Chemotherapy: Drugs B 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* manual section. Additional policy information for chemotherapy drug services can be found in manual sections:

- Chemotherapy: Drugs A Policy
- Chemotherapy: Drugs C Policy
- Chemotherapy: Drugs D Policy
- Chemotherapy: Drugs E-H Policy
- Chemotherapy: Drugs I-L Policy
- Chemotherapy: Drugs M Policy
- Chemotherapy: Drugs N-O Policy
- Chemotherapy: Drugs P-Q Policy
- Chemotherapy: Drugs R-S Policy
- Chemotherapy: Drugs T-Z Policy

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 Limit

Must be18 years of age 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-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 distributers must only distribute belantamab mafodotin-blmf to certified healthcare facilities.

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

Age Limit

Must be 18 years of age or older.

Billing

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

Suggested ICD-10-CM Diagnosis Codes

C90.00, C90.02

Prescribing Restrictions

Frequency of billing equals 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/m^2 once daily on days 1 through 5 of a 21-day cycle.

Billing

HCPCS code J9032 (injection, belinostat, 10 mg)

Bendamustine (Treanda® and Bendeka®)

Bendamustine is a bifunctional mechlorethamine derivative containing a purine-like benzimidazole ring. Mechlorethamine and its derivatives form electrophilic alkyl groups. These groups form covalent bonds with electron-rich nucleophilic moieties, resulting in interstrand DNA crosslinks. The bifunctional covalent linkage can lead to cell death via several pathways. Bendamustine is active against both quiescent and dividing cells. The exact mechanism of action of bendamustine remains unknown.

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 and older.

Billing

HCPCS code J9033, one unit (injection, bendamustine HCl [treanda], 1 mg).

HCPCS code J9034, one unit (injection, bendamustine HCl [bendeka], 1 mg).

Bendamustine Hydrochloride

Bendamustine is an alkylating agent (nitrogen mustard derivative) with a benzimidazole ring (purine analog) which demonstrates only partial cross-resistance (in vitro) with other alkylating agents. It leads to cell death via single and double strand DNA cross-linking. Bendamustine is active against quiescent and dividing cells. The primary cytotoxic activity is due to bendamustine (as compared to metabolites).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

Universal Criteria:

- Must be used for FDA approved indications and dosages.
- Prescribed or in consultation with an oncologist.
- Patient is at least 18 years of age.
- Patient has chronic lymphocytic leukemia (CLL) or indolent B-cell non-Hodgkin lymphoma (NHL):

A. Chronic lymphocytic leukemia (CLL):

- Patient has not received bendamustine therapy in the past, unless otherwise specified
- Patient does not have autoimmune hemolytic anemia or autoimmune thrombocytopenia, Richter's syndrome, or transformation to prolymphocytic leukemia

B. Indolent B-cell non-Hodgkin lymphoma (NHL):

- Patient has not received bendamustine therapy in the past, unless otherwise specified
- Patient with relapse within six months of either the first dose (monotherapy) or last dose (maintenance regimen or combination therapy) of rituximab

Authorization is for six months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS codes:

- J9056 (Injection, bendamustine hydrochloride (Vivimusta), 1 mg).
- J9058 (Injection, bendamustine hydrochloride (Apotex), 1 mg).
- J9059 (Injection, bendamustine hydrochloride (Baxter), 1 mg).

Prescribing Restriction(s)

Frequency of billing equals
CLL: Days 1 and 2 of a 28-day cycle, up to 6 cycles
NHL: Days 1 and 2 of a 21-day cycle, up to 8 cycles

Bevacizumab

Policy for intravitreal bevacizumub (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, C21.2, C21.8, C34.00 thru C34.92, C48.1 thru C48.2, C50.011 thru 50.929
C53.0 thru C53.9, C56.1 thru C57.4, C64.1 thru C64.9, C71.0 thru C71.9

