# Chemotherapy: Drugs I-L Policy

Page updated: May 2024

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 B Policy
- Chemotherapy: Drugs C Policy
- Chemotherapy: Drugs D Policy
- Chemotherapy: Drugs E-H 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.

# Ibritumomab Tiuxetan

For HCPCS codes A9542 and A9453, refer to the *Radiology: Oncology* section in this manual for information about diagnostic and treatment applications of this radiopharmaceutical injection.

# Idecabtagene Vicleucel (Abecma®)

Abecma is a chimeric antigen receptor (CAR)-positive T cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T cell activation domain and a 4-1BB costimulatory domain. Antigen-specific activation of Abecma results in CAR-positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-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

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 and refractory multiple myeloma (RRMM).

- 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).
- Eastern Cooperative Oncology Group (ECOG) performance status of less than or equal to two.
- Patient has no history of CNS disease (for example, seizure or cerebrovascular ischemia).
- Patient has no active infection or inflammatory disorders.
- Patient must have adequate bone marrow, cardiac, pulmonary, renal, and organ functions.
- Patient has not been previously treated with CAR-T therapy in RRMM.
- Abecma will not be used concurrently with another CAR-T therapy.
- Abecma 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.

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

Reauthorization: Repeat treatment is not approvable.

Abecma REMS

Because of the risk of Cytokine Release Syndrome (CRS) and neurologic toxicities, Abecma is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Abecma REMS. The required components of the Abecma REMS are:

- Healthcare facilities that dispense and administer Abecma must be enrolled and comply with the REMS requirements.
- Certified healthcare facilities must have on-site, immediate access to tocilizumab.

- Ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within two hours after Abecma infusion, if needed for treatment of CRS.
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer Abecma are trained in the management of CRS and neurologic toxicities.
- Further information is available at www.AbecmaREMS.com or contact Bristol-Myers Squibb at 1-888-423-5436.

## Age Limit

Must be 18 years of age or older.

## Billing

‹‹HCPCS code Q2055 (idecabtagene vicleucel, up to 510 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 (chemotherapy 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 Abecma:

1. Submit and receive back an approved *Treatment Authorization Request* (TAR)/Service Authorization Request (SAR).
2. ‹‹Bill using Q2055 (idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen [bcma] directed car-positive 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 (1) service line on the TAR/SAR request and enter "6"›› 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 six (6)›› is no more than the paid price on the provider submitted invoice.››
   - Abecma 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. Providers may also refer to the *UB-04 Completion: Outpatient Services* section of the Provider Manual.

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

## Suggested ICD-10 Diagnosis Codes

C90.00, C90.02

## Prescribing Restrictions

Frequency of billing equals one dose per lifetime.

‹‹Maximum billing unit(s) equals one dose/six units.››

# Ifosfamide

Ifosfamide is chemically related to the nitrogen mustards and a synthetic analog of cyclophosphamide.

## Indications

For the treatment of:

- Cervical cancer
- Hodgkin lymphoma
- Non-Hodgkin lymphoma
- Non-small cell lung cancer
- Osteogenic sarcoma
- Ovarian cancer
- Small cell lung cancer
- Soft tissue sarcoma
- Testicular cancer
- Uterine cancer

## Dosage

Recommended dosages cannot be provided because they vary widely depending on the malignancy being treated. The maximum dose is 15 grams. Increased dose is allowed for more than 15 grams if there is documentation that the patient body surface area is more than 2.0 meters$^2$.

## Billing

HCPCS code J9208 (injection, ifosfamide, 1 gm).

