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

Radium Ra 223 Dichloride

For information about diagnostic and treatment applications of Radium Ra 223 Dichloride (HCPCS code A9606), refer to the *Radiology: Oncology* section in this manual.

Ramucirumab (CYRAMZA®)

Ramucirumab is a recombinant human lgG1 monoclonal antibody and is a vascular endothelial growth factor receptor 2 (VEGFRs) antagonist that specifically binds VEGFR2 which blocks binding of VEGFR ligands VEGF-A, VEGF-C and VEGF-D. As a result, ramucirumab inhibits ligand-stimulated activation of VEGFR2, thereby inhibiting ligand-induced proliferation and migration of human endothelial cells.

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 J9308 (injection, ramucirumab, 5 mg).

Retifanlimab-dlwr (ZYNYZ™)

Retifanlimab is a humanized IgG_4 monoclonal antibody which is a programmed death receptor-1 (PD-1) blocking antibody. Retifanlimab binds to the PD-1 receptor, blocking interaction with its ligands, PD-L1 and PD-L2, and potentiating T-cell activity. PD-L1 and PD-L2 binding to the PD-1 receptor on T-cells inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors; therefore, signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors.

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 must have a diagnosis of Merkel cell carcinoma (MCC) with metastatic disease or recurrent, advanced locoregional disease not amenable to surgery or radiation.
- Patient has not received systemic therapy for MCC, including chemotherapy and prior PD-1 or PD-L1-directed therapy (for example, avelumab, pembrolizumab, atezolizumab, cemiplimab, dostarlimab, durvalumab, nivolumab, etc.).
- Patient does not have clinically significant pulmonary, cardiac, gastrointestinal or autoimmune disorders.

- Patient does not have active bacterial, fungal, or viral infections, including hepatitis A, B, and C.
- Provider will evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment.
- Patient is not pregnant or breastfeeding.

Initial authorization is for six months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response such as stabilization of disease or decrease in tumor size or spread.
- Patient has absence of disease progression or unacceptable toxicity such as immune-mediated adverse reactions, infusion-related reactions, complications of Allogeneic hematopoietic stem-cell transplantation (HSCT), etc.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9345 (injection, retifanlimab-dlwr, 1 mg).

Suggested ICD-10-CM Diagnosis Codes

C4A0, C4A4, C4A8, C4A9, C4A10, C4A20, C4A21, C4A22, C4A30, C4A31, C4A39, C4A51, C4A52, C4A59, C4A60, C4A61, C4A62, C4A70, C4A71, C4A72, C4A111, C4A112, C4A121, C4A122

Prescribing Restrictions

Frequency of billing equals 500 mg/500 units every four weeks.

Maximum billing units equals 500 mg/500 units.

Rituximab

Rituximab is a CD20-directed cytolytic antibody for intravenous (I.V.) administration.

Indications

Rituximab is used to treat both oncologic and non-oncologic diseases including the following conditions:

- Non-Hodgkin's Lymphoma
- Chronic Lymphocytic Leukemia
- Rheumatoid Arthritis
- Granulomatosis with polyangiitis (Wegener's Granulomatosis)
- Microscopic Polyangiitis

For the use of rituximab in non-oncologic conditions, refer to the *Injections: Drugs R Policy* section in the appropriate Part 2 Medi-Cal manual.

Age Limit

Must be 18 years of age and older.

Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab as a single agent or in combination with other agents, the use of rituximab for induction or maintenance therapy, and the patient's response to treatment.

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.

- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab.

Billing

HCPCS code J9312 (injection, rituximab, 10 mg).

One (1) unit of J9312 equals 10 mg of rituximab injection solution.

Rituximab-abbs

Rituximab-abbs is a CD20-directed cytolytic antibody for intravenous (I.V.) administration. Rituximab-abbs is biosimilar to rituximab for the listed indications.

Indications

Rituximab-abbs is used to treat the following oncologic diseases:

- Non-Hodgkin's Lymphoma (NHL)
- Chronic Lymphocytic Leukemia (CLL)

Age Limit

Must be 18 years and older.

Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab-abbs as a single agent or in combination with other agents, the use of rituximab-abbs for induction or maintenance therapy, and the patient's response to treatment.

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.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab-abbs.

Billing

HCPCS code Q5115 (injection, rituximab-abbs, biosimilar, 10 mg).

