Injections: Drugs I-M Policy

Page updated: September 2020

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:

Injections: Drugs A-D Policy

Injections: Drugs E-H Policy

Injections: Drugs N-R Policy

Injections: Drugs S-Z Policy

Injections: Hydration

Immunizations

Ibalizumab-uiyk

Ibalizumab-uiyk is a CD4-directed post-attachment HIV-1 inhibitor solution for intravenous (IV) administration.

Indications

Ibalizumab-uiyk, in combination with other antiretroviral agents, is used to treat human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multi-drug resistant HIV-1 infection failing their current antiretroviral regimen.

Age

18 years and older

Dosage

A single 2,000 mg IV loading dose is administered followed by a maintenance dose of 800 mg IV administered every two weeks thereafter.

Authorization

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

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

- The service is medically necessary for the treatment of multi-drug resistant HIV-1 infection in combination with other antiretroviral agent(s).
- The patient has a viral load ≥1,000 copies/mL.
- The patient has a history of receiving at least 6 months of antiretroviral treatment.
- The patient is receiving a failing antiretroviral treatment or has received a recently failed antiretroviral and is off therapy.
- Documentation of HIV-1 disease resistance to at least one antiretroviral medication from each of the following three classes of antiretroviral medications as measured by resistance testing:
  - Nucleoside reverse transcriptase inhibitors, and
  - Non-nucleoside reverse transcriptase inhibitors, and
  - Protease inhibitors.
- The physician's legible, complete, and signed treatment plan/order for ibalizumab-uiyk.

Required Codes

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

- B20 Human immunodeficiency virus [HIV] disease)

Billing

HCPCS code J1746 (injection, ibalizumab-uiyk, 10 mg)
One (1) unit of J1746 equals 10 mg of ibalizumab-uiyk

Ibandronate

Ibandronate sodium, 1 mg, (HCPCS J1740) is reimbursable for the treatment of women with post-menopausal osteoporosis.

Dosage

Dosing frequency is 3 mg every three months administered intravenously over 15 to 30 seconds by a health care provider. Ibandronate is contraindicated in patients with hypocalcemia or those who have a known hypersensitivity to ibandronate sodium.

Required Diagnosis Code

Restricted to ICD-10-CM diagnosis code M81.0.

Billing

Providers must submit the following documentation in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) on the claim or on an attachment:

- A diagnostic T score of -2.5 or more in women who have documented difficulty with the oral bisphosphonates dosing requirement, which includes an inability to sit upright for 30 to 60 minutes and/or difficulty in swallowing a pill; or,
- A diagnostic T score of -2.5 or more in women with documented esophagitis, gastritis, gastric or esophageal ulcers which prohibit the use of oral bisphosphonates.

Ibuprofen

The daily maximum dosage for HCPCS code J1741 (injection, ibuprofen, 100 mg) is 3,200 mg.

Authorization

For doses greater than 3,200 mg per day, an approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Idursulfase

For detailed billing policy information about idursulfase, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E-H Policy* manual section.

Imiglucerase

For detailed billing policy information about imiglucerase, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E-H Policy* manual section.

Imipenem, Cilastatin, and Relebactam (Recarbrio™)

Recarbrio is a combination of imipenem/cilastatin and relebactam. Imipenem is a penem antibacterial drug, cilastatin sodium is a renal dehydropeptidase inhibitor, and relebactam is a beta lactamase inhibitor. Cilastatin limits the renal metabolism of imipenem and does not have antibacterial activity. The bactericidal activity of imipenem results from binding to PBP 2 and PBP 1B in Enterobacteriaceae and Pseudomonas aeruginosa and the subsequent inhibition of penicillin binging proteins (PBPs). Inhibition of PBPs leads to the disruption of bacterial cell wall synthesis. Imipenem is stable in the presence of some beta lactamases. Relebactam has no intrinsic antibacterial activity. Relebactam protects imipenem from degradation by certain serine beta lactamases, such as Sulhydryl Variable (SHV), Temoneira (TEM), Cefotaximase-Munich (CTX-M) Enterobacter cloacae P99 (P99), Pseudomonas-derived cephalosporinase (PDC), and Klebsiella-pneumoniae carbapenemase (KPC).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Recarbrio is considered medically appropriate if all of the following criteria are met:

- Prescribed for FDA-approved indications and dosing regimens; and
- Patient must be 18 years of age or older; and
- Patient must have one of the following diagnosis
  - Complicated intra-abdominal infection (cIAI); or
  - Complicated urinary tract infection (cUTI), including pyelonephritis; and
- The prescriber must verify that limited or no alternative treatment options are available; and
- The prescriber to clinically document why the patient cannot use other clinically appropriate and cost-effective therapeutic equivalent alternatives, such as penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidine) in combination with metronidazole(s).

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0742 (injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg)

Prescribing Restriction(s)

Frequency of billing equals 1.25 gm/125 units every six hours for four to 14 days

Maximum billing units equals 1.25 gm/125 units

Immune Globulin

Immune globulin preparations contain highly purified (greater than 90 percent) polyvalent IgG. Immune globulin preparations are made from pooled human plasma from several thousand screened volunteer donors. ‹‹Cold alcohol fractionation is used to isolate the immunoglobulin.›› This is followed by further purification techniques including several specific treatments to inactivate or remove potentially present blood-borne pathogens. These include low pH treatment, solvent-detergent treatment, pasteurization and/or nanofiltration.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

TARs may be approved for any of the FDA-approved indications. In many instances, immune globulin is not considered first line therapy and may be used as second line therapy or in special circumstances. The TAR must not only state the diagnoses but also must contain sufficient clinical information to establish medical necessity.