# ‹‹Imetelstat for Injection (RYTELO)

Imetelstat is an oligonucleotide human telomerase inhibitor that binds to the template region of the RNA component of human telomerase (hTR), inhibits telomerase enzymatic activity and prevents telomere binding. Increased telomerase activity and human telomerase reverse transcriptase (hTERT) RNA expression have been reported in MDS and malignant stem and progenitor cells. Nonclinical studies showed imetelstat treatment led to reduction of telomere length, reduction of malignant stem and progenitor cell proliferation, and induction of apoptotic cell death.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all the following:

- Must be used for FDA approved indications and dosages.
- Prescribed by or in consultation with an oncologist.
- Patient is at least 18 years of age or older.
- Diagnosis of low to intermediate risk myelodysplastic syndromes (MDS).
- Patient has transfusion-dependent anemia requiring four or more red blood cell units over eight weeks.
- Patient has not responded to or have lost response to or is ineligible for erythropoiesis-stimulating agents (ESA).
- RYTELO will not be used in combination with an erythropoiesis stimulating agent.
- Patient does not have del(5q) cytogenetic abnormality.
- Patient has not received prior treatment with lenalidomide or hypomethylating agents.

Initial authorization is for six months.››

‹‹Re-authorization criteria:

- Patient has been on RYTELO for at least six months.
- Patient has not experienced disease progression while taking RYTELO.
- Patient has not experienced unacceptable toxicities or side effect while on RYTELO (e.g. cardiac failure, hemorrhage, etc.).

Re-authorization is for 12 months.

### Age Limits

Must be 18 years of age or older.

### Billing

HCPCS code J0870 (injection, imetelstat, 1 mg).››

## Inotuzumab Ozogamicin

Inotuzumab ozogamicin is a CD22-directed antibody-drug conjugate (ADC) for intravenous (I.V.) administration.

### Indications

Inotuzumab ozogamicin is used for the treatment of patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

### Age Limit

Must be 18 years of age or older.

### Dosage

A full course of inotuzumab ozogamicin consists of a single induction cycle followed by a maximum of five consolidation cycles:

- For induction: a dose of 0.8 mg/$m^2$ IV is administered on treatment day #1, followed by a dose of 0.5 mg/$m^2$ on days #8 and 15. The cycle length is 21 days.
- For consolidation: a dose of 0.5 mg/$m^2$ IV is administered on treatment days #1, 8, and 15. The cycle length is 28 days, up to a maximum of 6 consolidation cycles.

- The recommended dose and number of treatment cycles varies based on the patient's response to treatment and whether or not the patient will proceed to a hematopoietic stem cell transplant (HSCT).

### Authorization

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

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary to treat relapsed or refractory B-cell precursor ALL.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/chemotherapy order for inotuzumab ozogamicin.

### Billing

HCPCS code J9229 (injection, inotuzumab ozogamicin, 0.1 mg).

One (1) unit of J9229 equals 0.1 mg inotuzumab ozogamicin.

## Ipilimumab (Yervoy®)

Ipilimumab is a recombinant, human monoclonal antibody that binds to the cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4), a molecule on T cells that suppresses the immune response. Blockade of CTLA-4 has been shown to augment T-cell activation and proliferation, including the activation and proliferation of tumor infiltrating T-effector cells. Inhibition of CTLA-4 signaling can also reduce T-regulatory cell function, which may contribute to a general increase in T cell responsiveness, including the anti-tumor immune response.

### Indications

All FDA-approved indications.

### Dosage

FDA- approved dosages.

### Authorization

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

### Age Limit

Must be 12 years of age or older.

### Billing

HCPCS code J9228 (injection, ipilimumab, 1 mg).

One (1) unit of J9228 equals 1 mg of ipilimumab.

## Irinotecan

Irinotecan is used in the treatment of patients with metastatic cancer of the colon or rectum, small cell lung cancer or cervical cancer.

### Required Codes

Providers may be reimbursed for irinotecan when billed in conjunction with one of the following ICD-10-CM diagnosis codes:

C18.0 thru C20, C34.00 thru C34.92, C53.0 thru C53.9

### Billing

HCPCS code J9206 (injection, irinotecan, 20 mg).

CPT codes 96413 and 96415 may be billed in conjunction with irinotecan and are separately reimbursable.