One (1) unit of Q5115 equals 10 mg of rituximab-abbs.

Rituximab-arrx (Riabni™)

Rituximab-arrx is a monoclonal antibody. Rituximab products target the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab products mediate B-cell lysis. Possible mechanisms of cell lysis include complement dependent cytotoxicity (CDC) and antibody dependent cell mediated cytotoxicity (ADCC).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosing regimens.
- Patient has been screened for hepatitis B virus (HBV) infection prior to therapy initiation (for example, hepatitis B surface antigen [HBsAG] and hepatitis B core antibody measurements).

A. Non-Hodgkin's Lymphoma (NHL)

- Must be 18 years of age or older.
- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL (as a single agent).
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens.

B. Chronic Lymphocytic Leukemia (CLL)

- Must be 18 years of age or older.
- Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

C. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- Patient must be 18 years of age or older.
- Riabni must be used in combination with glucocorticoids such as methylprednisolone, prednisone, etc.

Initial approval is for 12 months.

Reauthorization:

- Patient continues to meet initial approval criteria.
- Patient does not have unacceptable toxicity such as infusion-related reactions. progressive multifocal leukoencephalopathy, tumor lysis syndrome, severe mucocutaneous skin reactions, etc.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code Q5123 (injection, rituximab-arrx, biosimilar, [Riabni], 10 mg).

Rituximab and Hyaluronidase

Rituximab and hyaluronidase human is a combination of rituximab, a CD20-directed cytolytic antibody, and hyaluronidase human, an endoglycosidase, for subcutaneous (SQ) administration.

Indications

Rituximab and hyaluronidase human is used to treat oncologic diseases including the following conditions:

- Non-Hodgkin's Lymphoma (NHL)
- Chronic Lymphocytic Leukemia (CLL)

Rituximab and hyaluronidase human is not indicated for the treatment of non-oncologic conditions.

Rituximab and hyaluronidase human is initiated only after patients have received at least one full dose of rituximab by intravenous (I.V.) infusion.

Age Limit

Must be18 years of age and older

Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab as a single agent or in combination with other agents, the use of rituximab for induction or maintenance therapy, and the patient's response to treatment.

- For NHL: 1,400 mg/23,400 units administered by SQ injection according to the recommended schedule for rituximab.
- For CLL: 1,600 mg/26,800 units administered by SQ injection according to the recommended schedule for rituximab.

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.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab and hyaluronidase human.

Note: Rituximab and hyaluronidase human is not indicated for the treatment of non-oncologic conditions.

Billing

HCPCS code J9311 (injection, rituximab, 10 mg and hyaluronidase).

One (1) unit of J9311 equals 10 mg of rituximab and hyaluronidase injection solution.

Rituximab-pvvr (Ruxience)

Rituximab-pvvr is a monoclonal antibody. Rituximab targets the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab products mediate B-cell lysis. Possible mechanisms of cell lysis include complement dependent cytotoxicity (CDC) and antibody dependent cell mediated cytotoxicity (ADCC).

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 Q5119 (injection, rituximab-pvvr, biosimilar, [ruxience],10 mg).

Rolapitant

Rolapitant injection is a substance P/neurokinin-1 (NK-1) receptor antagonist anti-emetic drug for intravenous (I.V.) administration.

Indications

Rolapitant is used in combination with dexamethasone and a 5-HT3 receptor antagonist to prevent nausea and vomiting symptoms associated with initial and repeat courses of highly-emetic cancer chemotherapy (HEC) or moderately-emetic cancer chemotherapy (MEC).

Age Limit

Must be 18 years of age and older.

Dosage

Single dose regimen for HEC or MEC:

- 166.5 mg I.V. given as a single dose within two hours before initiation of a chemotherapy cycle. Additional dose(s) given in less than two-week intervals is not considered medically necessary.

Authorization

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

Required Codes

The following ICD-10-CM diagnosis code is required for reimbursement:

- Z51.11 (Encounter for anti-neoplastic chemotherapy)

Billing

HCPCS code J2797 (injection, rolapitant, 0.5 mg).

One (1) unit of J2797 equals 0.5 mg of rolapitant injectable emulsion.

