Injections: Drugs M Policy

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This section outlines 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 *Injections: An Overview* section in this manual. Additional policy information for injection services can be found in the following sections of this manual:

- *Immunizations*
- *Injections: Drugs A Policy*
- *Injections: Drugs B Policy*
- *Injections: Drugs C Policy*
- *Injections: Drugs D Policy*
- *Injections: Drugs E Policy*
- *Injections: Drugs F Policy*
- *Injections: Drugs G Policy*
- *Injections: Drugs H Policy*
- *Injections: Drugs I Policy*
- *Injections: Drugs J-L Policy*
- *Injections: Drugs N-O Policy*
- *Injections: Drugs P-Q Policy*
- *Injections: Drugs R Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

Medroxyprogesterone Acetate

When administered as an injectable contraceptive, refer to the *Family Planning* section in the appropriate Part 2 manual for billing information.

When administered for the treatment of endometrial carcinoma, refer to the *Chemotherapy: Drugs E-O Policy* section in the appropriate Part 2 manual for billing information.

Authorization

An approved TAR is required for reimbursement only when the dose exceeds 1,000 mg per day.

Billing

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

Meloxicam injection (Anjeso™)

Meloxicam has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action of meloxicam, like that of other Nonsteroidal anti-inflammatory drugs (NSAIDs), is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2). Meloxicam is a potent inhibitor of prostaglandin synthesis in vitro. Meloxicam concentrations reached during therapy have produced in vivo effects. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Prostaglandins are mediators of inflammation. Because meloxicam is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

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

- Must be prescribed for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be used for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics.
- Must not be intended for long-term use.
- Must not be used in the setting of coronary artery bypass graft (CABG) surgery.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1738 (injection, meloxicam, 1 mg).

Prescribing Restriction

Frequency of billing equal to 30 mg/30 units once daily.

Maximum billing units equal to 30 mg/30 units.

Mepolizumab

Mepolizumab is an interleukin-5 (IL-5) antagonist (IgG1 kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Mepolizumab binds to IL-5 with a dissociation constant of 100 pM, inhibiting the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface. Inflammation is an important component in the pathogenesis of asthma and Eosinophilic Granulomatosis with Polyangiitis (EGPA). Multiple cell types (for example, mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (for example, histamine, eicosanoids, leukotrienes, cytokines) are involved in inflammation. Mepolizumab, by inhibiting IL-5 signaling, reduces the production and survival of eosinophils; however, the mechanism of mepolizumab action in asthma and EGPA has not been definitively established.

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:

- Asthma
  - Patient is six years of age or older; and
  - Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 300 cells/μL within previous 12 months or greater than or equal to150 cells/μL within six weeks of dosing; and

- Patient has inadequate asthma control (for example, hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimal dosages:
  - ❖ Inhaled corticosteroid; and
  - ❖ Long acting beta2-agonist, leukotriene modifier, or sustained release theophylline)
- Patient will not use Nucala as monotherapy
- Patient will not use Nucala in combination with another monoclonal antibody (for example, Cinqair, Dupixent, Fasenra, Xolair, etc.).

- Eosinophilic Granulomatosis with Polyangiitis
  - Patient is 18 years of age or older
  - Patient has a history or the presence of an eosinophil count of more than 1000 cells/μL or a blood eosinophil level of higher than 10 percent
  - Patient has two or more of the following disease characteristics of EGPA:
    - ❖ Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    - ❖ Neuropathy
    - ❖ Pulmonary infiltrates
    - ❖ Sinonasal abnormalities
    - ❖ Cardiomyopathy
    - ❖ Glomerulonephritis
    - ❖ Alveolar hemorrhage
    - ❖ Palpable purpura
    - ❖ Antineutrophil Cytoplasmic Antibody (ANCA) positivity
  - Patient has had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within two years prior to starting treatment with Nucala or has a refractory disease.

Initial authorization is for 12 months.

