Chemotherapy: Drugs D 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 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

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 Limit

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-fihj (Darzalex Faspro™)

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

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be 18 years of age or older.

Billing

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

Suggested ICD-10-CM Diagnosis Codes

C90.00, C90.01, C90.02

Prescribing Restrictions

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

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

Datopotamab deruxtecan-dlnk (DATROWAY®)

‹‹Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.››

TAR Requirement

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

Billing

‹‹HCPCS code J9011 (injection, datopotamab deruxtecan-dlnk, 1 mg).››

Daunorubicin

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

Indications

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

Dosage

The usual dose of daunorubicin is 45 mg/m^2 (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 m^2 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 Limit

Must be18 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 believed to exert its antineoplastic effects after hosphorylation and direct incorporation into DNA and inhibition of DNA methyltransferase, causing hypomethylation of DNA and cellular differentiation or apoptosis. Decitabine inhibits DNA methylation in vitro, which is achieved at concentrations that do not cause major suppression of DNA synthesis. Decitabine-induced hypomethylation in neoplastic cells may restore normal function to genes that are critical for the control of cellular differentiation and proliferation. In rapidly dividing cells, the cytotoxicity of decitabine may also be attributed to the formation of covalent adducts between DNA methyltransferase and decitabine incorporated into DNA. Non-proliferating cells are relatively insensitive to decitabine.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

- J0894 (injection, decitabine, 1 mg).
- J0893 (injection, decitabine [sun pharma] not therapeutically equivalent to J0894, 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 (denileuken 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 nine or 18 mcg/kg per 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).

‹‹Denileukin diftitox-cxdl (LYMPHIR)

Indications, Dosages and Age

Refer to the FDA-approved labeling.

Must be 18 years of age or older.

TAR Requirement

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

Billing

HCPCS code J9161 (injection, denileukin diftitox-cxdl, 1 mcg).››

Denosumab

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

Dexamethasone Tablets (Hemady)

Policy for the use of dexamethasone tablets (HCPCS code J8541) may be found in the *Non-Injectable Drugs* section of this manual.

Docetaxel

‹‹Indications and Dosages

Refer to the FDA-approved labeling.

Must be 18 years of age or older.››

TAR Requirement

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

Billing

HCPCS codes:

- J9171 (injection, docetaxel, 1 mg).
- ‹‹J9172 (injection, docetaxel, [docivyx] 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.

Prescribing Restriction(s)

Maximum billing unit(s) equal to 200 mg / 200 units

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

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 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 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) equals1,000 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 m^2.

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 m^2.

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 codes:

- Q2049 (injection doxorubicin hydrochloride, liposomal, imported Lipodox®, 10 mg)
- 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 Limit

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.

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.