E08.311, E08.3211 thru E08.3213, E08.3219, E08.3311 thru E08.3313, E08.3319
E08.3411 thru E08.3413E08.3419, E08.3511 thru E08.3513, E08.3519, E09.311
E09.3211 thru E09.3213, E09.3219, E09.3311 thru E09.3313, E09.3319
E09.3411 thru E09.3413, E10.311, E10.3211 thru E10.3213, E10.3219, E09.3419
E09.3511 thru E09.3513, E09.3519, E10.3311 thru E10.3313, E10.3319
E10.3411 thru E10.3413, E10.3419, E10. 3511 thru E10.3513, E10.3519, E11.311
E11.3211 thru E11.3213, E11.3219, E11.3311 thru E3313, E11.3319
E11.3411 thru E11.3413, E11.3419, E11.3511 thru E11.3513, E11.3519, E13.311
E13.3211 thru E13.3213, E13.3219, E13.3311 thru E13.3313, E13.3319
E13.3411 thru E13.3413, E13.3419, E13.3511 thru E13.3513, E13.3519

H34.8110 thru H34.8112, H34.8120 thru H34.8122, H34.8130 thru H34.8132
H34.8190 thru H34.8192, H34.8310 thru H34.8312, H34.8320 thru H34.8322
H34.8330 thru H34.8332, H34.8390 thru H34.8392, H35.3210 thru H35.3213
H35.3220 thru H35.3223, H35.3230 thru H35.3233, H35.3290 thru H35.3293
H35.351 thru H35.353, H35.359, 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-adcd (Vegzelma)

Bevacizumab products bind 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 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

Vegzelma 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.
- Vegzelma will be used as a treatment for one of the following conditions:

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).

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.

Glioblastoma, recurrent:

- Treatment of recurrent glioblastoma in adults

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)

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)

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 Limit

Must be 18 years of age or older.

Billing

HCPCS code: Q5129 (injection, bevacizumab-adcd [vegzelma], biosimilar, 10 mg).

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 Limit

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 lgG1 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 Limit

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.
- Alamsys will be used as a treatment for one the following:

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).

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.

Glioblastoma, recurrent:

- Treatment of recurrent glioblastoma in adults.

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).

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).

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 Limit

Must be 18 years of age or older.

Billing

HCPCS code Q5126 (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 a reversible inhibitor of the chymotrypsin-like activity of the 26S proteasome in mammalian cells. The 26S proteasome is a large protein complex that degrades ubiquitinated proteins. The ubiquitin-proteasome pathway plays an essential role in regulating the intracellular concentration of specific proteins, thereby maintaining homeostasis within cells. Inhibition of the 26S proteasome prevents this targeted proteolysis, which can affect multiple signaling cascades within the cell. This disruption of normal homeostatic mechanisms can lead to cell death. Experiments have demonstrated that bortezomib is cytotoxic to a variety of cancer cell types in vitro. Bortezomib causes a delay in tumor growth in vivo in nonclinical tumor models, including multiple myeloma.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be 18 years of age or older (Hospira, Dr Reddy’s, Fresenius Kabi and Maia brands).

No age restrictions on HCPCS code J9041.

Billing

HCPCS codes:

J9041 (injection, bortezomib [velcade], 0.1 mg).

J9046 (injection, bortezomib, [dr. reddy's], not therapeutically equivalent to J9041, 0.1 mg).

J9048 (injection, bortezomib [fresenius kabi], not therapeutically equivalent to J90410,1 mg).

J9049 (injection, bortezomib [hospira], not therapeutically equivalent to J9041, 0.1 mg).

J9051 (injection, bortezomib [maia], not therapeutically equivalent to J9041, 0.1 mg).

Required Codes

C83.10 thru C83.19, C90.00 thru C90.02.

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 Limit

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) equals180 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.
- 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 two 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 Limit

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).

One unit of Q2053 equals a single infusion of up to 200 million autologous anti-CD19 CAR-positive viable T cells.

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 “5” 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 five 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.

Required ICD-10-CM Diagnosis Codes

C83.10 through C83.19; C91.00 and C91.02

Prescribing Restrictions

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

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.