Continuation of therapy:

Approval may be granted for 12 months if:

- Asthma
  - Patient continues to meet initial coverage criteria; and
  - Asthma control has improved on Nucala treatment as demonstrated by at least one of the following:
    - ❖ A reduction in the frequency and/or severity of symptoms and exacerbations
    - ❖ A reduction in the use of systemic corticosteroids
    - ❖ Improvement from baseline in forced expiratory volume in one second (FEV1)
- Eosinophilic Granulomatosis with Polyangiitis
  - Patient continues to meet initial coverage criteria
  - Patient has beneficial response to treatment with Nucala as demonstrated by any of the following:
    - ❖ A reduction in the frequency of relapses
    - ❖ A reduction in the daily oral corticosteroid dose
    - ❖ Absence of active vasculitis

Age Limit

Must be six years of age or older.

Billing

HCPCS code J2182 (injection, mepolizumab, 1 mg).
One (1) unit of J2182 equal to 1 mg of mepolizumab solution.

Prescribing Restrictions

Frequency of billing equal to 300 mg/300 units every four weeks.

Maximum billing unit(s) equal to 300 mg/300 units.

Meropenem (B.Braun)

Meropenem is an antibacterial drug. It inhibits bacterial cell wall synthesis by binding to several of the penicillin-binding proteins, which in turn inhibit the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis; bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

Indications

All FDA-approved indications.

Dosage

FDA approved dosages.

TAR Requirement

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

Billing

HCPCS code J2184 (injection, meropenem [b. braun] not therapeutically equivalent to J2185, 100 mg).

Prescribing Restriction(s)

Frequency of billing equals 2 g/ 20 units every eight hours.
Maximum billing unit(s) equals 2 g/ 20 units.

Meropenem and Vaborbactam

Meropenem and vaborbactam is an antibiotic and a beta-lactamase inhibitor combination for intravenous (IV) infusion.

Indications

Meropenem and vaborbactam is used to treat complicated urinary tract infections (cUTI) including pyelonephritis caused by susceptible bacterial microorganisms such as *Escherichia coli, Klebsiella pneumonia*, and *Enterobacter cloacae species* complex.

Age Limit

Must be 18 years of age and older.

Dosage

For patients with an estimated glomerular filtration rate (eGFR) greater than or equal to 50 mL/min/1.73 m^2:

- The recommended dose is four grams (meropenem two grams and vaborbactam two grams) IV administered every eight hours for up to 14 days.

For patients with an eGFR of 30 to 49 mL/min/1.73m^2:

- The recommended dose is two grams (meropenem 1 gram and vaborbactam one gram) IV administered every eight hours for up to 14 days.

For patients with an eGFR of 15 to 29 mL/min/1.73m^2:

- The recommended dose is two grams (meropenem 1 gram and vaborbactam 1 gram) IV administered every 12 hours for up to 14 days.

For patients with an eGFR of less than15 mL/min/1.73m^2:

- The recommended dose is 1 gram (meropenem 0.5 gram and vaborbactam 0.5 gram) IV administered every 12 hours for up to 14 days.

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 to treat a complicated urinary tract infection (cUTI) including pyelonephritis caused by a susceptible bacterial microorganism such as *Escherichia coli, Klebsiella pneumoniae*, or *Enterobacter cloacae species* complex, based on urine or blood culture and sensitivity reporting.
- The patient's eGFR measurement.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for meropenem and vaborbactam.

Billing

HCPCS code J2186 (injection, meropenem and vaborbactam, 10 mg/10 mg, [20 mg])

One (1) unit of J2186 equals 10 mg of meropenem and 10 mg of vaborbactam.

Mesna

‹‹Mesna (HCPCS code J9209) is a uroprotective agent in patients who receive oxazaphosphorine alkylating agents including ifosfamide (HCPCS code J9208) and cyclophosphamide (HCPCS code J9075).›› The active ingredient is a synthetic sulfhydryl compound, which is rapidly metabolized to its major metabolite, mesna disulfide. In the kidney, mesna disulfide is reduced to the free thiol compound, mesna which reacts with urotoxic metabolites resulting in their detoxification.

