Chemotherapy: Drugs C 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 B 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

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

All FDA-approved indications.

Dosage

TAR Requirement

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

Age Limit

Must be 18 years of age or older.

Billing

HCPCS codes:

- J9043 (injection, cabazitaxel, 1 mg) (Jevtana).
- J9064 (injection, cabazitaxel [sandoz], not therapeutically equivalent to J9043, 1 mg).

One billing unit equals 1 mg.

Required ICD-10 Diagnosis Code

C61

Calaspargase pegol-mknl (ASPARLAS™)

L-asparaginase is an enzyme that catalyzes the conversion of the amino acid L-asparagine into aspartic acid and ammonia. The pharmacological effect of ASPARLAS is thought to be 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

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 all FDA-approved indications and dosages.
- Patient must be 1 month to 21 years old.
- Patient must have a diagnosis of acute lymphoblastic leukemia.
- Must be prescribed by or in consultation with an oncologist or a hematologist.
- Must be used in conjunction with multi-agent chemotherapy.
- Patient must not have a history of serious hypersensitivity reactions with pegylated L-asparaginase therapy.

Initial authorization is for 12 months.

Continued Therapy

- Patient has disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH.
- Patient has absence of unacceptable toxicity from drug such as hypersensitivity reactions, serious thrombotic events, severe hemorrhage, sever hepatotoxicity, pancreatitis, etc.

Reauthorization is for 12 months.

Age Limit

Must be one month to 21 years old.

Billing

HCPCS code: J9118 (injection, calaspargase pegol-mknl, 10 units).

Suggested ICD 10 Diagnosis Codes

C83.50 thru C83.59: Lymphoblastic (diffuse) lymphoma

C91.00 thru C91.02: Acute lymphoblastic leukemia

Note: Asparlas is available through the following specialty distributor: Cardinal Health™

New customers: please call 866-476-1340

Online Orders: https://orderexpress.cardinalhealth.com/ or
https://specialtyonline.cardinalhealth.com/

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

Billing

HCPCS code J9047 (injection, carfilzomib, 1 mg).

Carmustine

The mechanism of action of carmustine is not fully understood. While carmustine alkylates DNA and RNA, it is not cross-resistant with other alkylators. As with other nitrosoureas, it may also inhibit several key enzymatic processes by carbamoylation of amino acids in proteins. The metabolites may contribute to antitumor activity and toxicities of carmustine.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

- J9050 (injection, carmustine, 100 mg).
- J9052 (injection, carmustine [accord], not therapeutically equivalent to J9050, 100 mg).

Cemiplimab-rwlc (Libtayo)

Cemiplimab-rwlc is a monocolnal 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 Limit

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-Q* 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, C18.0 thru C20, C21.2, C21.8 C30.0 thru C31.9, C32.0 thru C32.9, C76.0

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 (chrimeric anatigen 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 Limit

Must be 18 years of age or older.

Billing

HCPCS code Q2056 (ciltacabtagene 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 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).››

Important Instructions for Billing:

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

- Submit and receive back an approved Treatment Authorization Request (TAR)/Service Authorization Request (SAR).
- Bill using Q2056.
- 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 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
- 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 38228.››

Required ICD-10 Diagnosis Codes

C90.00, C90.02

Prescribing Restriction(s)

Frequency of billing equals one dose per six units per lifetime.

Maximum billing unit(s) equals one dose per six 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 Limit

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/m^2 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).

Colony Stimulating Factors

Colony stimulating factors (CSF) are any number of glycoproteins responsible for the proliferation, differentiation, and functional activation of hematopoietic progenitor cells; specific factors are named for the cell lines that they stimulate. CSFs include granulocyte colony-stimulating factor (G-CSF) and granulocyte-macrophage colony-stimulating factor (GM-CSF). Treatment with CSFs can help the blood-forming tissue recover from the effects of chemotherapy and radiation therapy.

The following colony stimulating factors are benefits of the Medi-Cal program:

- Eflapegrastim-xnst (Rolvedon™)
- Filgrastim
- Filgrastim-aafi (Nivestym™)
- Filgrastim-ayow (Releuko®)
- Filgrastim-sndz
- Pegfilgrastim (Neulasta®)
- Pegfilgrastim-apgf (Nyvepria™)
- Pegfilgrastim-bmez (Ziextenzo)
- Pegfilgrastim-cbqv (Udenyca®)
- Pegfilgrastim-jmdb (Fulphila)
- Pegfilgrastim-fpgk (Stimufend®)
- Pegfilgrastim-pbbk (Fylnetra)
- ‹‹Tbo-Filgrastim (Granix®)››

Eflapegrastim-xnst (Rolvedon)