Routes of Administration

Immune globulin may be administered intravenously, intramuscularly or subcutaneously. In most cases, products are designed for a specific route of administration, although some preparations designed for intravenous administration can also be given subcutaneously. Subcutaneous and intramuscular products are generally more concentrated than intravenous preparations.

Billing

Intravenous immune globulin injections:

Table of Intravenous Immune Globulin Injections HCPCS Codes and Descriptions

HCPCS Code	Description
J1554	Injection, immune globulin (asceniv), 500 mg
J1459	Injection, immune globulin, (privigen), non-lyophilized (e.g. liquid), 500 mg
J1556	Injection, immune globulin, (bivigam), 500 mg
J1557	Injection, immune globulin, (gammaplex), non-lyophilized (e.g. liquid), 500 mg
J1561	Injection, immune globulin, (gamunex/ c/Gammaked), non-lyophilized (e.g. liquid), 500 mg
J1566	Injection, immune globulin, lyophilized (e.g. powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (octagam), non-lyophilized (e.g. liquid), 500 mg
J1569	Injection, immune globulin, (gammagard liquid), non-lyophilized (e.g. liquid), 500 mg
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), non-lyophilized (e.g. liquid), 500 mg
‹‹J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg››
J1599	Injection, immune globulin, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg

Intramuscular or subcutaneous immune injections:

Table of Intramuscular or Subcutaneous Immune Injections HCPCS Codes and Descriptions

HCPCS Code	Description
J1460	Injection, gamma globulin, intramuscular 1 cc
‹‹J1551	Injection, immune globulin (cutaquig), 100 mg››
J1555	Injection, immune globulin (cuvitru), 100 mg
J1558	Injection, immune globulin (xembify), 100 mg
J1559	Injection, immune globulin, (hizentra), 100 mg
J1560	Injection, gamma globulin, intramuscular over 10 cc
J1562	Injection, immune globulin, (vivaglobin), 100 mg
J1575	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immunoglobulin

Providers must use the correct code when submitting claims or the claim will be denied.

‹‹Immune Globulin Subcutaneous (Human) 20 Percent and 16.5 Percent Solution (Cuvitru™, Xembify® and Cutaquig®)

Immune globulin subcutaneous (human), 20 percent solution (Cuvitru and Xembify) and 16.5 percent solution (Cutaquiq), supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. They also contain a spectrum of antibodies capable of interacting with and altering the activity of cells of the immune system as well as antibodies capable of reacting with cells such as erythrocytes. The mechanism of action in primary humoral immunodeficiency (PI) has not been fully elucidated; however adequate doses may restore abnormally low immune globulin G levels to the normal range and thus help in preventing infections.››

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 two years of age or older
- Patient has a confirmed diagnosis of primary humoral immunodeficiency (PI) requiring IgG replacement therapy due to hypogammaglobulinemia or agammaglobulinemia and diagnosis is defined by 1 or 2 below:
    1. Diagnosis is based on European Society for Immunodeficiencies (ESID) and Pan-American Group for Immunodeficiency
    2. Diagnosis is based on the following criteria and patient requires IgG therapy to treat the PIs (which include but are not limited to the following):

<u>Common Variable Immunodeficiency (CVID):</u>

Patient is over four years of age with <u>all</u> of the following:

- Recurrent bacterial infections of the ears, nasal sinuses, bronchi and lungs
- Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy)
- The patient’s pretreatment IgG level is less than 500 mg/dL or equal to or greater than two standard deviations (SD) below the mean for age
- Low levels of IgA and/or IgM (more than two SD below mean for age)
- Lack of functional antibody response to vaccines (for example, tetanus or diphtheria, MMR, hemophilus or Pneumovax)››

‹‹Chronic Granulomatous Disease (CGD):

Patient has abnormal Nitroblue Tetrazolium (NBT) reduction test or respiratory burst in activated neutrophils (less than 5 percent of control) with one of the following:

- Genetic testing showing mutation in gp91, p22, p47 or p67 phox
- Absent mRNA for one of the above genes by Northern blot analysis
- Maternal cousins, uncles or nephews with an abnormal NBT or respiratory burst
- Recurrent bacterial or fungal infections of lung, skin, lymph nodes, and liver, etc. (CGD-type infections include Staphylococcus aureus, Burkholderia cepacia complex, Serratia marcescens, Nocardia and Aspergillus)
- Formation of granulomata in tissues or organs
- Failure to thrive and hepatosplenomegaly or lymphadenopathy

DiGeorge syndrome:

Patient has reduced numbers of CD3+ T cells (less than 500/mm3) and two out of three of a-c below or d alone or e alone:

a. Genetic testing showing deletion of chromosome 22q11.2
b. Hypocalcemia of greater than 3 weeks' duration that requires therapy
c. Conotruncal cardiac defect (truncus arteriosus, tetrology of Fallot, interrupted aortic arch or aberrant right subclavian); or
d. Patient has reduced numbers of CD3+ T cells (less than 1500/mm3) and a deletion of chromosome 22q11.2; or
e. Patient has recurrent infections and classic features such as abnormal facial features, cardiac defect, hypoplastic thymus, hypocalcemia, and cleft palate

IgA Deficiency:

Patient is over four years of age with one of the following:

- Serum IgA of less than 7 mg/dl (0.07 g/L) but normal serum IgG and IgM and other causes of hypogammaglobulinemia have been excluded (Patient has a normal IgG antibody response to vaccination)
- Serum IgA at least two SD below normal for age but normal serum IgG and IgM, and other causes of hypogammaglobulinemia have been excluded (Patient has a normal IgG antibody response to vaccination)
- Frequent upper respiratory tract infections, persistent or recurrent infections, autoimmune disease and allergies››

‹‹IgG subclass deficiency:

Patient is seven years or older with all of the following:

- Recurrent/severe ear and/or sinus infections
- Measurement of IgG subclass level showing deficiency (based on lab and age) or equal to or greater than two SD below the mean for age. Repeated at least once in separate sample. Normal levels of IgM and IgA
- Poor response to some vaccines (for example, Pneumovax)

Severe Combined Immunodeficiency (SCID):

Patient has at least one of the following:

- Molecular or genetic confirmation of mutation in the cytokine common gamma chain (γc) or in one of these genes; JAK3, RAG1 or RAG2, IL-7Rα
- ADA activity of less than two percent of control or mutations in both alleles of ADA
- Autologous CD3+ T cells less than 300 cells/microL in typical SCID and 300 to less than 1500 cells/microL in leaky SCID
- Detection of T-cells of maternal origin with normal lymphocyte count
- Serious or life-threatening infections, especially viral infections, which may result in pneumonia and chronic diarrhea, failure to thrive
- Absent or extremely low T cell mitogen response
- Very low levels of IgA and IgM; absent to elevated IgE
- Positive family history of SCID or positive SCID newborn screening test
- Pretreatment IgG level less than 200 mg/dL

Wiskott-Aldrich Syndrome (WAS):

Patient is male with congenital thrombocytopenia (less than 70,000 platelets/mm3), small platelets, and at least one of the following:

- Genetic testing showing mutation of the WAS gene
- Absent WAS messenger RNA (mRNA) on Northern blot analysis of lymphocytes
- Absence of WAS protein (WASP) in lymphocytes
- Maternal male cousins, uncles, or nephews with small platelets and thrombocytopenia››

- ‹‹Eczema (localized or generalized)
- Unusual bleeding and bruises, congenital or early onset thrombocytopenia, and small platelet size
- Defective antibody responses to some vaccine antigens (for example, Pheumovax)
- Recurrent bacterial or viral infections
- Elevated IgA and IgE, low to normal IgG and IgM levels
- Autoimmune diseases, lymphoma, leukemia, or brain tumor

X-linked agammaglobulinemia (XLA; Bruton's Agammaglobulinemia or Congenital Agammaglobulinemia):

Male patient with less than 2 percent CD19+ B cells and at least one of the following:

- Genetic testing with mutation in Bruton's Tyrosine Kinase (BTK)
- Absent BTK mRNA on Northern blot analysis of neutrophils or monocytes
- Absent BTK protein in monocytes or platelets
- Maternal cousins, uncles, or nephews with less than 2% CD19+ B cells
- Recurrent or severe bacterial infections, especially with small or absent tonsils and lymph nodes
- Onset of recurrent bacterial infections in the first five years of life, serum IgG, IgM, and IgA more than two SD below normal for age, absent isohemagglutinins and /or poor response to vaccines, and other causes of hypogammaglobulinemia have been excluded

X-linked hyper IgM syndrome (XHIM):

Patient is male and has a serum IgG concentration at least two SD below normal for age and one of the following:

- Genetic testing with a mutation in the CD40L gene
- Patient's maternal cousins, uncles, or nephews have confirmed diagnosis of XHIM.
- One or more of the following infections or complications:
  - Recurrent bacterial infections in the first five years of life
  - Pneumocystis carinii infection in the first year of life
  - Neutropenia
  - Cryptosporidium-related diarrhea
  - Sclerosing cholangitis
  - Parvovirus-induced aplastic anemia››

- ‹‹Absent CD40 ligand cell surface staining on activated CD41 T cells as assessed by binding to soluble CD40 or by binding of monoclonal antibody to CD40 ligand.
- Serum concentration of IgG is less than 200 mg/dL; IgM may be low, normal or elevated.

Initial authorization is for 12 months

Continued therapy:

- Patient continues to meet initial coverage criteria.
- Patient has experienced positive clinical response as evidenced by at least one of the following:
  - Patient has a decrease in the frequency of infections
  - Patient has a decrease in the severity of infections
  - Patient previously received intravenous immune globulin or is continuing therapy with subcutaneous immune globulin

Reauthorization is for 12 months››

Age Limits

Must be two years of age or older

Billing

‹‹HCPCS code J1551 (injection, immune globulin (cutaquig), 100 mg)››

HCPCS code J1555 (injection, immune globulin (cuvitru), 100 mg)

HCPCS code J1558 (injection, immune globulin (xembify), 100 mg)

‹‹Inclisiran (Leqvio®)

Inclisiran is a double-stranded small interfering ribonucleic acid (siRNA), conjugated on the sense strand with triantennary N-Acetylgalactosamine (GalNAc) to facilitate uptake by hepatocytes. In hepatocytes, inclisiran utilizes the RNA interference mechanism and directs catalytic breakdown of mRNA for proprotein convertase subtilisin/kexin type 9 (PCSK9). This increases LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation.

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 a cardiologist, endocrinologist, a lipid specialist or other specialist with expertise in treating heterozygous familial hypercholesterolemia (HeFH)
- Patient has a diagnosis of HeFH and elevated LDL-C; OR a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or ASCVD-Risk Equivalents and elevated LDL-C

Diagnosis of HeFH is confirmed by at least one of the following:

- Genetic testing showing mutations of pathogenic variants of the low-density lipoprotein receptor (LDL-R) gene, or pathogenic variants of the apolipoprotein (ApoB) gene, mutations in (PCSK9) or homozygous mutations in the LDL-R adaptor protein-1
- A first-degree relative with familial hypercholesterolemia, elevated cholesterol or early heart disease that may indicate familial hypercholesterolemia››

  - ‹‹A low-density lipoprotein-cholesterol (LDL-C) level of equal to or greater than 190 mg/dL, or lower with strong family histories and/or physical findings such as xanthomas, xanthelasmas (cholesterol deposits in the eyelids or skin) or corneal arcus
  - A Dutch Lipid Clinic Network Criteria score of six or more
  - A diagnosis of a “definite” or “probable” FH per the Simon Broome FH diagnostic criteria››

Diagnosis of ASCVD or ASCVD-Risk Equivalents based on a history of ASCVD (coronary heart disease [CHD], cardiovascular disease [CVD], or peripheral arterial disease [PAD]) as shown by at least one of the following:

  - Angina (stable or unstable)
  - Prior myocardial infarction or acute coronary syndrome; or
  - History of stroke or transient ischemic attack; or
  - Peripheral artery disease
  - Coronary or other arterial revasculrization
  - ASCVD-R-risk equivalents such as DM, heterozygous familial hypercholesterolaemia, etc.