Indications

Mesna is indicated for use as a prophylactic agent in reducing the incidence of drug induced hemorrhagic cystitis in patients receiving ifosfamide or cyclophosphamide.

Dosage

The mesna dosage is 60 percent of the total daily dose of ifosfamide or cyclophosphamide divided into three separate aliquots and administered at the time of, and at four and eight hours after, each dose of chemotherapy. The maximum daily dose of mesna should be 9 gms or 45 units per day. Medical justification is required to allow more if the cyclophosphamide dose is greater than 6.8 gms or the ifosfamide dose is greater than 15 gms.

Billing

HCPCS code J9209 (injection, mesna, 200 mg).

Mesna is reimbursable only if billed in conjunction with ifosfamide or cyclophosphamide. CPT® code 96375 (therapeutic, prophylactic or diagnostic injection; each additional sequential intravenous push of a new substance/drug) is reimbursable when billed in conjunction with mesna.

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 equal to 50 mg.

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

Methoxy polyethylene glycol-epoetin beta (Mircera®)

Methoxy polyethylene glycol-epoetin beta is an erythropoietin receptor activator with greater activity in vivo as well as increased half-life, in contrast to erythropoietin. A primary growth factor for erythroid development, erythropoietin, is produced in the kidney and released into the bloodstream in response to hypoxia. In responding to hypoxia, erythropoietin interacts with erythroid progenitor cells to increase red blood cell (RBC) production. Production of endogenous erythropoietin is impaired in patients with chronic kidney disease (CKD) and erythropoietin deficiency is the primary cause of their anemia.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosage.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Patient has a diagnosis of anemia associated with CKD with one of the following criteria:
  - Adult patients on dialysis and adult patients not on dialysis, or
  - Pediatric patients five to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.
- Must be prescribed by or in consultation with a hematologist or nephrologist.
- Must have tried and failed, is intolerant to, or has a contraindication to a clinically appropriate formulary alternative.
- Patient was assessed for iron deficiency anemia and has adequate iron stores as indicated by current (within the last three months) serum ferritin level of 100 mcg/L or more, or serum transferrin saturation of greater than or equal to 20 percent.

- Pretreatment hemoglobin (Hgb) is less than 10 g/dL.
- Patient does not have uncontrolled hypertension.
- Other causes of anemia have been ruled out (for example, vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) before initiating Mircera.
- Following initiation of therapy and after each dose adjustment, monitor hemoglobin weekly until the hemoglobin level is stable and sufficient to minimize the need for RBC transfusion.
- Must not be used in combination with another erythropoiesis stimulating agent.
- Must not be used for the following:
  - Treatment of anemia due to cancer chemotherapy, or
  - Substitute for RBC transfusions in patients who require immediate correction of anemia.

Important Dosing Information

Patients with CKD:

- Individualize dosing and use the lowest dose of Mircera sufficient to reduce the need for RBC transfusions.
- Do not target Hgb level of greater than 11 g/dL.

For all patients with CKD:

- When initiating or adjusting therapy, monitor Hgb levels at least weekly until stable, then at least monthly.
- Do not increase the dose more frequently than once every four weeks. Decreases in dose can occur more frequently. Avoid frequent dose adjustments.
- If hemoglobin levels rise rapidly (for example, more than one g/dL in any two-week period), reduce the dose of Mircera by 25 percent or more as needed to reduce rapid responses.

- For patients with inadequate response, if the Hgb has not increased by more than one g/dL after four weeks of therapy, increase the dose by 25 percent.
- For patients with inadequate response over a 12-week escalation period, increasing the Mircera dose further is not recommended. Use the lowest dose that will maintain a Hgb level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue Mircera if responsiveness does not improve.
- Administer Mircera either intravenously or subcutaneously in adult patients, and only intravenously in pediatric patients.