Eflapegrastim-xnst is a recombinant human granulocyte growth factor that binds to G-CSF receptors on myeloid progenitor cells and neutrophils, triggering signaling pathways that control cell differentiation, proliferation, migration and survival.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Rolvedon 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.
- Drug is being used for prophylaxis in patients with solid tumors or non-myeloid malignancy under one the following conditions:
  - Patient is receiving mylosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20 percent
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10 to 20 percent and at least one of the following risk factors for febrile neutropenia:
    - ❖ Older than 65 years of age receiving full dose intensity chemotherapy
    - ❖ History of recurrent febrile neutropenia from chemotherapy
    - ❖ Extensive prior exposure to chemotherapy
    - ❖ Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation

- ❖ Persistent neutropenia (ANC less than or equal to1000/mm^3)
- ❖ Bone marrow involvement by tumor
- ❖ Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
- ❖ Recent surgery and/or open wounds
- ❖ Poor performance status
- ❖ Renal dysfunction (creatinine clearance less than 50 mL/min)
- ❖ Liver dysfunction (elevated bilirubin more than 2.0 mg/dL)
- ❖ Chronic immunosuppression in the post-transplant setting, including organ transplant

– The patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome

Initial authorization is for six months.

Reauthorization is for six months for patients who continue to meet the above criteria.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code: J1449, (injection, eflapegrastim-xnst, 0.1 mg).

Prescribing Restriction(s)

Frequency of billing is 13.2 mg/132 units.

Maximum billing unit(s) is 13.2 mg/132 units once per chemotherapy cycle.

Filgrastim

Filgrastim is a Medi-Cal benefit when used for patients with severe neutropenia.

Dosage

The specific dosage of filgrastim is variable depending on which condition or disease is being treated.

Required Codes

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

C92.00, C92.30, C92.40, C92.50, C92.60, C92.90, C92.A0, C92.Z0

D46.0 thru D46.9, D70.0 thru D70.1. D70.4 thru D70.9, D72.819

Z48.290, Z51.11, Z94.81

Billing

HCPCS code J1442 (injection, filgrastim [g-csf], excludes biosimilars, 1 microgram).

When billing for more than 1,200 mcg, providers must document in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) on the claim or on an attachment that the patient weighs more than 100 kg.

Filgrastim-aafi (Nivestym)

Colony-stimulating factors are glycoproteins which act on hematopoietic cells by binding to specific cell surface receptors and stimulating proliferation, differentiation commitment, and some end-cell functional activation.

Endogenous G-CSF is a lineage-specific colony-stimulating factor that is produced by monocytes, fibroblasts, and endothelial cells. G-CSF regulates the production of neutrophils within the bone marrow and affects neutrophil progenitor proliferation, differentiation, and selected end-cell functions (including enhanced phagocytic ability, priming of the cellular metabolism associated with respiratory burst, antibody-dependent killing, and the increased expression of some cell surface antigens). G-CSF is not species-specific and has been shown to have minimal direct in vivo or in vitro effects on the production or activity of hematopoietic cell types other than the neutrophil lineage.

Indications

All FDA-approved indications.

Authorization

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

Suggested ICD-10 Diagnosis Codes

D70.0, D70.1, D70.4, D70.8, D70.9 or Z51.11

Billing

HCPCS code Q5110 (injection, filgrastim-aafi, biosimilar [Nivestym], 1 mcg).

Filgrastim-ayow (Releuko)

Filgrastim-ayow is a filgrastim biosimilar.

Filgrastim is a granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. G-CSFs stimulate the production, maturation, and activation of neutrophils to increase both their migration and cytotoxicity.

Indication

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

- Must be for FDA- approved indications and dosages.
- It is being prescribed for ONE of the following conditions:
  - Patient has nonmyeloid malignany and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and Releuko is being used to decrease the incidence of infection, as manifested by febrile neutropenia
  - Patient has acute myeloid leukemia (AML) and Releuko is being used to reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment
  - Patient has nonmyeloid malignancy and is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) and Releuko is being used to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia
  - Patient has symptomatic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia and Releuko is being used to reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers)
- Must not be used in combination with other granulocyte colony-stimulating factors (G-CSF) such as Neupogen, Granix, Zarxio, Nivestym, etc.

Initial approval is for six months.

Continued therapy

Patient continues to meet initial approval requirements.

Reauthorization is for six months.

Billing

HCPCS code Q5125 (injection, filgrastim-ayow, biosimilar, [releuko], 1 microgram).

Filgrastim-sndz

Filgrastim-sndz is a leukocyte growth factor for intravenous (IV) or subcutaneous (SQ) administration. Filgrastim-sndz is biosimilar to filgrastim.

Indications

Filgrastim-sndz is used to enhance neutrophil production for the following indications:

- Non-myeloid malignancies in patients receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
- Acute myeloid leukemia (AML) in patients receiving induction or consolidation chemotherapy.
- Non-myeloid malignancies in patients receiving myeloablative chemotherapy prior to a bone marrow transplant.
- Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis in patients receiving cell therapy.
- Severe chronic neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Dosage

The recommended dose of filgrastim-sndz varies depending on the treatment indication.

Age Limit

All ages.