- Patient has ASCVD and a serum LDL-C equal to or greater than 70 mg/dL at baseline or ASCVD-risk equivalent and a serum LDL-C equal to or greater than100 mg/dL at baseline
- Patient is on statin and is receiving high dose (atorvastatin 80 mg or rosuvastatin 40 mg) or a maximally tolerated dose (defined as the maximum dose of statin that can be taken on a regular basis without intolerable adverse events) with or without ezetimibe or
  - Patient is not on statin, and has a documentation of intolerance to all doses of at least two different statins; OR intolerance to only one statin with a documented history of rhabdomyolysis attributed to that statin
- If patient is on statin and/or ezetimibe), patient should be on a stable dose for equal to or greater 30 days prior to treatment initiation
- Patient must have tried and failed, is intolerant to or has a clinical contraindication to a PCSK9 inhibitor [e.g., Repatha (evolocumab) or Praluent (alirocumab)]
- Patient will not take Leqvio concurrently with other PCSK9 inhibitor [e.g., Repatha (evolocumab) or Praluent (alirocumab)]

Initial approval is for six months››

‹‹Continuation of therapy

- Patient continues to meet initial coverage criteria
- Positive clinical response as evidenced by reduction of LDL-C from baseline

Reauthorization is for 12 months

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J1306 (injection, inclisiran, 1 mg)

Required ICD-10 Diagnosis Codes

E78.00, E78.01, E78.2, E78.4, E78.49, E78.5, E78.9.

Prescribing Restriction(s)

Frequency of billing equals 284 mg/ 284 units initially, again at three months, and then every six months.

Maximum billing unit(s) equals 284 mg/284 units››

IncobotulinumtoxinA

For more detailed billing policy information about incobotulinumtoxinA, refer to the "Botulinum Toxins A and B" topic in the *Injections: Drugs A-D Policy* manual section.

Inebilizumab-cdon (Uplizna)

The precise mechanism by which inebilizumab-cdon exerts its therapeutic effects in Neuromyelitis Optica Spectrum Disorder (NMOSD) is unknown, but is presumed to involve binding to CD19, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, inebilizumab-cdon results in antibody-dependent cellular cytolysis.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Inebilizumab-cdon is considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with an immunologist, hematologist, or other physician specialized in the treatment of the disease
- Patient must have a diagnosis of NMOSD
- All vaccines must be administered at least four weeks prior to inebilizumab treatment initiation
- Patient has been screened for hepatitis B virus (HBsAg and anti-HBc measurements) and active tuberculosis prior to treatment initiation
- Patient is anti-aquaporin-4 (AQP4) antibody seropositive
- Patient has a history of one or more relapses that required rescue therapy during the previous 12 months or two or more relapses requiring rescue therapy during the previous 24 months
- Patient will not receive inebilizumab concurrently with other biologics used to treat NMOSD (e.g., eculizumab (Soliris), or satralizumab (Enspryng)).

Initial authorization is for six months

Continued therapy:

- Patient continues to meet initial approval criteria
- The patient had clinical benefit evidenced by any one of the following:
  - Reduction in frequency and number of attacks
  - Disease stabilization while on inebilizumab treatment
  - Reduction in number of NMOSD-related hospitalizations
- Absence of unacceptable toxicity from the drug such as serious or life-threatening infusion related reactions, serious infections including Progressive Multifocal Leukoencephalopathy (PML), hypogammaglobulinemia necessitating intravenous Immunoglobulin (IVIG) or leading to recurrent infections

Reauthorization is for 12 months

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J1823 (injection, inebilizumab-cdon, 1 mg)

Suggested ICD-10-CM Codes

G36.0

Prescribing Restrictions

Frequency of billing equal to 300 mg/300 units initially, 300 mg/ 300 units after two weeks, then beginning six months after initial dose, 300 mg/300 units every six months.

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

Infliximab

Infliximab (Remicade) is a tumor necrosis factor (TNF) inhibitor. It binds and inhibits TNF alpha, reducing inflammation and altering immune response. Infliximab biosimilar products include Avsola™ (infliximab-axxq), Inflectra® (infliximab-dyyb), Ixifi™ (infliximab-qbtx) and Renflexis® (infliximab-abda).