For adult patients with CKD on dialysis:

- Initiate Mircera treatment when hemoglobin is less than 10 g/dL.
- If the Hgb level approaches or exceeds 11 g/dL, reduce or interrupt the dose of Mircera.
- Starting dose of Mircera for anemia in adult CKD patients who are not currently treated with an ESA is 0.6 mcg/kg body weight administered as a single intravenous or subcutaneous injection every two weeks.
- Once the Hgb stabilizes, administer monthly using a dose that is twice that of the every-two-week dose and subsequently titrated as necessary.

For adult patients with CKD not on dialysis:

- Consider initiating Mircera treatment only when hemoglobin level is less than 10 g/dL and the following considerations apply:
  - The rate of Hgb decline indicates the likelihood of requiring a RBC transfusion, and
  - Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal.
- If the Hgb level is greater than 10 g/dL, reduce or interrupt the dose of Mircera, and use the lowest dose of Mircera sufficient to reduce the need for RBC transfusions.
- Starting dose of Mircera for anemia in adult CKD patients who are not currently treated with an ESA is 0.6 mcg/kg body weight administered as a single IV or SC injection once every two weeks.

- Once the Hgb stabilizes, Mircera may be administered monthly using a dose that is twice that of the every-two-week dose and subsequently titrated as necessary.

Initial approval is for six months (12 weeks of therapy).

Continuation of Therapy

- Patient continues to meet initial approval criteria,
- Hgb level is less than 11 g/dL and/or Hematocrit (Hct) is less than 33 percent,
- Patient was assessed for iron deficiency anemia and has adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20 percent,
- Documentation of positive response to therapy as evidenced by increase in Hgb of at least one g/dL after at least 12 weeks of therapy.

Reauthorization is for six months (12 weeks of therapy).

Age Limit

Must be five years of age or older for J0887 (for ESRD on dialysis) and 18 years or older for J0888 (for non-ESRD use).

Billing

HCPCS codes:

- J0887 (injection, epoetin beta, 1 mcg, [for ESRD on dialysis])

  One (1) unit of J0887 equals one (1) mcg of epoetin beta.
- J0888 (injection, epoetin beta, 1 mcg, [for non-ESRD use])

  One (1) unit of J0888 equals one (1) mcg of epoetin beta.

Billing Notes:

- Providers must bill with the appropriate code for the patient's diagnosis for approval.
- Claims billed for the treatment of anemia due to cancer chemotherapy or for use as a substitute for RBC transfusions in patients who require immediate correction of anemia, which can be billed with J0888, are not a covered benefit and will be denied.
- There are other codes for non-ESRD use that may be more appropriate for the patient's condition (for example, J0885 [Injection, epoetin alfa, (for non-esrd use), 1000 units]).

Suggested ICD-10-CM Codes

- For J0887 (end stage renal disease): N18.6
- For J0888 (non-ESRD diagnoses): D63.1, I12.9, I13.0, I13.10, N18.30 thru N18.5, N18.9.

‹‹Methylprednisolone acetate (DEPO-MEDROL)

Methylprednisolone is an intermediate-acting, synthetic glucocorticoid. Glucocorticoids, naturally occurring and synthetic, are adrenocortical steroids. Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt retaining properties, are used in replacement therapy in adrenocortical deficiency states. Their synthetic analogs are used primarily for their anti-inflammatory effects in disorders of many organ systems. Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune response to diverse stimuli.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J1010 (injection, methylprednisolone acetate, 1 mg).››

‹‹Methylprednisolone Sodium Succinate

In a tissue-specific manner, corticosteroids regulate gene expression subsequent to binding specific intracellular receptors and translocation into the nucleus. Corticosteroids exert a wide array of physiologic effects including modulation of carbohydrate, protein, and lipid metabolism and maintenance of fluid and electrolyte homeostasis. Moreover cardiovascular, immunologic, musculoskeletal, endocrine, and neurologic physiology are influenced by corticosteroids. Decreases inflammation by suppression of migration of polymorphonuclear leukocytes and reversal of increased capillary permeability.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2919, (injection, methylprednisolone sodium succinate, 5 mg).››

Metronidazole

After diffusing into the organism, interacts with DNA to cause a loss of helical DNA structure and strand breakage resulting in inhibition of protein synthesis and cell death in susceptible organisms.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J1836 (injection, metronidazole, 10 mg).