Authorization

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

Required Codes

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

- D70.0 (Congenital agranulocytosis)
- D70.1 (Agranulocytosis secondary to cancer chemotherapy)
- D70.4 (Cyclic neutropenia)
- D70.8 (Other neutropenia)
- D70.9 (Neutropenia, unspecified)
- Z51.11 (Encounter for antineoplastic chemotherapy)

Billing

HCPCS code Q5101 (injection, filgrastim-sndz, biosimilar, [Zarxio], 1 microgram).

One (1) unit of Q5101 equals 1 microgram of filgrastim-sndz.

Pegfilgrastim (Neulasta)

Pegfilgrastim is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment and end cell functional activation.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirements

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

Billing

HCPCS code J2506 (injection, pegfilgrastim, excludes biosimilar, 0.5 mg).

One (1) unit equals 0.5 mg.

Suggested ICD-10-CM Diagnosis Codes

D70.1, T45.1X5S, T45.1X5D, T45.1X5A, T45.1X5, T45.1X, T45.1

Prescribing Restriction(s)

Maximum billing unit(s) equals 6 mg/12 units.

Pegfilgrastim-apgf (Nyvepria), Pegfilgrastim-bmez (Ziextenzo)

Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

Indications

All FDA-approved indications.

Dosages

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

- Q5122 (injection, pegfilgrastim-apgf [nyvepria], biosimilar, 0.5 mg).
- Q5120 (injection, pegfilgrastim-bmez, [ziextenzo], biosimilar, 0.5 mg).

Prescribing Restrictions

Frequency of billing equals 6 mg/12 units per chemotherapy cycle.

Maximum billing units equals mg/12 units.

Pegfilgrastim-cbqv (Udenyca), Pegfilgrastim- jmdb (Fulphila)

Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Required ICD-10-CM Diagnosis Codes

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

- D70.1 (Agranulocytosis secondary to cancer chemotherapy)
- Z51.11 (Encounter for antineoplastic chemotherapy)

Billing

HCPCS codes:

- Q5111 (injection, pegfilgrastim-cbqv, [udenyca], biosimilar, 0.5 mg)
  One (1) unit of Q5111 equals 0.5 mg of pegfilgrastim-cbqv.
- Q5108 (injection, pegfilgrastim-jmdb, [fulphila], biosimilar, 0.5 mg)
  One (1) unit of Q5108 equals 0.5 mg of pegfilgrastim-jmdb.

Pegfilgrastim-fpgk (Stimufend), Pegfilgrastim-pbbk (Fylnetra)

Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosages.
- Drug is being used for prophylaxis in patients with solid tumors or non-myeloid malignancy under one the following conditions:
  - Patient is receiving mylosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20 percent
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10 to 20 percent and at least one of the following risk factors for febrile neutropenia:
    - ❖ Ages older than 65 years receiving full dose intensity chemotherapy
    - ❖ History of recurrent febrile neutropenia from chemotherapy
    - ❖ Extensive prior exposure to chemotherapy

- ❖ Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
- ❖ Persistent neutropenia (ANC less than or equal to 1000/mm3)
- ❖ Bone marrow involvement by tumor
- ❖ Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
- ❖ Recent surgery and/or open wounds
- ❖ Poor performance status
- ❖ Renal dysfunction (creatinine clearance less than 50 mL/min)
- ❖ Liver dysfunction (elevated bilirubin more than 2.0 mg/dL)
- ❖ Chronic immunosuppression in the post-transplant setting, including organ transplant

– The patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome

Initial authorization is for six months.

Reauthorization is for six months for patients who continue to meet the above criteria.

Billing

HCPCS codes:

- Q5127 (injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg).
- Q5130 (injection, pegfigrastim-pbbk (fylnetra), biosimilar, 0.5 mg).

Prescribing Restriction(s)

Frequency of billing is 6 mg/12 units one per chemotherapy cycle.

Maximum billing unit(s) is 6 mg/12 units.

‹‹Tbo-Filgrastim (GRANIX)

Tbo-filgrastim is a human granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. Tbo-filgrastim binds to G-CSF receptors and stimulates proliferation of neutrophils. G-CSF is known to stimulate differentiation commitment and some end-cell functional activation, which increases neutrophil counts and activity.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Required ICD-10-CM Diagnosis Codes

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

D70.1	Z51.11
D70.2	Z51.89

Billing

HCPCS code J1447 (injection, tbo-filgrastim, 1 microgram).››

Cyclophosphamide

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.

Age Limit

Must be 18 years of age and older (Sandoz Brand Only).

TAR Requirement

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

Billing

HCPCS codes:

J9072 (injection, cyclophosphamide, [Dr. Reddy's], 5 mg).

J9073 (injection, cyclophosphamide [Ingenus], 5 mg).

J9074 (injection, cyclophosphamide [Sandoz], 5 mg).

J9075 (injection, cyclophosphamide, not otherwise specified, 5 mg).

‹‹Cyclophosphamide (Auromedics brand), Cyclophosphamide (Baxter 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 codes:

J9071 (injection, cyclophosphamide, [auromedics], 5 mg).

‹‹J9076 (injection, cyclophosphamide [baxter], 5 mg).››

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.