For additional information about billing CPT codes 96413 and 96415, refer to “Intravenous Infusion” in the *Chemotherapy: An Overview* manual section.

## Irinotecan Liposome (ONIVYDE®)

Irinotecan liposome is a topoisomerase 1 inhibitor encapsulated in a lipid bilayer vesicle or liposome. Topoisomerase 1 relieves torsional strain in DNA by inducing single-strand breaks. Irinotecan liposome and its active metabolite SN-38 bind reversibly to the topoisomerase 1-DNA complex and prevent re-ligation of the single-strand breaks, leading to exposure time-dependent double-strand DNA damage and cell death.

## Dosages

FDA-approved dosages

## Indication

All FDA-approved indications.

## TAR Requirement

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

## Age Limit

Must be 18 years of age or older.

## Suggested ICD-10-CM Diagnosis Codes

C25.0 thru C25.9, Z85.07

## Billing

HCPCS code J9205 (injection, irinotecan liposome, 1 mg).

# Isatuximab-irfc (Sarclisa®)

Isatuximab-irfc is an IgG1-derived monoclonal antibody that binds to CD38 expressed on the surface of hematopoietic and tumor cells, including multiple myeloma cells. Isatuximab-irfc induces apoptosis of tumor cells and activation of immune effector mechanisms including antibody-dependent cell-mediated cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), and complement dependent cytotoxicity (CDC). Isatuximab-irfc inhibits the ADP-ribosyl cyclase activity of CD38. Isatuximab-irfc can activate natural killer (NK) cells in the absence of CD38-positive target tumor cells and suppresses CD38-positive T-regulatory cells. The combination of isatuximab-irfc and pomalidomide enhanced ADCC activity and direct tumor cell killing compared to that of isatuximab-irfc alone in vitro, and enhanced antitumor activity compared to the activity of isatuximab-irfc or pomalidomide alone in a human multiple myeloma xenograft model.

## 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 J9227 (injection, isatuximab-irfc, 10 mg).

### Suggested ICD-10-CM Diagnosis Codes

C90.00, C90.01, C90.02.

### Prescribing Restrictions

Frequency of billing equals 10 mg/kg every week for four weeks followed by every two weeks.

## Ixabepilone

Ixabepilone is covered for patients with malignant neoplasm of the breast; providers must document in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim that one of the following conditions was met:

- In combination with capecitabine for the treatment of metastatic or locally advanced breast cancer after failure of an anthracycline and a taxane; or
- As monotherapy for the treatment of metastatic or locally advanced breast cancer after failure of an anthracycline, taxane and capecitabine

### Dosage

The maximum daily dosage is 90 mg unless documentation provided notes that the body surface area is greater than 2.25 $m^2$. Claims billed for quantities exceeding the daily limitation require appropriate documentation for payment.

### Required Codes

Claims must include an ICD-10-CM diagnosis code in the range of C50.011 thru C50.929.

### Billing

HCPCS code J9207 (injection, ixabepilone, 1 mg)

# Lanreotide (by Cipla)

Lanreotide, the active component of Lanreotide Injection is an octapeptide analog of natural somatostatin. The mechanism of action of lanreotide is believed to be similar to that of natural somatostatin.

## 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:

A. Universal Criteria

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Patient has tried Somatuline Depot and has a documented intolerance, contraindication; or it was clinically inappropriate.
- Lanreotide is being used for one of the following diagnoses:
  - Acromegaly
  - Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

B. Acromegaly

- Patient meets the above Universal Criteria.
- Must be prescribed by or in consultation with an endocrinologist.
- Patient has a diagnosis of acromegaly based on biochemical tests and medical history.
- Patient had an inadequate response to surgery and/or radiotherapy, or surgery and/or radiotherapy is not an option.
- Documentation of a high pretreatment insulin-like growth factor 1 (Insulin growth factor 1 [IGF-1]) level for age and/or gender based on the laboratory reference range.
- Documentation of elevated growth hormone (GH) level defined as a GH level equal to or greater than 1ng/mL following an oral glucose tolerance test (OGTT).

C. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

- Patient meets the above Universal Criteria.
- Must be prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.
- Patient has a diagnosis of neuroendocrine tumor originating from the pancreas, midgut, hindgut or are of unknown origin, and disease is unresectable, locally advanced or metastatic.
- Tumor is well or moderately differentiated confirmed by histology.
- Tumor lesions are measurable by a CT or MRI scan.

Initial authorization is for six months.

Continued therapy

- Patient continues to meet initial authorization criteria.
- For acromegaly, patient's insulin-like growth factor 1 (IGF-1) level for age and gender has reduced or normalized; or patient has a reduction in pretreatment serum growth hormone (GH) concentration.
- For GEP-NETs, patient has shown documented clinical response such as lack of disease progression and does not have unacceptable toxicity.

Reauthorization is for 12 months.

## Age Limit

Must be 18 years of age or older

## Billing

HCPCS code J1932 (injection, lanreotide, [cipla], 1 mg).

## Prescribing Restriction(s)

Frequency of billing equals120 mg /120 units every four weeks.

Maximum billing unit(s) equals 120 mg /120 units.

# Leucovorin Calcium

Leucovorin is one of several active, chemically reduced derivatives of folic acid. Leucovorin is a mixture of the diastereoisomers of the 5-formyl derivative of tetrahydrofolicacid. The biologically active compound of the mixture is the (-)-l-isomer, known as Citrovorum factor, or (-)-folinic acid.

Administration of leucovorin can counteract the therapeutic and toxic effects of folic acid antagonists such as methotrexate, which act by inhibiting dihydrofolate reductase.

In contrast, leucovorin can enhance the therapeutic and toxic effects of fluoropyrimidines used in cancer therapy, such as 5-fluorouracil. Concurrent administration of leucovorin does not appear to alter the plasma pharmacokinetics of 5-fluorouracil. 5-fluorouracil is metabolized to fluorodeoxyuridylic acid, which binds to and inhibits the enzyme thymidylate synthase (an enzyme important in DNA repair and replication).

## Indications

Leucovorin is indicated for:

- Leucovorin calcium rescue is indicated after high dose methotrexate therapy in osteosarcoma.
- Leucovorin calcium is indicated in the treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible.
- Leucovorin calcium is indicated for use in combination with 5-fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.

## Required Codes

One of the following ICD-10-CM codes is required for reimbursement:

C18.0 thru C20, C40.00 thru C41.9

### Dosage

The recommended dosage varies according to the clinical condition being treated. See the appropriate literature for dosing schedules.

The maximum allowable dose is 400 mg daily. A dose greater than 400 mg will be allowed if documentation shows that the body surface area is greater than 2 $m^2$.

### Billing

HCPCS code J0640 (injection, leucovorin calcium, up to 50 mg).

## Leuprolide (Camcevi®)

Leuprolide is an agonist of gonadotropin releasing hormone (GnRH) receptors. Animal and human studies indicate that following an initial stimulation of gonadotropins, chronic administration of leuprolide results in suppression of ovarian and testicular steroidogenesis. This effect is reversible upon discontinuation of drug therapy. In humans, subcutaneous administration of single daily doses of leuprolide result in an initial increase in circulating levels of leutinizing hormone (LH) and follicle stimulating hormone (FSH), leading to a transient increase in levels of the gonadal steroids (testosterone and dihydrotestosterone in males). However, continuous daily administration of leuprolide results in decreased levels of LH and FSH. In males, testosterone is reduced to below castration levels. These decreases generally occur within two to four weeks after initiation of treatment, and castration levels of testosterone in prostatic cancer patients have been demonstrated for periods of up to five years.