Prescribing Restriction(s)

Maximum billing unit(s) equals 4 g/400 units per day.

Micafungin

Micafungin is a semi-synthetic water-soluble lipopeptide of the echinocandin class of antifungal agents. It inhibits the synthesis of 1, 3 beta-D-glucan, an integral component of fungal cell wall synthesis. It exhibits fungicidal activity against Candida species and fungistatic activity against Aspergillus species.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Billing

HCPCS codes:

J2248 (injection, micafungin sodium, 1 mg).

J2247 (injection, micafungin sodium [par pharm] not therapeutically equivalent to J2248, 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 150 mg/150 units daily.

Maximum billing unit(s) equals 150 mg/150 units.

Midazolam (VERSED, NAYZILAM®)

Midazolam is a short-acting benzodiazepine central nervous system (CNS) depressant.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

J2250 (injection, midazolam hydrochloride, per 1 mg).

J2251 (injection, midazolam hydrochloride [wg critical care] not therapeutically equivalent to J2250, per 1 mg).

‹‹Mirikizumab (OMVOH)

Mirikizumab is a humanized IgG4 monoclonal antibody that selectively binds to the p19 subunit of human IL-23 cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is involved in mucosal inflammation and affects the differentiation, expansion, and survival of T cell subsets, and innate immune cell subsets, which represent sources of pro-inflammatory cytokines. Mirikizumab inhibits the release of pro-inflammatory cytokines and chemokines.

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 for an FDA-approved indication and dosage.
- Patient must be 18 years old.
- Must be prescribed by or in consultation with a gastroenterologist.
- Patient has been evaluated and, if applicable, treated for active or latent Tuberculosis infection prior to initiating treatment with mirikizumab-mrkz.››

‹‹Patient has baseline liver enzymes and bilirubin levels prior to treatment initiation.

- Patient's age-appropriate immunizations are current.
- Inadequate response, intolerance, or contraindication to at least one of the following: infliximab, adalimumab, golimumab, vedolizumab, tofacitinib or ustekinumab.

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response as evidenced by disease improvement or stabilization compared to baseline.
- Liver enzymes and bilirubin levels are being monitored for at least 24 weeks of treatment and routinely thereafter as needed.

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code C9168 (Injection, mirikizumab-mrkz, 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 300 mg / 300 units every four weeks.
Maximum billing unit(s) equals 300 mg / 300 units.››

Mitomycin

HCPCS code J7315 (mitomycin, ophthalmic, 0.2 mg) has a daily maximum of 0.2 mg.

Authorization

An approved TAR is required for reimbursement only when the dose exceeds 0.2 mg per day.

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 *Chemotherapy: Drugs E-O Policy* section of this manual for the use of mitoxantrone in malignant conditions.

Indications

For reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (for example, patients whose neurologic status is significantly abnormal between relapses).

Mitoxantrone is not indicated in the treatment of patients with primary progressive multiple sclerosis.

Dosage

The recommended dose is 12 mg/m^2 given as a short (approximately five to 15 minutes), intravenous infusion every three months.

The maximum dosage is 38 mg per day.

Billing

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

Mometasone Furoate Sinus Implant (Sinuva)

Mometasone furoate (Sinuva) sinus implant is a self-expanding, bioabsorbable, corticosteroid-eluting implant. Mometasone furoate is a corticosteroid demonstrating potent anti-inflammatory activity. The precise mechanism of corticosteroid action on inflammation is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (for example, mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (for example, histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation.

