Chemotherapy: Drugs N-O 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 the following 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 I-L Policy*
- *Chemotherapy: Drugs M Policy*
- *Chemotherapy: Drugs P-Q Policy*
- *Chemotherapy: Drugs R-S Policy*
- *Chemotherapy: Drugs T-Z Policy*.

Nadofaragene firadenovec-vncg (Adstiladrin®)

Adstiladrin is a non-replicating adenoviral vector-based gene therapy designed to deliver a copy of a gene encoding a human interferon-alfa 2b (IFNα2b) to the bladder urothelium. Intravesical instillation of Adstiladrin results in cell transduction and transient local expression of the IFNα2b protein that is anticipated to have anti-tumor effects.

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:

- 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.
- Patient has a Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (CIS) with or without papillary tumors following transurethral resection.
  - BCG-unresponsive high-risk NMIBC is defined as persistent disease following adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG
- Adequate BCG is defined as the administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course.
- Patient had declined or is ineligible for cystectomy.

- Prior to treatment, patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components). Residual CIS (Tis components) not amenable to complete resection is allowed.
- Patient does not have extra-vesical (for example, urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma.
- Patient is not immunosuppressed or immunodeficient.
- Patient does not have a hypersensitivity to interferon alfa.

Initial approval is for six months.

Continuation of Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive treatment response defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Patient does not have high-grade recurrence.
- Patient does not have unacceptable toxicity.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9029 (intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose).

Suggested ICD-10-CM Diagnosis Codes

C65.1, C65.2, C65.9

Prescribing Restriction(s)

Frequency of billing equals 75 ml every three months for up to 12 months (four doses).

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Naxitamab-gqgk (Danyelza®)

Naxitamab-gqgk binds to the glycolipid GD2. GD2 is a disialoganglioside that is overexpressed on neuroblastoma cells and other cells of neuroectodermal origin, including the central nervous system and peripheral nerves. In vitro, naxitamab-gqgk was able to bind to cell surface GD2 and induce complement dependent cytotoxicity (CDC) and antibody dependent cell-mediated cytotoxicity (ADCC).

Indications

All FDA-approved indications.

Dosage

FDA-approves 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 one year of age or older.
- Patient must have a diagnosis of high-risk, refractory or relapsed neuroblastoma (NB) in the bone or bone marrow.
- Patient has a partial response, minor response, or stable disease to prior therapy.
- Patient is resistant to standard therapy.
- Patient has been off chemotherapy and immunotherapy for a minimum of three weeks.
- Must be used in combination with granulocyte-macrophage colony-stimulating factor (GM- CSF) for example: sargramostim.
- Patient is not a pregnant female.

Authorization is for six months.

Continuation of therapy**:**

- Patient continues to meet initial approval criteria.
- Patient has shown positive clinical benefit as evidenced by lack of disease progression or reduction in tumor size or spread.
- Absence of unacceptable toxicity such as neurotoxicity (peripheral neuropathy, neurological disorders of the eye, and prolonged urinary retention) or severe hypertension.

Reauthorization is for six months.

Age Limit

Must be one year of age or older.

Billing

HCPCS code J9348, (injection, naxitamab-gqgk, 1 mg).

Suggested ICD-10 Diagnosis Codes

C74.0 thru C74.92.

Prescribing Restrictions

Frequency of billing equals 3 mg/kg/dose IV x1 on days one, three, five of 28-day cycle until complete or partial response achieved, then give x5 additional cycles q28 days, then may give subsequent cycles q56 days.

Necitumumab (Portrazza™)

Necitumumab is a recombinant human lgG1 monoclonal antibody that binds to the human epidermal growth factor receptor (EGFR) and blocks the binding of EGFR to its ligands. Expression and activation of EGFR has been correlated with malignant progression, induction of angiogenesis and inhibition of apoptosis. Binding of necitumumab induces EGFR internalization and degradation in vitro. In vitro, binding of necitumumab also led to antibody-dependent cellular cytotoxicity (ADCC) in EGFR-expressing cells.

In in vivo studies using xenograft models of human cancer, including non-small cell lung carcinoma, administration of necitumumab to implanted mice resulted in increased antitumor activity in combination with gemcitabine and cisplatin as compared to mice receiving gemcitabine and cisplatin alone.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J9295 (injection, necitumumab, 1 mg).

Required ICD-10-CM Diagnosis Codes

C25.4 and C25.9

Nelarabine

Nelarabine is reimbursable for treatment of patients with lymphosarcoma or acute lymphoid leukemia.

