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

Margetuximab-cmkb (Margenza™)

Margetuximab-cmkb binds to the extracellular domain of the human epidermal growth factor receptor 2 protein (HER2). Upon binding to HER2-expressing tumor cells, margetuximab-cmkb inhibits tumor cell proliferation, reduces shedding of the HER2 extracellular domain and mediates antibody-dependent cellular cytotoxicity (ADCC). In vitro, the modified Fc region of margetuximab-cmkb increases binding to activating Fc receptor FCGR3A (CD16A) and decreases binding to inhibitory Fc receptor FCGR2B (CD32B). These changes lead to greater in vitro ADCC and NK cell activation.

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 J9353 (injection, margetuximab-cmkb, 5 mg).

Prescribing Restrictions

Frequency of billing equals 15 mg/kg for the initial dose, then every three weeks for all subsequent doses.

Medroxyprogesterone

Medroxyprogesterone acetate is indicated for adjunctive therapy and palliative treatment of inoperable, recurrent and metastatic endometrial carcinoma.

Dosage

If improvement is noted and the disease appears to be stabilized, it may be possible to maintain improvement with as little as 400 mg per month.

Authorization

For doses greater than 1,000 mg per day, an approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS code J1050 (injection, medroxyprogesterone acetate, 1 mg).

Melphalan Flufenamide (Pepaxto®)

Melphalan flufenamide is a peptide conjugated alkylating drug. Due to its lipophilicity, melphalan flufenamide is passively distributed into cells and thereafter enzymatically hydrolyzed to melphalan. Similar to other nitrogen mustard drugs, cross-linking of DNA is involved in the antitumor activity of melphalan flufenamide. In cellular assays, melphalan flufenamide inhibited proliferation and induced apoptosis of hematopoietic and solid tumor cells. Additionally, melphalan flufenamide showed synergistic cytotoxicity with dexamethasone in melphalan resistant and non-resistant multiple myeloma cell lines.

Indication

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 J9247 (injection, melphalan flufenamide hydrochloride, 1 mg).

Suggested ICD-10 Diagnosis Codes

C90.00, C90.02

Prescribing Restrictions

Frequency of billing equals 40 mg/40 units on day one of each 28-day cycle.

Maximum billing unit(s) equals 40 mg/40 units.

Melphalan Injection (Apotex Brand)

Melphalan is an alkylating agent of the bischloroethylamine type. As a result, its cytotoxicity appears to be related to the extent of its interstrand cross-linking with DNA, probably by binding at the N7 position of guanine. Like other bifunctional alkylating agents, it is active against both resting and rapidly dividing tumor cells.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Melphalan will be considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages.
- Prescribed by or in consultation with an oncologist or hematologist.
- Patient is 18 years of age or older.
- Patient has a diagnosis of multiple myeloma.
- Patient is taking this drug for palliative treatment.
- Documentation that the patient is unable to tolerate oral therapy.

Initial authorization is for 12 months.

Re-authorization:

- Patient continues to meet the initial criteria.
- Positive clinical response as evident by stabilization of disease.
- Patient has no disease progression or unacceptable toxicity (for example, myelotoxicity).

Re-authorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9249 (injection, melphalan [apotex], 1 mg).

Melphalan for Injection (Evomela®)

Melphalan is an alkylating agent of the bischloroethylamine type. As a result, its cytotoxicity appears to be related to the extent of its interstrand cross-linking with DNA, probably by binding at the N7 position of guanine. Like other bifunctional alkylating agents, it is active against both resting and rapidly dividing tumor cells.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Evomela will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens.
- Patient must be 18 years of age or older.
- Patient is taking this as:
  - A high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation
    - ❖ Must document approval of stem cell transplantation and tentative procedure date; or
  - A palliative treatment when oral therapy is not appropriate.

Approval duration: one month for stem cell transplant and six months for palliative treatment.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient is responding positively to therapy with improvement or stabilization of disease.
- Patient has no unacceptable toxicity such as anaphylaxis.

Reauthorization is for 12 months for palliative treatment.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9246 (injection, melphalan (evomela), 1 mg).

Melphalan Hydrochloride Injection, Not Otherwise Specified (NOS)

Melphalan is an alkylating agent which is a derivative of mechlorethamine that inhibits DNA and RNA synthesis via formation of carbonium ions; cross-links strands of DNA; acts on both resting and rapidly dividing tumor cells.

Indications

All FDA-approved indications.