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 for FDA-approved indications and dosing regimens
- Patient must be six years of age or older

- The service is medically necessary
- Alternative, conventional therapy has been tried or considered, has failed, or is contra-indicated
- Patient was screened and showed absence of latent (untreated) tuberculosis prior to therapy initiation
- Patient has been screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
- Patient has no active infection
- A physician's legible, complete, and signed treatment plan/order for infliximab or an infliximab biosimilar

Initial authorization is for six months

Reauthorization:

This may be granted if:

- Patient continues to meet initial coverage criteria
- Patient has shown a positive clinical response such as symptoms improvement or lack of disease progression

Reauthorization will be for 12 months

Age Limits

Must be six years of age or older

Billing

HCPCS code J1745 (injection, infliximab, excludes biosimilar, 10 mg)
One (1) unit of J1745 equal to 10 mg of infliximab

HCPCS code Q5103 (injection, infliximab-dyyb, biosimilar, [inflectra], 10 mg)
One (1) unit of Q5103 equal to 10 mg of infliximab-dyyb

HCPCS code Q5104 (injection, infliximab-abda, biosimilar, [renflexis], 10 mg)
One (1) unit of Q5104 equal to 10 mg of infliximab-abda

HCPCS code Q5109 (injection, infliximab-qbtx, biosimilar, [ixifi], 10 mg)
One (1) unit of Q5109 equal to 10 mg of infliximab-qbtx

HCPCS code Q5121 (injection, infliximab-axxq, biosimilar, [avsola], 10 mg)
One (1) unit of Q5121 equal to 10 mg of infliximab-axxq

‹‹Insulin aspart (Fiasp®)

Insulin aspart is a rapid-acting human insulin analog. Receptor-bound insulin lowers blood glucose by facilitating cellular uptake of glucose into skeletal muscle and adipose tissue and by inhibiting the output of glucose from the liver. Insulin inhibits lipolysis in the adipocyte, inhibits proteolysis, and enhances protein synthesis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

- J1811 (Insulin [Fiasp] for administration through DME [i.e., insulin pump] per 50 units)
- J1812 (Insulin [Fiasp], per 5 units)

Insulin lispro-aabc (Lyumjev™)

Insulin lispro is a rapid-acting human insulin analog. Receptor-bound insulin lowers glucose by stimulating peripheral glucose uptake by skeletal muscle and fat and by inhibiting hepatic glucose production. Insulins inhibit lipolysis and proteolysis and enhance protein synthesis.

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:

- Being used for an FDA-approved indication.
- Patient-specific, clinically significant reason why the patient cannot use other clinically appropriate and cost-effective therapeutic equivalent alternatives such as insulin lispro (Humalog), insulin aspart (Novolog, Fiasp)

Authorization is for 12 months.

Billing

HCPCS codes:

- J1813 (Insulin [Lyumjev] for administration through DME [i.e., insulin pump] per 50 units)
- J1814 (Insulin [Lyumjev] per 5 units)››

Iron Sucrose

Iron sucrose injection is an iron replacement solution for intravenous (IV) administration.

Indications

Iron sucrose is indicated in the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD).

Age

Two years and older

Dosage

The recommended dose and frequency varies depending on the patient's age, condition, and response to therapy. The maximum daily dose is 400 mg.

Authorization

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

Required Codes

One ICD-10-CM code from each of the following code ranges is required for reimbursement:

- D50.0, D50.1, D50.8 or D50.9 (Iron deficiency anemia)
- N18.1-N18.9 (Chronic kidney disease (CKD))

Billing

HCPCS code J1756 (injection, iron sucrose, 1 mg)
One unit of J1756 equal to 1 mg of iron sucrose

Labetalol (Trandate)

Labetalol hydrochloride is an adrenergic receptor blocking agent that has both selective alpha$_1$- and nonselective beta-adrenergic receptor blocking actions.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

- J1920 (Injection, labetalol hydrochloride, 5 mg)
- ‹‹J1921 (Injection, labetalol hydrochloride (Hikma) not therapeutically equivalent to J1920, 5 mg)››

Prescribing Restriction

Maximum billing unit(s) equals 300 mg/60 units

Lacosamide

Lacosamide injection is indicated for intravenous use as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. The precise mechanism by which lacosamide exerts its antiepileptic effects in humans remains to be fully elucidated.

Dosage

The initial dose should be 100 mg intravenously in two divided doses and can be increased at weekly intervals by 100 mg per day in two divided doses up to the recommended maintenance dose of 200 to 400 mg per day.

The maximum daily dose is 400 mg.

Billing

HCPCS code C9254 (injection, lacosamide, 1 mg)

Lanadelumab-flyo (Takhzyro)

Lanadelumab-flyo is a human monoclonal antibody that inhibits the proteolytic activity of kallikrein to reduce the generation of bradykinin in patients with hereditary angioedema (HAE).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- FDA-approved indications and dosages
- Patient must be 12 years of age or older
- Diagnosis of HAE confirmed by one of the following two options:
  - Low C4 level and low C1-INH antigenic or functional level
  - Normal C4 level and normal C1-INH level, and both of the following:
    - History of recurrent angioedema
    - Family history of angioedema
- Patient is using medication for prophylaxis against acute attacks of hereditary angioedema for one of the following two options:
  - Short-term prophylaxis prior to surgery, dental procedures or intubation

  - Long-term prophylaxis and the individual has failed, or is intolerant to, or has a contraindication (such as pregnant or breastfeeding individuals) to 17 alpha-alkylated androgens (for example, danazol) or antifibrinolytic agents (for example, aminocaproic acid)

- Patient must not use Takhzyro with other FDA-approved products for long-term prophylaxis of HAE attaches such as Cinryze or Haegarda.
- Dose must not exceed 300 mg every two weeks.

Age Limits

Must be 12 years of age or older

Billing

HCPCS code J0593 (injection, lanadelumab-flyo, 1 mg)

Prescribing Restrictions

Frequency of billing equal to Every two weeks

Maximum billing units equal to 300 mg which equals 300 units

Lanreotide (Somatuline® Depot)

Lanreotide is a synthetic octapeptide analogue of natural somatostatin, which is a peptide inhibitor of multiple endocrine, neuroendocrine and exocrine mechanisms. Lanreotide displays a greater affinity for somatostatin type 2 (SSTR2) and type 5 (SSTR5) receptors found in pituitary gland, pancreas and growth hormone (GH) secreting neoplasms of pituitary gland and a lesser affinity for somatostatin receptors 1, 3 and 4. Lanreotide reduces GH secretion and also reduces the levels of insulin-like growth factor 1

Indications

All FDA-approved indications

Dosage

All FDA-approved dosages.