Dosage

The maximum daily dosage on days one, three and five is 4,050 mg unless documented body surface area (BSA) is greater than 2.7 m^2. Treatment may be repeated in 21 days.

Required Codes

Nelarabine is reimbursable only when billed in conjunction with ICD-10-CM diagnosis codes C83.50 thru C83.59 or C91.00 thru C91.02.

Billing

HCPCS code J9261 (injection, nelarabine, 50 mg).

‹‹Nivolumab and hyaluronidase-nvhy (OPIVO Qvantig™)

Indications, Dosages and Age

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 code J9289 (Injection, nivolumab, 2 mg and hyaluronidase-nvhy).

Prescribing Restrictions

Frequency of billing equals 1200 mg/600 units every two weeks.

Maximum billing units equals 1200 mg/600 units.››

Nivolumab (OPDIVO®)

Nivolumab is a programmed death receptor-1 (PD-1) blocking antibody. Nivolumab is a human immunoglobulin G4 (IgG4) monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth.

Indications

All FDA approved indications.

Dosage

FDA approved dosages.

TAR Requirement

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

Age Limit

Must be 12 years of age and older.

Billing

HCPCS code J9299 (injection, nivolumab, 1 mg).

One (1) unit of J9229 equals 1 mg of nivolumab.

Nivolumab and Relatlimab-rmbw (Opdualag™)

Relatlimab is a human IgG4 monoclonal antibody that binds to the LAG-3 receptor, blocks interaction with its ligands, including MHC II, and reduces LAG-3 pathway-mediated inhibition of the immune response. Antagonism of this pathway promotes T cell proliferation and cytokine secretion.

Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Nivolumab is a human IgG4 monoclonal antibody that binds to the PD-1 receptor, blocks interaction with its ligands PD-L1 and PD-L2 and reduces PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth.

The combination of nivolumab (anti-PD-1) and relatlimab (anti-LAG-3) results in increased T-cell activation compared to the activity of either antibody alone. In murine syngeneic tumor models, LAG-3 blockade potentiates the anti-tumor activity of PD-1 blockage, inhibiting tumor growth and promoting tumor regression.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Nogapendekin Alfa Inbakicept-pmln (ANKTIVA)

Nogapendekin alfa inbakicept-pmln is an IL-15 receptor agonist. IL-15 is *trans*-presented by the IL-15 receptor α to the shared IL-2/IL-15 receptor (βc and γc) on the surface of CD4+ and CD8+ T cells and NK cells. Binding of nogapendekin alfa inbakicept-pmln to its receptor results in proliferation and activation of NK, CD8+, and memory T cells without proliferation of immuno-suppressive Treg 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 prescribed by or in consultation with an oncologist or urologist.
- Must be for an FDA-approved indication and dosage.
- Patient must be 18 years of age or older.
- Patient has a diagnosis of Bacillus Calmette-Guérin (BCG)-negative nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
- Pregnancy testing and advice on contraception are provided to patient of reproductive potential prior to initiating treatment.

- Patient tried and was unresponsive to adequate BCG therapy, defined as administration of at least five of six doses of an initial induction course plus either of at least two of three doses of maintenance therapy or at least two of six doses of a second induction course).
- Must be used in combination with BCG.

Initial authorization is for six months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient achieved complete response from the induction period, defined by negative results for cystoscopy (with TURBT/biopsies as applicable) and urine cytology.
- Patient has an absence of disease recurrence, disease progression, and unacceptable toxicity.

Reauthorization is for 12 months. Maximum total treatment duration is 37 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J9028 (injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram).

Prescribing Restriction(s)

Maximum billing unit(s) is equal to 400 mcg/400 units.

TAR Requirement

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

Age Limits

Must be 12 years of age or older.

Billing

HCPCS code J9298 (injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg).

Prescribing Restriction(s)

Frequency of billing equals 480 mg nivolumab and 160 mg relatlimab/160 units every four weeks.

Maximum billing unit(s) equals 480 mg nivolumab and 160 mg relatlimab/160.

Obecabtagene autoleucel (AUCATZYL®)

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.

Required ICD-10-CM Codes

C91.00, C91.02

Billing

‹‹HCPCS code Q2058 (Obecabtagene autoleucel, 10 up to 400 million CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion).

