Injections: Drugs S Policy

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This section outlines policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Injections: An Overview* section in this manual. Additional policy information for injection services can be found in the following sections of this manual:

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

Sargramostim (LEUKINE®)

Sargramostim is a recombinant human granulocyte-macrophage colony stimulating factor (rhu GM-CSF) produced by recombinant DNA technology in a yeast expression system. GM-CSF is a hematopoietic growth factor which induces partially committed progenitor cells to divide and differentiate in the granulocyte-macrophage pathways including neutrophils, monocytes/macrophages and myeloid-derived dendritic cells.

Indications

All FDA approved indications.

Dosage

FDA approved dosages.

TAR Requirement

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

Billing

HCPCS code J2820 (injection, sargramostim [GM-CSF], 50 mcg).

Suggested ICD-10 Diagnosis CodesD70.1

T66	Z52.001
Z51.11	Z94.81
Z51.89	Z94.84

Sebelipase Alfa (Kanuma®)

Sebelipase alfa is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme that binds to cell surface receptors via glycans expressed on the protein and is subsequently internalized into lysosomes. Sebelipase alfa catalyzes the lysosomal hydrolysis of cholesteryl esters and triglycerides to free cholesterol, glycerol, and free fatty acids.

Indications

All FDA-approved indications.

Dosage

FDA-approved indications dosages.

TAR Requirements

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

Required ICD-10-CM Diagnosis Code

E75.5

Billing

HCPCS code J2840 (injection, sebelipase alfa, 1 mg)

Secretin

Secretin stimulates pancreatic ductal cells to secrete pancreas fluid in large volumes that contain carbonate.

Indication

All FDA-approved indications.

TAR Requirement

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

Billing

HCPCS code J2850 (injection, secretin, synthetic, human, 1 mcg).

‹‹Secukinumab (COSENTYX)

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.››

‹‹TAR Requirement

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

TAR Criteria

The TAR must include clinical documentation that demonstrates the following:

- Must be used for an FDA-approved indication and dosage.
- Must be administered intravenously.
- Must be 18 years of age or older.
- Patient has been evaluated and, if applicable, treated for active or latent Tuberculosis infection prior to initiating treatment with seckukinumab.
- Patient's age-appropriate immunizations are current.
- Psoriatic arthritis:
  - Inadequate response, intolerance, or contraindication to at least one of the following: etanercept, infliximab, adalimumab, certolizumab
- Ankylosing spondylitis or non-radiographic axial spondyloarthritis
  - Inadequate response, intolerance, or contraindication to at least one of the following: infliximab, etanercept, adalimumab, certolizumab, golimumab, and their biosimilars

Initial authorization is for 12 months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has shown positive clinical response as evidenced by disease improvement or disease stabilization compared to baseline.

Reauthorization is for 12 months.››

‹‹Age Limits

Must be 18 years of age or older.

Billing

HCPCS code C9166 (injection, secukinumab, intravenous, 1 mg).

Prescribing Restriction(s):

Frequency of billing equals every four weeks.››

Siltuximab (SYLVANT)

Siltuximab is a human-mouse chimeric monoclonal antibody that binds human interleukin-6 (IL-6) and prevents the binding of IL-6 to both soluble and membrane-bound IL-6 receptors.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Authorization

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for an FDA-approved indication and dosage.
- Must have a diagnosis of multicentric Castleman's Disease (MCD).
- Must be negative for human immunodeficiency virus (HIV) and human herpes virus-8 (HHV-8).
- Must be free of all severe infections.
- Will not receive live vaccines during treatment with siltuximab.

Authorization is for 12 months.

Age Limits

Must be 18 years of age and older.

Billing

HCPCS code J2860 (injection, siltuximab, 10 mg).

Prescribing Restriction(s)

Frequency of billing equal to every three weeks.

Sodium Ferric Gluconate Complex in Sucrose

Sodium ferric gluconate complex in sucrose is an iron replacement product. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport. Additionally, iron is necessary for metabolism and various enzymatic processes.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be six years of age or older.

Billing

HCPCS code J2916 (injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg).

Somatropin for HIV-Associated Wasting

Somatropin is used for the treatment of HIV-associated wasting and is reimbursable only with an approved TAR. A TAR will be granted in four-week intervals to a maximum of 12 continuous weeks of therapy. Treatment must be reevaluated after four weeks and eight weeks of therapy.