Authorization

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

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J1930 (injection, lanreotide, 1 mg)

Prescribing Restrictions

Frequency of billing equals 120 mg/120 units every 4 weeks.

Maximum billing unit(s) equals 120 mg/120 units

Laronidase

For detailed billing policy information about laronidase, refer to the "Enzyme Replacement Drugs" topic in the *Injections: Drugs E-H Policy* section of the manual.

‹‹Lecanemab-irmb (LEQEMBI®)

Lecanemab-irmb is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. LEQEMBI reduces amyloid beta plaques.

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.
- Patient must be 50 to 90 years old.
- Must be prescribed by or in consultation with a neurologist, geriatrician or psychiatrist.
- Patient must have a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild AD dementia and must have all of the following:
  - A global Clinical Dementia Rating (CDR) score of 0.5 or 1.0.››

  - ‹‹Memory Box score of 0.5 or greater.
  - Positive amyloid pathology by either visual read of PET or CSF assessment.
  - Mini-Mental State Examination (MMSE) score of 22 or more.
  - Objective evidence of cognitive impairment at screening.
- Patient does not have any of the following:
  - Any neurological condition (other than Alzheimer's disease) which may be contributing to cognitive impairment.
  - History of transient ischemic attacks, stroke, or seizures within the prior 12 months.
  - Evidence of clinically significant lesions that could indicate a dementia diagnosis other than Alzheimer's disease on brain MRI.
  - Bleeding disorder that is not under control.
- Patient does not have baseline Brain MRI (within the past year) that shows evidence of any of the following: more than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter), a single macrohemorrhage greater than 10 mm at greatest diameter, an area of superficial siderosis, vasogenic edema, cerebral contusion, encephalomalacia, aneurysms, vascular malformations, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease or space occupying lesions or brain tumors
- Patient is not using anticoagulants or antiplatelets (except for aspirin at a prophylaxis dose or less).
- Patients receiving cholinesterase inhibitors or memantine or both must be on stable dose for at least 12 weeks.
- Leqembi will not be used in combination with any other amyloid beta-directed antibodies (for example, aducanumab [Aduhelm]).
- Patient must have an MRI at baseline and at 5th, 7th and 14th infusions to monitor for amyloid- related imaging abnormalities (ARIA).
  - Patients should be evaluated for brain hemorrhage, bleeding disorders, or cerebral abnormalities to assess potential risk for ARIA.

Initial approval is for 12 months.

<u>Continued therapy:</u>

- Patient has shown clinical benefit as evidenced by at least one of the following or shown by other standard assessment scales:
  - A reduction in amyloid beta plaque from baseline in PET imaging of brain.››

  - ‹‹An improvement from baseline in Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB) score.
  - An improvement from baseline in MMSE score.
  - Change from baseline in Alzheimer Disease Assessment Scale - Cognitive Subscale 14 (ADAS-cog14)
- Patient does not have unacceptable toxicity such as severe infusion-related reactions, amyloid related imaging abnormalities-edema (ARIA-E), amyloid related imaging abnormality hemorrhage (ARIA-H), angioedema (swelling) and anaphylaxis (allergic reaction) etc.

Reauthorization is for 12 months.

Age Limits

Must be 50 to 90 years of age.

Billing

HCPCS code: J0174, Injection, lecanemab-irmb, 1 mg

Required ICD-10-CM Diagnosis Codes

Primary diagnosis: G30.0, G30.1, G30.8, G30.9, G31.84

Secondary diagnosis: F03.90, F03.91.

Guidance for Dually Eligible/Medi-Medi Enrollees

CMS's 2023 Coverage Criteria:

Leqembi is covered under Medicare Part B. Medi-Cal is obligated to pay the Coinsurance and/or Deductibles. On April 7, 2022, CMS issued a National Coverage Determination (NCD) that covers monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease approved by the Food and Drug Administration (FDA). As of July 6, 2023, Medicare more broadly covers Leqembi (lecanemab-irmb) under this NCD.

The FDA gave traditional approval for Leqembi for treatment in July 2023. Medicare covers the drugs with traditional FDA approval in this class when a prescribing clinician or their staff decides the Medicare coverage criteria is met and also submits information to help answer treatment questions in a qualifying study. Providers can participate in the CMS National Patient Registry (or another CMS-approved study) to get Medicare payment for treating their patients with Leqembi. Additional information can be found in the Provider Fact Sheet for Registry through the Alzheimer's CED Registry Resources.››

‹‹To receive Medicare coverage, individuals will need to:

1. Be enrolled in Medicare,
2. Be diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, with documented evidence of beta-amyloid plaque on the brain, and
3. Have a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

Clinicians participating in the registry will only need to complete a short, easy-to-use data submission. Individuals with Medicare should speak to their physician about whether this drug is right for them. See Registry Resources for additional information.››

Lefamulin Injection (Xenleta)

Lefamulin is a semi-synthetic antibacterial agent. Lefamulin is a pleuromutilin that inhibits bacterial protein synthesis through interactions (hydrogen bond, hydrophobic interactions, and Van der Waals forces) with the A- and P- sites of the peptidyl transferase center in the domain V of the 23s ribosomal RNA of the 50S subunit. The binding pocket of the bacterial ribosome closes around the mutilin core for an induced fit that prevents correct positioning of transfer RNA.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

TAR approval requires clinical documentation to show the following:

- For FDA-approved indications and treatment regimens and
- Must be 18 years of age or older and
- Must verify negative pregnancy status in females of child-bearing age and
- Must establish diagnosis; microbiologic Gram stain and culture of sputum for Community-acquired Pneumonia (CAP) and

- Must show justification for failure to use formulary alternatives such as macrolides, fluoroquinolones, or beta-lactam antibiotics, such as allergy or intolerance.

