosphamide, doxorubicin, and prednisone)

Initial Authorization is for 12 months.

**Renewal Criteria**

- Recipient continues to meet initial approval criteria
- Recipient has experienced positive clinical response defined by stabilization of disease or decrease in tumor size or spread
- Recipient does not have unacceptable toxicity from the drug such as progressive multifocal leukoencephalopathy, peripheral neuropathy, anaphylaxis, infusion reactions, neutropenia, etc.

Reauthorization is for 12 months.

**Age Limits**

Must be 18 years of age or older.

**Billing**

HCPCS code J9042 (injection, brentuximab vedotin, 1 mg)
Prescribing Restrictions
Frequency of billing equals 180 mg/180 units every three weeks or 120 mg/120 units every two weeks
Maximum billing unit(s) equals 180 mg/180 units

**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:

**Universal Criteria**
- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with an oncologist or a hematologist.
- 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 does not have active or serious infection or inflammatory disorders
• Patient has not previously received treatment with a CAR T-cell immunotherapy
• The provider facility is accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) for Immune Effector Cell Therapy (IECT)
• Outpatient administration is restricted to Hospital Outpatient Services only

Mantle Cell Lymphoma (MCL)
• Patient must meet the universal criteria above
• 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:
  - 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

Relapsed or Refractory B-Precursor ALL
• Patient must meet the universal criteria above
• Patient must have a diagnosis of relapsed or refractory B-precursor Acute Lymphoblastic Leukemia (ALL) defined as one of the following:
  - Primary refractory disease
  - First relapse if first remission is 12 months or less
  - Relapsed or refractory disease after two or more lines of systemic therapy
  - Relapsed or refractory disease at least 100 days after allogeneic stem cell transplantation (HSCT); OR
• A patient with Philadelphia chromosome positive (Ph+) disease is eligible if one of the following is met:
  - Patient is intolerant to tyrosine kinase inhibitor (TKI) therapy
Patient has relapsed/refractory disease despite treatment with at least 2 different TKIs
• Patient has adequate renal, hepatic, pulmonary and cardiac function
• Patient has an ECOG performance status of zero or one
• Patient does not have the following:
  – Central nervous system (CNS) abnormalities
  – Active graft-vs-host disease

Initial Authorization is for three months (one dose only)
Reauthorization is not approvable.

Yescarta and Tecartus REMS:
The goals of the Yescarta and Tecartus REMS are to mitigate the risks of cytokine release syndrome (CRS) and neurological toxicities by:

1. Ensuring that hospitals and their associated clinics that dispense Yescarta and/or Tecartus are specially certified and have on-site, immediate access to tocilizumab
2. Ensuring those who prescribe, dispense, or administer Yescarta and/or Tecartus are aware of how to manage the risks of CRS and neurological toxicities

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).

Administration code: CPT code 96413 (Chemotherapy administration, intravenous infusion technique; up to 1 hour single, single or initial substance/drug).

Important Instructions for Billing
Due to systems limitations, providers are to take the following steps when submitting claims.

For Tecartus:
• Submit and receive back an approved TAR
• Bill using Q2053 (Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose)
Completion of claim forms:
- Claims are restricted to hospital outpatient services. Note that claims from pharmacies and clinics will be denied.
- Outpatient claims may be billed by paper claim using UB-04 or electronically using 837I.
- Providers must submit one service line on the TAR request and enter “4” in the Units box.
- On the 837I or UB-04 claim form, provider must submit one claim line to represent one 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 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 Forms page on the Medi-Cal Providers website, forms section for completion of 837I and UB-04 claim forms.
- Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 96413.

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 equals 1 mg
Carboplatin

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

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

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<td>C90.30</td>
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<tr>
<td>C90.12</td>
<td>C90.32</td>
</tr>
</tbody>
</table>

**Billing**

HCPCS 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 equals Every 21 days
Maximum billing unit(s) equals 350 mg equals 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)
**Ciltacabtagene autoleucel: cilta-cel (Carvykti™)**

Carvykti is a BCMA-directed, genetically modified autologous T cell immunotherapy, which involves reprogramming a patient’s own T cells with a transgene encoding a CAR (chimeric antigen receptor) that identifies and eliminates cells that express BCMA. The CARVYKTI CAR protein features two BCMA-targeting, single-domain antibodies designed to confer high avidity against human BCMA, a 4-1BB co-stimulatory domain and a CD3-zeta (CD3ζ) signaling cytoplasmic domain. Upon binding to BCMA-expressing cells, the CAR promotes T cell activation, expansion, and elimination of target cells.

**Indications**

All FDA-approved indications.

**Dosage**

FDA-approved dosages.

**TAR Requirement**

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

**TAR Criteria**

The TAR must include clinical documentation that demonstrates the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with an oncologist or a hematologist.
- Patient must have a diagnosis of relapsed or refractory multiple myeloma (RRMM).
- RRMM is histologically or cytologically confirmed according to International Myeloma Working Group (IMWG) criteria.
- Patient has received four or more myeloma treatment regimens including a proteasome inhibitor (for example, bortezomib, carfilzomib, ixazomib), an immunomodulatory agent (for example, lenalidomide, pomalidomide, thalidomide) and an anti-CD38 antibody (for example, daratumumab, daratumumab/hyaluronidase, isatuximab).
• Patient has an Eastern Cooperative Oncology Group (ECOG) performance status grade of zero or one
• Patient has no current or prior history of central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of multiple myeloma
• Patient has left ventricular ejection fraction of 45 percent or more
• Patient has no active infection or inflammatory disorders
• Patient has not been previously treated with CAR-T therapy in RRMM
• Carvykti will not be used concurrently with another CAR-T therapy
• Carvykti must be administered at a healthcare facility certified by the manufacturer based on the Risk Evaluation and Mitigation Strategy (REMS) requirements defined by the FDA
• Outpatient administration is restricted to Hospital Outpatient Services only

Approval is for three months (one treatment only).
Reauthorization is not approvable.