### 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 J1952 (leuprolide injectable, camcevi, 1 mg).

### Suggested ICD-10-CM Diagnosis Codes

C61, D07.5, Z85.46

### Prescribing Restrictions

Frequency of billing equals 42 mg/42 units every six months

Maximum billing unit(s) equals 42 mg/42 units

## Leuprolide Acetate Depot Suspension

Leuprolide acetate, a gonadotropin releasing hormone (GnRH) agonist, acts as a potent inhibitor of gonadotropin secretion when given continuously in therapeutic doses. Animal and human studies indicate that after an initial stimulation, chronic administration of leuprolide acetate results in suppression of testicular and ovarian steroidogenesis.

### Indications

For the palliative treatment of advanced prostate cancer.

### Dosage

The recommended dosing schedule is as follows:

- 7.5 mg monthly
- 22.5 mg every three months
- 30 mg every four months
- 45 mg every six months

### Required Code

ICD-10-CM diagnosis code C61

### Billing

HCPCS Code J9217 (Leuprolide acetate [for depot suspension] per 7.5 mg).

**Note:** This is the only HCPCS code that should be used when billing leuprolide acetate (depot suspension) for prostate cancer treatment.

## Leuprolide Acetate Implant

Leuprolide acetate implant is reimbursable when used in the treatment of malignant neoplasm of the prostate (ICD-10-CM diagnosis code C61) for male patients 21 years of age or older. The implant is placed under the skin of the patient's upper inner arm and must be removed and replaced with a new implant every 12 months.

### Billing

HCPCS code J9219 (leuprolide acetate implant, 65 mg)

Reimbursement for code J9219 is limited to once in 12 months.

## Levoleucovorin

Levoleucovorin is the pharmacologically active isomer of 5 formyl tetrahydrofolic acid. Levoleucovorin does not require reduction by the enzyme dihydrofolate reductase in order to participate in reactions utilizing folates as a source of "onecarbon" moieties. Administration of levoleucovorin can counteract the therapeutic and toxic effects of folic acid antagonists such as methotrexate, which act by inhibiting dihydrofolate reductase.

### Indications

All FDA-approved indications

### Dosage

FDA-approved dosages

### TAR Requirement

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

### Age Limits

Must be 6 years of age or older.

### Billing

HCPCS code J0641 (injection, levoleucovorin, 0.5 mg).

## Lisocabtagene Maraleucel (Breyanzi®)

Breyanzi is a CD19-directed genetically modified autologous T-cell immunotherapy that involves reprogramming a patient's own T cells with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells. Following anti-CD19 CAR T-cell engagement with CD19-expressing target cells, the CD28, 4-1BB (CD137), 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 cascade 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

Breyanzi 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.
- Must be prescribed by or in consultation with an oncologist or a hematologist.
- Patient must have a diagnosis of one of the following large B-cell lymphoma subtypes (LBCL):
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including:
    - de novo DLBCL
    - DLBCL, transformed from indolent lymphoma
  - High-grade B-cell lymphoma
  - Primary mediastinal large B-cell lymphoma
  - Follicular lymphoma, grade 3B
- Patient has relapsed or refractory disease after receiving two or more lines of systemic therapy.
  - Patients may have received prior autologous or allogeneic Hematopoietic stem cell transplantation (HSCT)
- Eastern Cooperative Oncology Group (ECOG) performance status equal to or less than two.
- Creatinine clearance equal to or greater than 30 mL/min.
- Alanine aminotransferase (ALT) equal to or less than five times the upper limit of normal.
- Left ventricular ejection fraction equal to or greater than 40 percent.

- Adequate bone marrow function, as determined by the treating physician.
- No primary central nervous system (CNS) lymphoma.
  - Authorized patients may include those with secondary CNS lymphoma involvement
- No active infection or inflammatory disorders.
- No prior CAR T-cell therapy in relapsed or refractory (R/R) LBCL.
- Must be administered in a healthcare facility certified by the manufacturer based on the Risk Evaluation and Mitigation Strategy (REMS) called the Breyanzi REMS Program.
- Outpatient administration is restricted to Hospital Outpatient Services only.