Documentation of recent hospitalization and parenteral antibiotics and/or locally validated risk factors for MRSA may also satisfy TAR requirements.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0691 (injection, lefamulin, 1 mg)

Prescribing Restrictions

Frequency of billing equal to 150 mg/150 units every 12 hours for five to seven days

Maximum billing units equal to 150 mg/150 units

Lenacapavir (Sunlenca®)

Sunlenca is an HIV-1 antiretroviral agent. It is a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (p24) subunits in hexamers. Surface plasmon resonance sensorgrams showed dose-dependent and saturable binding of lenacapavir to cross-linked wild-type capsid hexamer with an equilibrium binding constant (KD) of 1.4 nM. Lenacapavir inhibits HIV-1 replication by interfering with multiple essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA (by blocking nuclear import proteins binding to capsid), virus assembly and release (by interfering with Gag/Gag-Pol functioning, reducing production of capsid protein subunits), and capsid core formation (by disrupting the rate of capsid subunit association, leading to malformed capsids).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code: J1961 (Injection, lenacapavir, 1 mg)

Required ICD-10-CM Diagnosis Code

B20

Prescribing Restriction(s)

Frequency of billing equals 927 mg/927 units every 24 weeks from the date of previous injection

Maximum billing unit(s) equals 927 mg/927 units

Leuprolide (Lupron Depot/Lupron Depot-Ped/Lupron Depot-3 month)

Leuprolide acetate, a gonadotropin releasing hormone (GnRH) agonist, acts as a potent inhibitor of gonadotropin secretion when given continuously in therapeutic doses. Animal and human studies indicate that after an initial stimulation, chronic administration of leuprolide acetate results in suppression of testicular and ovarian steroidogenesis.

Refer to “Leuprolide Acetate Depot Suspension” in the *Chemotherapy: Drugs E-O Policy* section of the appropriate Part 2 manual for information on the use of leuprolide in malignant disease.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS Code: J1950 (Injection, leuprolide acetate [for depot suspension], per 3.75 mg)

Required ICD-10-CM Diagnosis Codes

- D25.0 thru D25.9
- E22.8
- F64.0 thru F64.9
- N80.0 thru N80.9
- Z87.890

Prescribing Restrictions

Frequency of billing is once every 30 days

Leuprolide Acetate (Fensolvi®)

Leuprolide acetate, a gonadotropin releasing hormone (GnRH) agonist, acts as a potent inhibitor of gonadotropin secretion (LH and follicle stimulating hormone [FSH]) when given continuously in therapeutic doses. Following an initial stimulation of GnRH receptors, chronic administration of leuprolide acetate results in downregulation of GnRH receptors, reduction in release of Luteinizing Hormone (LH), FSH and consequent suppression of ovarian and testicular production of estradiol and testosterone respectively. This inhibitory effect is reversible upon discontinuation of drug therapy.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be 2 to 12 years of age.

Billing

HCPCS code J1951 (injection, leuprolide acetate for depot suspension [Fensolvi], 0.25 mg)

Suggested ICD-10 Diagnosis Codes

E22.8

Prescribing Restriction (s)

Frequency of billing is 45 mg/180 units every six months

Maximum billing unit(s) is 45 mg/180 units

Levetiracetam

Levetiracetam, 10 mg (HCPCS code J1953) has a maximum daily dose of 3,000 mg. Claims billed for quantities exceeding the daily limitation require appropriate documentation for payment.

Levoleucovorin (Khapzory)

Levoleucovorin counteracts the toxic (and therapeutic) effects of folic acid antagonists (for example, methotrexate) which act by inhibiting dihydrofolate reductase. Levoleucovirin is the levo isomeric and pharmacologic active form of leucovorin (levoleucovorin does not require reduction by dihydrofolate reductase). A reduced derivative of folic acid, leucovorin supplies the necessary cofactor blocked by methotrexate. Leucovorin enhances the activity (and toxicity) of fluorouracil by stabilizing the bindings of 5-fluoro-2'-deoxyuridine-5'-monophosphate (FdUMP; a fluorouracil metabolite) to thymidylate synthetase resulting in inhibition of this enzyme.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 6 years of age or older

Billing

HCPCS code J0642 (injection, levoleucovorin [Khapzory], 0.5 mg)

Linezold (Hospira)

Linezolid is a synthetic antibacterial agent of the oxazolidinone class, which has clinical utility in the treatment of infections caused by aerobic Gram-positive bacteria. The in vitro spectrum of activity of linezolid also includes certain Gram-negative bacteria and anaerobic bacteria. Linezolid binds to a site on the bacterial 23S ribosomal RNA of the 50S subunit and prevents the formation of a functional 70S initiation complex, which is essential for bacterial reproduction. The results of time-kill studies have shown linezolid to be bacteriostatic against enterococci and staphylococci. For streptococci, linezolid was found to be bactericidal for the majority of isolates.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2021 (injection, linezolid [hospira] not therapeutically equivalent to J2020, 200 mg).

Prescribing Restriction(s)

Frequency of billing equals 1200 mg/ 6 units per 24 hours.

Maximum billing unit(s) equals1200 mg/ 6 units.

Linezolid (Zyvox®)

Refer to the *Non-Injectable Drugs* section in this manual for more information.