TAR Requirement

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

TAR Criteria

Sinuva is considered medically appropriate when all the following criteria are met:

- Must be FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Sinuva is prescribed and implanted by or in consultation with an otolaryngologist.
- Patient has undergone ethmoid sinus surgery.
- Patient has a diagnosis of recurrent nasal polyps and chronic sinusitis.
- Patient must have tried and failed inhaled nasal corticosteroids for at least three months at the maximum recommended dosage, unless intolerant to or has a contraindication to it.
- Patient does not have a known hypersensitivity to mometasone furoate or any ingredient in Sinuva sinus implant.

Initial approval is for 90 days.

Reauthorization

- For repeat implant placement, patient must have ethmoid sinus polyps grade greater than or equal to one on either side.
- One time repeat allowable after 90 days if patient meets criteria for repeat placement.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J7402 (mometasone furoate sinus implant [Sinuva],10 mcg).

Prescription Restrictions

Maximum billing units equals one implant equals1,350 mcg/135 units each nostril
Frequency of billing equals May repeat one time after 90 days. One repeat in a lifetime.

Morphine

Morphine is a full opioid agonist and is relatively selective for the mu-opioid receptor, although it can bind to other opioid receptors at higher doses. The principal therapeutic action of morphine is analgesia. Like all full opioid agonists, there is no ceiling effect for analgesia with morphine. Clinically, dosage is titrated to provide adequate analgesia and may be limited by adverse reactions, including respiratory and central nervous system (CNS) depression.

The precise mechanism of the analgesic action is unknown. However, specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and are thought to play a role in the analgesic effects of this drug.

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 (fresenius kabi brand only).

Billing

HCPCS codes:

J2270 (injection, morphine sulfate, up to 10 mg).

J2272 (injection, morphine sulfate [fresenius kabi] not therapeutically equivalent to J2270, up to 10 mg).

Moxifloxacin

Moxifloxacin is a member of the fluoroquinolone class of antibacterial agents. The bactericidal action of moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV required for bacterial DNA replication, transcription, repair, and recombination.

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 J2281 (injection, moxifloxacin [fresenius kabi] not therapeutically equivalent to J2280, 100 mg).

Prescribing Restriction(s)

Frequency of billing equals 400 mg/4 units every 24 hours.

Maximum billing unit(s) equals 400 mg/4 units.

Propel Sinus Implants

Billing

HCPCS code S1091 (stent, non-coronary, temporary, with delivery system [Propel])

- Effective April 1, 2021, use S1091 to bill Propel sinus implants (Propel, Propel Mini and Propel Contour).
- Providers must submit a TAR justifying medical necessity.
- Providers must include an invoice showing the acquisition cost of the product in addition to the product National Drug Code (NDC) for appropriate reimbursement.

Mycophenolate Mofetil

MPA exhibits a cytostatic and reversible effect on T and B lymphocytes. It is an inhibitor of type I and type II inosine monophosphate dehydrogenase (IMPDH) which inhibits *de novo* guanosine nucleotide synthesis and blocks DNA synthesis. MPA shifts transcriptional activities in human CD4+ T-lymphocytes by suppressing the Akt/mTOR and STAT5 pathways, causing the T-cells to become less responsive to antigenic stimulation. MPA enhances the expression of negative costimulators such as CD70, PD-1, CTLA-4, and transcription factor FoxP3 as well as decreasing the expression of positive costimulators CD27 and CD28. T and B lymphocytes are dependent on this pathway for proliferation. MPA helps in the production of cytokines from lymphocytes and monocytes such as GM-CSF, IFN-γ, IL-17, and TNF-α. MPA also prevents glycosylation of lymphocyte and monocyte glycoproteins involved in intercellular adhesion to endothelial cells and can inhibit leukocytes into sites of inflammation and graft rejection.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be three months of age or older.

Billing

HCPCS code J7519 (injection, mycophenolate mofetil, 10 mg).

Suggested ICD-10-CM Diagnosis Codes

T86, Z94

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.