Administration code: CPT® code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).››

Important Instructions for Billing

Due to system limitations, providers are to take the following steps when submitting a TAR/SAR and claims for Aucatzyl:

TAR/SAR Submission

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific *Service Authorization Request* (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter "6" in the Units box.

Claim Submission

1. ‹‹Bill using Becabtagene autoleucel, 10 up to 400 million CD19 car-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion.››
2. Completion of claim forms:
   - This billing methodology is restricted to hospital outpatient services and Hemophilia Treatment Centers (HTCs). Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ On the 837I or *UB-04* claim form, provider must submit six (6) claim lines to represent one (1) service.
     - ❖ Each claim line represents one unit.

Claims submitted with one or two claim lines will be denied.

- ❖ Provider must submit an invoice for reimbursement.
- ❖ This process will ensure that the total reimbursement paid for the six (6) claim lines is no more than the paid price on the provider submitted invoice.
- ❖ Aucatzyl must be billed on its own with no other drug or biological.

1. Providers are advised to take the following steps to ensure that Aucatzyl claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Aucatzyl” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006 Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “Aucatzyl” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
2. Providers note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
3. ‹‹Payment for Aucatzyl shall be once in a lifetime reimbursement under Q2058 or any other code (HCPCS, CPT or by NDC).››
4. For instructions regarding physical claim form completion, refer to the Forms page on the Medi-Cal Providers website and forms section *UB-04 Completion: Outpatient Services* for completion of 837I and *UB-04* claim forms.
5. ‹‹Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.››

Prescribing Restriction(s)

Frequency of billing is a single treatment course (once in a lifetime treatment).

Reauthorization: Never

Obinutuzumab (Gazyva®)

Obinutuzumab is a monoclonal antibody that targets the CD20 antigen expressed on the surface of pre B- and mature B-lymphocytes. Upon binding to CD20, obinutuzumab mediates B-cell lysis through:

- Engagement of immune effector cells
- Directly activating intracellular death signaling pathways, and/or
- Activation of the complement cascade.

The immune effector cell mechanisms include antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis.

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 J9301 (injection, obinutuzumab, 10 mg).

Ofatumumab (ARZERRA®)

Ofatumumab is an IgG1 human monoclonal antibody which binds specifically to both the small and large extracellular loops of the CD20 molecule. The CD20 molecule is expressed on normal B lymphocytes and on B-cells of chronic lymphocytic leukemia. The binding of ofatumumab to the CD20 molecule results in B-cell lysis in vitro. Data suggest that possible mechanisms of cell lysis include complement-dependent cytotoxicity and antibody-dependent, cell-mediated cytoxicity.

Indications

All FDA approved indications.

Dosage

FDA approved dosage.

TAR Requirement

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

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9302 (injection, ofatumumab, 10 mg), one billing unit equals 10 mg.

ICD-10 Diagnosis Codes

C83.00-83.09, C88.0, C91.10, C91.12.

Prescribing Restriction(s)

Frequency of billing equals 2000 mg/200 units.

Maximum billing unit(s) equals 2000 mg/200 units weekly.

Olaratumab

Olaratumab (Lartruvo™) is a platelet-derived growth factor receptor alpha (PDGFR-α) blocking antibody indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

Indications

Olaratumab is indicated for the treatment of adult patients with STS.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must state that the patient has STS with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

Dosage

Administer olaratumab at 15 mg/kg as an intravenous infusion over 60 minutes on days one and eight of each 21-day cycle until disease progression or unacceptable toxicity.

For the first eight cycles, olaratumab:

- Is administered with doxorubicin. Pre-medicate with diphenhydramine and dexamethasone intravenously prior to Lartruvo on day one of cycle one.
- Is for intravenous infusion only.
- Is not to be administered as an intravenous push or bolus.

Billing

HCPCS code J9285 (injection, olaratumab, 10 mg).

Oxaliplatin

Oxaliplatin is a platinum-based antineoplastic agent.

Indications

Oxaliplatin is indicated in the treatment of advanced colorectal cancer, stage III colon cancer (adjuvant) and gastric cancer.

Dosage

Advanced colorectal cancer: 85 mg/m^2 every 14 days until disease progression or unacceptable toxicity

Stage III colon cancer (adjuvant): 85 mg/m^2 every 14 days for a total of six months (12 cycles)

Gastric cancer: 100 mg/m^2 every 14 days

Required Codes

Oxaliplatin is reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: C16.0 thru C16.9 and C18.0 thru C20.

Billing

HCPCS code J9263 (injection, oxaliplatin, 0.5 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.