Romidepsin (Istodax)

Romidepsin is a histone deacetylase (HDAC) inhibitor. HDACs catalyze the removal of acetyl groups from acetylated lysine residues in histones, resulting in the modulation of gene expression. HDACs also deacetylate non-histone proteins, such as transcription factors. In vitro, romidepsin causes the accumulation of acetylated histones and induces cell cycle arrest and apoptosis of some cancer cell lines with IC50 (half maximal inhibitory concentration) values in the nanomolar range. The mechanism of the antineoplastic effect of romidepsin observed in nonclinical and clinical studies has not been fully characterized.

Indications

All FDA-approved indications.

TAR Requirement

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

Diagnosis Restrictions

One of the following to ICD-10-CM diagnosis codes is required for reimbursement: C84.00 thru C84.19 dosage.

Dosage

FDA-approved dosages.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9319 (injection, romidepsin, lyophilized, 0.1 mg).

One billing unit equals 0.1 mg.

Romidepsin Non-Lyophilized

Romidepsin is a histone deacetylase (HDAC) inhibitor. HDACs catalyze the removal of acetyl groups from acetylated lysine residues in histones, resulting in the modulation of gene expression. HDACs also deacetylate non-histone proteins, such as transcription factors. In vitro, romidepsin causes the accumulation of acetylated histones, and induces cell cycle arrest and apoptosis of some cancer cell lines with IC50 values in the nanomolar range. The mechanism of the antineoplastic effect of romidepsin observed in nonclinical and clinical studies has not been fully characterized.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosing regimens.
- Patient must be 18 years of age or older.

- Patient must have one of the following diagnoses:
  - Cutaneous T-cell lymphoma (CTCL)
  - Peripheral T-cell lymphoma (PTCL)
- Patient must have received at least one prior therapy with relapse or disease progression.

Initial authorization is for six months.

Continued Therapy:

- Patient continues to meet initial coverage criteria
- Patient has shown positive clinical response as evidenced by disease stabilization or lack of disease progression

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9318 (injection, romidepsin, non-lyophilized, 0.1 mg).

Suggested ICD-10-CM Diagnosis Codes

C84.00 thru C84.49, C84.A0 thru C84.A9

Prescribing Restrictions

Frequency of billing equals 14 mg/m^2 on days one, eight and 15 of a 28-day cycle. Repeat cycles every 28 days.

Romiplostim

‹‹Romiplostim increases platelet production through binding and activation of the thrombopoietin (TPO) receptor, a mechanism analogous to endogenous TPO.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2802 (injection, romiplostim, 1 microgram).

Suggested ICD-10-CM Diagnosis Codes

D69.3, T66.XXXA

Prescribing Restriction(s)

Frequency of billing is equal to 10 micrograms / 10 units weekly.

Maximum billing unit(s) is equal to 10 micrograms / 10 units.››

Sacituzumab Govitecan-hziy (Trodelvy™)

Sacituzumab govitecan-hziy is a Trop-2 directed antibody and topoisomerase inhibitor conjugate composed of the humanized monoclonal antibody sacituzumab (hRS7 IgG1-kappa), the drug SN-38 and CL2A (a hydrolysable linker). Sacituzumab govitecan-hziy binds to Trop-2-expressing cancer cells and is internalized with subsequent release of SN-38, via hydrolysis of the linker, which interacts with topoisomerase I and prevents re-ligation of topoisomerase I-induced single strand breaks causing DNA damage resulting in apoptosis and cell death. Sacituzumab govitecan-hziy decreased tumor growth in mouse xenograft models of triple-negative breast cancer.

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 J9317 (injection, sacituzumab govitecan-hziy, 2.5 mg).

Suggested ICD-10 Diagnosis Codes

C50.011 thru C50.319, C50.411, C50.919, C50.929, C65.1 thru C65.9, C66.1 thru C66.9, C67.0 thru C67.9, C68.8 thru C68.9, D05.00 thru D05.02

Prescribing Restrictions

Frequency of billing equals 10 mg/kg once weekly on days 1 and 8 of 21-day treatment cycles.

Samarium Sm-153 Lexidronam

For HCPCS code A9604, refer to the *Radiology: Oncology Therapeutic Radiopharmaceuticals* section in this manual.