TAR Requirement

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

TAR Criteria

Melphalan hydrochloride will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens.
- Patient must be 18 years of age or older.
- Patient must have a diagnosis of multiple myeloma.
- Patient is taking this as palliative treatment.
- Patient is unable to take oral therapy.

Approval duration is six months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient is responding positively to therapy with improvement or stabilization of disease.
- Patient has no disease progression or unacceptable toxicity.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9245 (injection, melphalan hydrochloride, not otherwise specified, 50 mg).

Prescribing Restriction

Frequency of billing equals 16 mg/m² every 14 days for four doses, then every four weeks.

Methotrexate

Injectable methotrexate is reimbursable when used in the treatment of both malignant and non-malignant diseases.

Dosage

Due to the wide variety of diseases and dosages in which methotrexate is used, a usual, recommended or maximum dose cannot be stated.

Billing

HCPCS code J9260 (injection, methotrexate sodium, 50 mg).

One (1) unit equals 50 mg.

Note: If less than 50 mg is administered, one unit may be submitted on the claim form.

‹‹Methotrexate (JYLAMVO, XATMEP)

Policies for methotrexate (Jylamvo) (HCPCS code J8611) and methotrexate (Xatmep) (HCPCS code J8612) are located in the *Non-Injectable Drugs* section in the Part 2 manual.››

Mirvetuximab Soravtansine-gynx (Elahere™)

Mirvetuximab soravtansine-gynx is an antibody-drug conjugate (ADC). The antibody is a chimeric IgG1 directed against folate receptor alpha (FRα). The small molecule, DM4, is a microtubule inhibitor attached to the antibody via a cleavable linker. Upon binding to FRα, mirvetuximab soravtansine-gynx is internalized followed by intracellular release of DM4 via proteolytic cleavage. DM4 disrupts the microtubule network within the cell, resulting in cell cycle arrest and apoptotic cell death.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages.
- Prescribed by or in consultation with an oncologist.
- Patient must be 18 years of age or older.
- Patient has tumors that are positive for FRα expression.
- Patient has not responded to or is no longer responding to treatment with platinum-based chemotherapy.
- Conduct an ophthalmic exam (visual acuity and slit lamp exam) prior to initiation of mirvetuximab soravtansine, every other cycle for the first eight cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Patient has received one to three prior systemic treatment regimens.
- Patient does not have moderate or severe hepatic impairment (total bilirubin more than 1.5 ULN).

Initial approval is for six months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response as evidenced by disease stabilization, decrease in tumor size, or lack of tumor spread.
- Patient has unacceptable toxicity such as ocular toxicities, pneumonitis, severe peripheral neuropathy, pulmonary toxicity, etc.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code: J9063 (Injection, mirvetuximab soravtansine-gynx, 1 mg).

Suggested ICD-10 Diagnosis Codes

C48.1, C48.2, C48.8, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.8

Mitomycin (Jelmyto™)

Jelmyto is for pyelocalyceal use only. Mitomycin inhibits the synthesis of deoxyribonucleic acid (DNA). The guanine and cytosine content correlates with the degree of mitomycin-induced cross-linking. At high concentrations of the drug, cellular RNA and protein synthesis are also suppressed.

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 J9281 (mitomycin pyelocalyceal instillation, 1 mg).

‹‹Mitomycin is packaged in two 40mg vials (80mg in total). It may be necessary to discard the unused portion of a vial. Providers may bill for a quantity equal to the amount given to the patient plus the amount wasted. Providers must follow the steps in billing wastage based on JW modifier policy.››

Suggested ICD-10-CM Diagnosis Codes

C65.1, C65.2, C65.9

Prescribing Restrictions

Frequency of billing equals initially, 60 mg/ 60 units weekly for six weeks. After three months, maintenance monthly dose of 60 mg/ 60 units for a maximum of 11 additional doses.

Maximum billing unit(s) equals 60 mg/60 units.

Mitoxantrone

Injectable mitoxantrone is a synthetic antineoplastic anthracenedione that intercalates into deoxyribonucleic acid causing crosslinks and strand breaks. It also interferes with ribonucleic acid (RNA) and is a potent inhibitor of topoisomerase II, an enzyme responsible for uncoiling and repairing damaged DNA. It has a cytocidal effect on both proliferating and non-proliferating cultured human cells, suggesting lack of cell cycle phase specificity.

Refer to “mitoxantrone” in the *Injections: Drugs M Policy* section of this manual for the use of mitoxantrone in non-malignant conditions.

