Injections: Drugs I Policy

Page updated: March 2024

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 J-L Policy*
- *Injections: Drugs M 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*

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 Limit

Must be 18 years of age 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 equal to or greater than 1,000 copies/mL.
- The patient has a history of receiving at least six 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 Policy* manual section.

Imiglucerase

For detailed billing policy information about imiglucerase, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E 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 Limit

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
J1459	Injection, immune globulin, (privigen), non-lyophilized (e.g., liquid), 500 mg
‹‹J1552	Injection, immune globulin (alyglo), 500 mg››
J1554	Injection, immune globulin (asceniv), 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 five 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 three 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 two 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 two percent 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 Limit

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 Limit

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 B Policy* manual section.

‹‹Indigotindisulfonate (BLUDIGO®)

Policy for indigotindisulfonate (BLUDIGO) (HCPCS code J9220) is located in the *Radiology: Diagnostic* section of the Part 2 provider manual.››

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 Limit

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 Limit

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.

‹‹Infliximab-dyyb (Zymfentra)

Infliximab-dyyb neutralizes the biological activity of TNFα by binding with high affinity to the slouble and transmembrane forms of TNFα and inhibit binding of TNFα with its receptors. Infliximab-dyyb has shown biological activities, such as such as TNFα neutralization activity and TNFα binding affinities, complement component 1q (C1q) binding affinity and crystallizable fragment (Fc) receptor binding affinities in a wide variety of in vitro bioassays. The relationship of these biological response markers to the mechanism(s) by which infliximab-dyyb exerts its clinical effects is unknown.

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:

Universal Criteria:

- Used for all FDA approved indications and dosages; **and**
- Patient is at least 18 years of age or older; **and**
- Used in Crohn’s disease or ulcerative colitis as maintenance treatment of moderately to severely active disease; **and**
- Zymfentra is prescribed by or in consultation with a gastroenterologist; **and**››

‹‹Crohn's Disease

Used as Initial Therapy:

A. Documentation of current use of an infliximab intravenous induction therapy for at least 10 weeks; **and**

B. Patient meets one of the following (a, b, c or d):

a. Patient has tried or is currently taking systemic corticosteroids (for example, prednisone and methylprednisolone), or there is a contraindication to corticosteroids

b. Patient has tried one conventional systemic therapy for Crohn's disease (for example, azathioprine, 6-mercaptopurine, or methotrexate)

❖ Exceptions to above: Patient has tried at least one other biologic used for Crohn's disease (not including a biosimilar). Examples: Humira, etc.

c. Patient had ileocolonic resection

d. Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas

Approval is for six months.

- Patient is currently on an Infliximab Product.

A. Patient has been established on therapy for at least six months; **and**

B. Patient meets at least one of the following:

a. Patient experienced a beneficial clinical response from baseline using at least one objective measure (for example, fecal markers, serum markers, imaging studies, etc.); **or**

b. Patient experienced an improvement in at least one symptom (fatigue, stool frequency, hematocrit, etc.) compared to baseline

Initial authorization is for 12 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.

Ulcerative Colitis

Used as Initial Therapy:

A. Documentation of current use of an Infliximab intravenous induction therapy for at least 10 weeks; **and**

B. Patient meets one of the following:

a. Patient had a trial of one systematic agent or was intolerant of these agents for ulcerative colitis (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a corticosteroid (e.g. prednisone or methylprednisolone); **or**

b. Patient meets both of the following:

❖ Patient has pouchitis; **and**

❖ Patient has tried therapy with an antibiotic (for example, metronidazole, ciprofloxacin, etc.), probiotic, or corticosteroid enema.

Approval is for six months.

- Patient is currently on Infliximab Product.

A. Patient has been established on therapy for at least six months; **and**

B. Patient meets at least one of the following:

a. Patient experienced a beneficial clinical response from baseline using at least one objective measure (for example, fecal markers, serum markers, imaging studies, etc.); **or**

b. Patient experienced an improvement in at least one symptom (fatigue, stool frequency, etc.) compared to baseline

Initial authorization is for 12 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 18 years of age or older.

Billing

HCPCS code J1748 (injection, infliximab-dyyb [zymfentra], 10 mg).

Prescribing Restriction(s)

Frequency of billing equals once every two weeks
Maximum billing unit(s) equals 120 mg/12 units every two weeks››

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 five 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 five units)

Iron Sucrose

‹‹Indications, Dosages and Age

Refer to the FDA-approved labeling.››

Must be two years of age 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

The primary diagnosis code for chronic kidney disease (CKD) and one of the following secondary diagnosis codes for iron deficiency must be entered, as applicable, for the service date.

CKD (primary diagnosis)

‹‹ICD-10-CM diagnosis codes: N18.1, N18.2, N18.30, N18.31, N18.32, N18.4, N18.5, N18.6, N18.9››

And one of the following:

Iron deficiency anemia (secondary diagnosis)

ICD-10-CM diagnosis codes: D50.0, D50.1, D50.8, D50.9, D63.1

Billing

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

‹‹Isoniazid (RIFAMPIN)

Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

TAR Requirement

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

Billing

HCPCS code J1834 (injection, isoniazid, 1 mg).››

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.