Sipuleucel-T

Sipuleucel-T consists of autologous peripheral blood mononuclear cells that have been activated during a defined culture period with a recombinant human protein, PAP-GM-CSF, consisting of prostatic acid phosphatase (PAP), an antigen expressed in prostate cancer tissue, linked to granulocyte-macrophage colony-stimulating factor (GM-CSF), an immune cell activator. The patient's peripheral blood mononuclear cells are obtained via a standard leukapheresis procedure approximately three days prior to the infusion date.

Sipuleucel-T is classified as an autologous cellular immunotherapy with an unknown mechanism of action. Sipuleucel-T is designed to induce an immune response targeted against PAP, an antigen expressed in most prostate cancers.

Indications

For the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

The patient should not be receiving simultaneous chemotherapy and should not be receiving immunosuppressive therapy.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must document the following:

- Evidence of metastases.
- Testosterone levels less than 50 ng/dL.
- Two sequential rising prostate specific antigen (PSA) levels usually obtained two weeks to three months apart or other evidence of disease progression.

Dosage

Each dose of sipuleucel-T contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF.

The recommended course of therapy is three complete doses, given at approximately two-week intervals. In controlled clinical trials, the median dosing interval between infusions was two weeks (range 1 to 15 weeks). The maximum dosing interval has not been established.

Billing

HCPCS code Q2043 (sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion). One unit equals one infusion.

Sirolimus Protein-Bound Particles (albumin-bound) (Fyarro™)

Sirolimus in FYARRO is an inhibitor of mechanistic target of rapamycin kinase (mTOR, previously known as mammalian target of rapamycin). mTOR, a serine threonine kinase, is downstream of the PI3K/AKT pathway, controls key cellular processes such as cell survival, growth and proliferation, and is commonly dysregulated in several human cancers. In cells, sirolimus binds to the immunophilin, FK Binding Protein-12 (FKBP-12), to generate an immunosuppressive complex. The sirolimus-FKBP-12 complex binds to and inhibits activation of the mechanistic target of rapamycin complex 1 (mTORC1). Inhibition of mTOR by sirolimus has been shown to reduce cell proliferation, angiogenesis, and glucose uptake in in vitro and in vivo studies. In a nonclinical study in athymic mice bearing human tumor xenografts, intravenous administration of FYARRO resulted in higher tumor accumulation of sirolimus, inhibition of an mTOR target in the tumor, and tumor growth inhibition compared to administration of an oral formulation of sirolimus at the same weekly total dose.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirements

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

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9331 (injection, sirolimus protein-bound particles, 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 100 mg/m^2 administered on Days one and eight of each 21-day cycle.

Sodium Thiosulfate (Pedmark®)

Cisplatin-induced ototoxicity is caused by irreversible damage to hair cells in the cochlea hypothesized to be due to a combination of reactive oxygen species (ROS) production and direct alkylation of DNA leading to cell death. Sodium thiosulfate interacts directly with cisplatin to produce an inactive platinum species. In addition, sodium thiosulfate can enter cells through the sodium sulfate cotransporter 2 and cause intracellular effects such as the increase in antioxidant glutathione levels and inhibition of intracellular oxidative stress. Both activities may contribute to the ability of sodium thiosulfate to reduce the risk of ototoxicity.

Concurrent incubation of sodium thiosulfate with cisplatin decreased the in vitro cytotoxicity of cisplatin to tumor cells; delaying the addition of sodium thiosulfate to these cultures prevented the protective effect.

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 at least one month of age to 18 years of age.
- It must be prescribed by or in consultation with an oncologist.
- Patient has a diagnosis of localized, non-metastatic solid tumors.
- Drug is being used for prophylaxis of ototoxicity.
- Patient will receive a chemotherapy treatment regimen that includes a cumulative cisplatin dose that is at least 200 mg/m^2 with individual cisplatin doses to be infused over six hours or less but at least 10 hours before the next cisplatin infusion.
- Must document baseline serum sodium and potassium and as clinically indicated.
  - Baseline serum sodium must be less than 145 mmol/L
- Patient has no previous hypersensitivity to sodium thiosulfate or other thiol agents (for example, amifostine trihydrate, N-acetylcysteine, MESNA, or captopril).

Initial authorization is for six months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Documentation of positive clinical response.
- Serum sodium is not greater than 145 mmol/L.

Reauthorization is for 12 months.

Age Limit

Must be at least one month of age to 18 years of age.

Billing

HCPCS code J0208 (injection, sodium thiosulfate [pedmark], 100 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.