REMS
• Due to the risk of cytokine release syndrome (CRS) and neurologic toxicities, Carvykti is available only through a restricted program under a REMS called the Carvykti REMS.
• Healthcare facilities that dispense and administer Carvykti must be enrolled and must comply with the REMS requirements.
• Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer Carvykti are trained in the management of CRS and neurologic toxicities.
Age Limits
Must be 18 years of age or older.

Billing
HCPCS code «Q2056» (cilta-cabtagene autoleucel, up to 100 million autologous B-cell maturation antigen [bcma] directed CAR-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose).

Administration code: CPT code 96413 (chemo administration, intravenous infusion; up to one hour, single or initial substance/drug).

Important Instructions for Billing
Due to systems limitations, providers are to take the following steps when submitting claims for Carvykti:

2. Bill using «Q2056».
3. Completion of claim forms:
   - Claims are restricted to hospital outpatient services. Note that claims from pharmacies and clinics will be denied
   - Outpatient claims may be billed by paper claim using UB-04 or electronically using 837I
   - Providers must submit one (1) service line on the TAR/SAR request, and enter “5” in the Units box
   - On the 837I or UB-04 claim form, providers must submit one claim line to represent one (1) service
     ❖ Claims submitted with more than one claim line will be denied
   - Providers must submit an invoice for reimbursement
   - This process will ensure that the total reimbursement paid for the quantity of five (5) is no more than the paid price on the provider submitted invoice
   - Carvykti must be billed on its own with no other drug or biological
4. For instructions regarding physician claim form completion, refer to the page on the Medi-Cal Providers website, for completion of 837I and UB-04 claim forms.

5. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 96413

**Required ICD-10 Diagnosis Codes**

C90.00, C90.02

**Prescribing Restriction(s)**

Frequency of billing equals one dose/five units per lifetime

Maximum billing unit(s) equals one dose/five units

**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 equals 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 equals 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.
Cyclophosphamide (Auromedics brand)

Cyclophosphamide is an alkylating agent that prevents cell division by cross-linking DNA strands and decreasing DNA synthesis. It is a cell cycle phase nonspecific agent. Cyclophosphamide also possesses potent immunosuppressive activity. It is a prodrug that must be metabolized to active metabolites in the liver.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirements

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosing regimens

- Patient has a diagnosis of one of the following malignant diseases:
  - Malignant lymphomas (Stages III and IV of the Ann Arbor staging system), Hodgkin's disease, lymphocytic lymphoma (nodular or diffuse), mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma
  - Multiple myeloma
  - Leukemias: chronic lymphocytic leukemia, chronic granulocytic leukemia (it is usually ineffective in acute blastic crisis), acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia (cyclophosphamide given during remission is effective in prolonging its duration)
  - Mycosis fungoides (advanced disease)
  - Neuroblastoma (disseminated disease)
  - Adenocarcinoma of the ovary
  - Retinoblastoma
  - Carcinoma of the breast
• Patient does not have hypersensitivity to cyclophosphamide
• Patient does not have urinary outflow obstruction

Approval is for 12 months

Billing
HCPCS code J9071 (injection, cyclophosphamide, [auromedics], 5 mg)

**Daratumumab (Darzalex®)**
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**
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 J9145 (injection, daratumumab, 10 mg)

**Suggested ICD-10-CM Diagnosis Codes**
C90.00, C90.01, C90.02
Daratumumab and Hyaluronidase-fihi (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-fihi)

Suggested ICD-10-CM Diagnosis Codes
C90.00, C90.01, C90.02

Prescribing Restrictions
Frequency of billing equals 1,800 mg/ 180 units every week
Maximum billing unit(s) equals 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, monocyctic, 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 Lipsome (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 equals 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 equals 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 service 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 J9272 (injection, dostarlimab-gxly, 10 mg)

Prescribing Restrictions
Frequency of billing equals 500 mg/50 units every three weeks for four doses, then three weeks after dose four, continue with 1,000 mg/100 units every six weeks.
Maximum billing unit(s) equals 1,000 mg/100 units
**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
- C50.011 thru C50.929
- C56.1 thru C57.4
- C88.2 thru C90.32
- D47.Z9

**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 (Imfinzi)**
Durvalumab is a human immunoglobulin G1 kappa monoclonal antibody which blocks programmed cell death ligand 1 (PD-L1) binding to programmed death-1 (PD-1) and cluster of differentiation 80 (CD80) (B7.1); PD-L1 blockade leads to increased T-cell activation, allowing T-cells to kill tumor cells. PD-L1 is an immune check point protein expressed on tumor cells and tumor infiltrating cells and down regulates anti-tumor T-cell function by binding to PD-1 and B7.1; blocking PD-1 and B7.1 interactions restores antitumor T-cell function.

**Indications**
All FDA-approved indications.
Dosage
All FDA-approved dosages.

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

Age
Must be 18 years of age or older.

Billing
HCPCS code J9173 (injection, durvalumab, 10 mg).
One (1) unit of J9173 equals 10 mg of durvalumab.
Legend
Symbols used in the document above are explained in the following table.

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