Indications

For the treatment of:

- Acute myeloid leukemia
- Hodgkin lymphoma
- Non-Hodgkin lymphoma
- Prostate cancer

Dosage

The recommended dose varies depending on the disease being treated.

The maximum dosage is 38 mg per day.

Billing

HCPCS code J9293 (injection, mitoxantrone HCl, per 5 mg).

Mitoxantrone may be billed in conjunction with CPT code 96413 (chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug).

Mogamulizumab-kpkc (Poteligeo)

Mogamulizumab-kpkc is a defucosylated, humanized lgG1 kappa monoclonal antibody that binds to CCR4, a G protein-coupled receptor for CC chemokines that is involved in the trafficking of lymphocytes to various organs. Non-clinical in vitro studies demonstrate mogamulizumab-kpkc binding targets a cell for antibody-dependent cellular cytotoxicity (ADCC) resulting in depletion of the target cells. CCR4 is expressed on the surface of some Tcell malignancies and is expressed on regulatory T-cells (Treg) and a subset of Th2 T-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 J9204 (injection, mogamulizumab-kpkc, 1 mg).

Prescribing Restrictions

Frequency of billing equals every 28 days (four doses in the first 28 day-cycle, then two doses every 28 days thereafter).

Maximum billing unit(s) equals 908 mg/ 908 units.

Mosunetuzumab-axgb (Lunsumio™)

Mosunetuzumab-axgb is a T-cell engaging bispecific antibody that binds to the CD3 receptor expressed on the surface of T-cells and CD20 expressed on the surface of lymphoma cells and some healthy B-lineage cells.

In vitro, mosunetuzumab-axgb activated T-cells, caused the release of proinflammatory cytokines, and induced lysis of B-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 J9350 (injection, mosunetuzumab-axgb, 1 mg).

Suggested ICD-10-CM Diagnosis Codes

C82.00 thru C82.09, C82.10 thru C82.19, C82.20 thru C82.29, C82.30 thru C82.39, C82.80 thru C82.89, C82.90 thru C82.99

Prescribing Restrictions

Frequency of billing equals every seven days.

Maximum billing units equals 60 mg/60 units.

Motixafortide (APHEXDA™)

Motixafortide is an inhibitor of the C-X-C Motif Chemokine Receptor 4 (CXCR4) and blocks the binding of its cognate ligand, stromal-derived factor-1α (SDF-1α)/C-X-C Motif Chemokine Ligand 12 (CXCL12).

SDF-1α and CXCR4 play a role in the trafficking and homing of human hematopoietic stem cells to the marrow compartment. Once in the marrow, stem cell CXCR4 can help anchor these cells to the marrow matrix, either directly via SDF-1α or through the induction of other adhesion molecules.

Treatment with motixafortide resulted in leukocytosis, and elevations in circulating hematopoietic stem and progenitor cells into the peripheral circulation in mice, rats, dogs, and humans.

Stem cells mobilized by motixafortide were capable of engraftment with long-term repopulating capacity in a rodent transplantation model.

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.
- Patient must have a diagnosis of histologically confirmed Multiple Myeloma.

- Patient is eligible for autologous hematopoietic stem cell transplantation.
- Motixafortide will be used to mobilize hematopoietic stem cells for collection prior to autologous transplantation.
- It will be used in combination with filgrastim.
- Patient does not have a history of autologous or allogeneic-HCT.

Approval duration is for one treatment cycle (two doses only).

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code: J2277 (injection, motixafortide, 0.25 mg).

Prescribing Restrictions

Frequency of billing equals 1.25 mg/kg ten to 14 hours prior to initiation of apheresis. Can administer a second dose ten to 14 hours prior to a third apheresis.

Moxetumomab pasudotox-tdfk (Lumoxiti)

Moxetumomab pasudotox is a CD22-directed cytotoxin composed of a recombinant murine immunoglobulin genetically fused to truncated Pseudomonas exotoxin (PE38). Moxetumomab pasudotox binds CD22 on the cell surface of B-cells and is internalized. Moxetumoman pasudotox internalization results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis, and apoptotic cell death.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Recommendations

It is recommended that:

- Patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog.
- Patient is greater than or equal to 18 years of age.
- Patient has not previously received six or more cycles of treatment with Lumoxiti.
- Patient must not have severe renal impairment (CrCl is less than or equal to 29 mL/min).

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J9313 (injection, moxetumomab pasudotox-tdfk, 0.01 mg).

Prescribing Restrictions

Frequency of billing equals on days one, three and five of each 28-day cycle for six cycles.

Maximum Billing units equals 9.1 mg equals 910 units.

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.