Initial authorization is for three months (1 dose only).

## Reauthorization

Reauthorization is not approvable.

## Breyanzi REMS Requirements

- All hospitals and their associated clinics must be certified and enrolled in the Breyanzi REMS to be able to infuse Breyanzi.
- All relevant staff involved in the prescribing, dispensing, or administering of Breyanzi are trained on Breyanzi REMS requirements, and must successfully complete the Breyanzi REMS Knowledge Assessment.

## Age Limit

Must be 18 years of age or older.

## Billing

HCPCS code Q2054 (lisocabtagene maraleucel, up to 110 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; 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 Breyanzi:

1. Submit and receive back an approved *Treatment Authorization Request* (TAR)/Service Authorization Request (SAR).
2. Bill using Q2054 (lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose).
3. Completion of claim forms:
   - 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 “6” in the *Units* box
   - On the 837I or *UB-04* claim form, provider 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 six (6) is no more than the paid price on the provider submitted invoice
   - Breyanzi 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. Providers may also refer to the *UB-04 Completion: Outpatient Services* section of the Provider Manual.
5. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 96413.

### Suggested ICD-10-CM Diagnosis Codes

C83.30 thru C83.39, C83.90 thru C83.99, C82.40 thru C82.59, C85.20 thru C85.29

## Loncastuximab Tesirine-lpyl (Zynlonta™)

Loncastuximab tesirine-lpyl is an antibody-drug conjugate (ADC) targeting CD19. The monoclonal IgG1 kappa antibody component binds to human CD19, a transmembrane protein expressed on the surface of cells of B-lineage origin. The small molecule component is SG3199, a PBD dimer and alkylating agent.

Upon binding to CD19, loncastuximab tesirine-lpyl is internalized followed by release of SG3199 via proteolytic cleavage. The released SG3199 binds to the DNA minor groove and forms highly cytotoxic DNA interstrand crosslinks, subsequently inducing cell death. Loncastuximab tesirine-lpyl had anticancer activity in animal models of lymphoma.

### 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 J9359 (injection, loncastuximab tesirine-lpyl, 0.075 mg).

### Suggested ICD-10-CM Diagnosis Codes

C83.30 thru C83.39

### Prescribing Restrictions

Frequency of billing equals 0.15 mg/kg every three weeks for two cycles, then 0.075 mg/kg every three weeks for subsequent cycles.

## Lurbinectedin (Zepzelca)

Lurbinectedin is an alkylating drug that binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death.

Lurbinectedin inhibited human monocyte activity in vitro and reduced macrophage infiltration in implanted tumors in mice.

### 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 all of the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Patient must have a diagnosis of small cell lung cancer (SCLC).
- Patient has experienced disease progression or relapse following initial platinum-based chemotherapy (i.e., cisplatin, carboplatin, etc.).
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status (PS) less than or equal to two.
- Patient must not be a pregnant or breast-feeding female.
- Patient does not have central nervous system (CNS) involvement.
- Patient does not have active infection such as HIV (human immunodeficiency virus), Hepatitis B, Hepatitis C, etc.

Initial authorization is for six months.

Continued therapy:

- Patient continues to meet initial coverage criteria.
- Patient does not have unacceptable toxicity such as severe hypersensitivity reactions, severe hepatic toxicity or severe myelosuppression.
- Patient shows positive clinical benefit as evidenced by lack of disease progression, disease stabilization, or reduction in tumor size or spread.

Reauthorization is for 12 months.

## Age Limit

Must be 18 years of age or older.

## Billing

HCPCS code J9223 (injection, lurbinectedin, 0.1 mg).

## Suggested ICD-10-CM Diagnosis Codes

C33, C34.00 thru C34.02, C34.10 thru C34.12, C34.2, C34.30 thru C34.32, C34.80 thru C34.82, C34.90 thru C34.92

## Prescribing Restrictions

Frequency of billing equals 3.2 mg/$m^2$ every 21 days.

## 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. |