Lumasiran (Oxlumo)

Lumasiran reduces levels of glycolate oxidase (GO) enzyme by targeting the hydroxyacid oxidase 1 (HAO1) messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference. Decreased GO enzyme levels reduce the amount of available glyoxylate, a substrate for oxalate production. As the GO enzyme is upstream of the deficient alanine: glyoxylate aminotransferase (AGT) enzyme that causes PH1, the mechanism of action of lumasiran is independent of the underlying AGXT gene mutation.

OXLUMO is not expected to be effective in primary hyperoxaluria type 2 (PH2) or type 3 (PH3) because its mechanism of action does not affect the metabolic pathways causing hyperoxaluria in PH2 and PH3.

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 for FDA-approved indications and dosages
- Must be prescribed by, or in consultation with, a nephrologist, endocrinologist, or other healthcare provider who is specialized in treating primary hyperoxaluria type 1 (PH1)
- Patient has a diagnosis of PH1 confirmed with one of the following:
  - Genetic testing confirmation of mutation of Alanine glyoxylate aminotransferase (AGXT)
  - Liver biopsy demonstrating decreased or absent activity of AGT for type 1 disease; and
- Patient has at least one of the following:
  - Elevated urinary oxalate excretion persistently greater than 0.7 mmol/1.73 m2/day or above the upper limit of normal (ULN) for age
  - Urinary oxalate-to-creatinine ratio greater than ULN for age in two of three single-void collections
  - Elevated urinary glycolic acid (glycolate) concentration

- Patient has tried and failed at least three months of pyridoxine (vitamin B6) at up to the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
- Patient has not had a kidney or liver transplant
- Patient does not have a history of extrarenal systemic oxalosis

Initial approval is for six months

Reauthorization

- Patient continues to meet the initial approval criteria
- Patient has experienced clinical benefit as evidenced by reduction in signs and symptoms of PH1 with lumasiran treatment
- Patient has shown improvement or normalization of laboratory values such as urinary oxalate excretion from baseline, or the percent change in spot urinary oxalate-to-creatinine ratio from baseline

Reauthorization is for 12 months

Billing

HCPCS code J0224 (injection, lumasiran, 0.5 mg)

Required ICD-10 Diagnosis Codes

E72.53

Prescribing Restriction(s)

Frequency of billing equals every 28 days

The recommended dose is based on body weight.

Recommended Dose Based on Body Weight Table

Body Weight	**Loading Dose**	**Maintenance Dose (begin one month after the last loading dose)**
Less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly)
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly)

Luspatercept-aamt (Reblozyl®)

Luspatercept-aamt is an erythroid maturation agent. It is a recombinant fusion protein that binds several endogenous TGF-β superfamily ligands, thereby diminishing Smad2/3 signaling. Luspatercept-aamt promoted erythroid maturation through differentiation of late-stage erythroid precursors (normoblasts) in mice. In a model of β-thalassemia, luspatercept-aamt decreased abnormally elevated Smad2/3 signaling and improved hematology parameters associated with ineffective erythropoiesis in mice.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Reblozyl 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
- Reblozyl must be prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and treatment of β-thalassemia.
- Patient has a clinically documented diagnosis of β-thalassemia or Hemoglobin E/β-thalassemia. (β-thalassemia with mutation and/or multiplication of alpha globin is allowed)
- Patient is regularly transfused, defined as: 6-20 Red Blood Cell (RBC) units in the 24 weeks prior and no transfusion-free period for equal to or greater than 35 days during that period
- Patient does not have a diagnosis of Hemoglobin S/β-thalassemia or alpha (α)-thalassemia (for example, Hemoglobin H)
- Patient is not pregnant or breastfeeding

- Patient must not have any of the following conditions:
  - Active hepatitis C (HCV) infection
  - Active infectious hepatis B (HBV) as demonstrated by a positive HCV-RNA test of sufficient sensitivity
  - Known human immunodeficiency virus (HIV) that is not controlled by antiretroviral (ART) therapy
  - Recent deep vein thrombosis or stroke requiring medical intervention less than or equal to 24 weeks prior
  - Major organ damage as evidenced by any of the following:
    - ❖ Liver disease with an ALT greater than 3x the ULN or history of evidence of cirrhosis
    - ❖ Heart disease, heart failure NYHA classification three or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within six months of treatment
    - ❖ Lung disease, including pulmonary fibrosis or pulmonary hypertension which are clinically significant, that is, equal to or greater than Grade 3
    - ❖ Renal insufficiency such as creatinine clearance less than 60 mL/min

Initial authorization will be for six months.

Continuation of therapy:

- Patient continues to meet the initial coverage criteria
- Patient has experienced a clinically significant reduction in transfusion burden from baseline
- Patient has an absence of unacceptable toxicity from the drug such as severe thromboemobolic events or hypertension

Reauthorization will be for 12 months

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0896 (injection, luspatercept-aamt, 0.25 mg)

Suggested ICD-10 Diagnosis Codes

D46.1, D46.4, D46.9, D46.A, D46.B, D46.Z, D56.1, D56.5

Prescribing Restriction(s)

Frequency of billing equal to 1.25 mg/kg every three weeks

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 18years 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 Limits

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 2 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 1 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

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

18 years 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 J9070). 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 (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 5 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 4 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 Limits

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.

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).

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 1 on either side
- One time repeat allowable after 90 days if patient meets criteria for repeat placement

Age Limits

Must be 18 years of age or older

Billing

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

Prescription Restrictions

Maximum billing units equals1 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 Limits

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 Limits

Must be 3 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.
‡	References: 1) The 2014 ERS/ATS (European Respiratory Society/ American Thoracic Society) Task Force Report Guidelines on Severe Asthma and 2) The 2007 NAEPP (National Asthma Education and Prevention Program) Expert Panel Report 3, U.S. Department of Health and Human Services National Institutes of Health.