Initial Therapy: Criteria

Criteria for the initial 28 days of treatment of HIV-associated wasting with somatropin:

- Documentation in the medical record of complete history and physical examination including:
  - History of nutritional status including appetite, estimation of caloric intake, gastrointestinal function including presence of diarrhea and number of daily stools, and history of endoscopic procedures
  - Psychosocial evaluation, including presence of significant anxiety and/or depression affecting food intake
- Record of the following measurements:
  - Height, weight, ideal body weight, body mass index (BMI)
  - Body cell mass (BCM) by bioelectrical impedance analysis (BIA)
  - Serial measurements – weekly

- Patients must meet one of the following criteria for HIV-associated wasting:
  - 5 percent BCM loss within the preceding six months
  - In men: BCM less than 35 percent of total body weight and BMI less than 27 kg/m^2
  - In women: BCM less than 23 percent of total body weight and BMI less than 27 kg/m^2
  - BMI less than 20 kg/m^2
  - BMI greater than 20 kg/m^2 and less than 25 kg/m^2 and
    - 10 percent unintentional weight loss within the preceding 12 months or
    - 7.5 percent unintentional weight loss within the preceding six months
- Patients should have an evaluation of gastrointestinal function with attention to the presence of malabsorption, a review of food intake, amount of daily calories and estimate of physical activity level.
- An active malignancy other than Kaposi's sarcoma has been excluded clinically, through diagnostic laboratory examination, and/or radiographically.
- Male patients should have a serum testosterone level and, if low, a trial of testosterone replacement therapy.
- Patients must have a viral load assay and a CD4 count and must be undergoing treatment with an appropriate antiretroviral therapy regimen.
- Patients should have a trial with an appetite stimulant if they have inadequate caloric intake and anorexia.
- For male patients, an initial trial of androgen is recommended for HIV-associated wasting. If this is omitted, a statement should be provided documenting the clinical decision to proceed directly with somatropin therapy.
- Patients must receive somatropin within recommended dosing guidelines for body weight.

Reassessment of Therapy Through 12 Weeks: Criteria

Criteria for reassessment of therapy through 12 weeks:

- Treatment must be re-evaluated after four weeks and eight weeks of therapy. Repeat weight assessment and documentation is required at four weeks and eight weeks of therapy to assure weight stabilization.
- Therapy must be discontinued in patients who continue to lose weight in the first four weeks of treatment.
- If, after four weeks of therapy, weight loss has stopped or if the patient is gaining weight, somatropin may be continued for another 28 days.
- If, after eight weeks of therapy, the patient is losing or has failed to gain weight from the original measurement, somatropin must be stopped.
- If the patient had initially gained weight at four weeks but has neither gained nor lost weight at the eight-week re-evaluation, somatropin may be continued for another 28 days.
- A maximum of 12 weeks of treatment is allowed with authorization. Claims without authorization will be denied.

Note: Authorization is limited to four-week intervals.

Continued Therapy Beyond 12 Weeks: Criteria

Criteria for continued therapy beyond the initial 12 weeks:

- All patients must stop somatropin following the initial 12-week treatment for an eight-week period of observation unless there is documentation that HIV-associated wasting is still present. During the eight-week observation period, body weight, BMI and BCM should be monitored on a weekly basis.
- Therapy beyond 12 weeks may be continued with a patient who has demonstrated a beneficial response to somatropin during the initial 12 weeks of therapy (defined as a two percent or greater increase in body weight or BCM) and
  - Still exhibits evidence of wasting (BMI less than 20 kg/m^2) or
  - Has a BCM not yet normalized (BCM less than 40 percent in non-obese men or less than 28 percent in non-obese women).
- As long as the patient continues to gain weight or BCM, somatropin may be extended every 28 days, with authorization, until BCM and/or weight are normalized.
- Once BCM and/or weight have normalized, somatropin should be stopped.

Reinitiating Somatropin Therapy Within Six Months: Criteria

Criteria for reinitiating somatropin therapy within six months:

- Patients may resume somatropin therapy within six months of initial therapy if there is documentation of an unintentional five percent loss of body weight or BCM loss of greater than five percent or any of the criteria for HIV-associated wasting within six months after completion of an uninterrupted 12-week course of somatropin therapy.
- Reinitiating somatropin is allowed for up to an additional 12 weeks, with reassessments required at the same four and eight week intervals during the second 12-week course of therapy. A recent copy of the patient's BIA documenting the BCM loss is required with TAR submission.

Repeat Somatropin Therapy After Cessation: Criteria

Criteria for repeat somatropin therapy six months after cessation of treatment:

- If the patient has not re-initiated somatropin six months after completing an uninterrupted 12-week course of therapy, somatropin may be repeated, provided the criteria for initial 28 days of therapy are met. Reinitiating somatropin is allowed for up to an additional 12 weeks, with reassessments required at the same four- and eight-week intervals during the second 12-week course of therapy. A recent copy of the patient's BIA is required with TAR submission.
- Trials of alternate treatment may be omitted if previous use in the patient was unsuccessful. The use of somatropin beyond the initial 12-week course must meet the criteria stated above for continued treatment.

Sotalol

Sotalol has both beta-adrenoreceptor blocking (Vaughan Williams Class II) and cardiac action potential duration prolongation (Vaughan Williams Class III) antiarrhythmic properties. Intravenous sotalol hydrochloride is a racemic mixture of d- and l-sotalol. Both isomers have similar Class III antiarrhythmic effects, while the l-isomer is responsible for virtually all of the beta-blocking activity.

Indications

Sotalol is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AFIB/AFL]) in patients with symptomatic AFIB/AFL who are currently in sinus rhythm. Because sotalol can cause life-threatening ventricular arrhythmias, it should be reserved for patients in whom AFIB/AFL is highly symptomatic. Sotalol is indicated for patients 18 years of age and older.

Authorization

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

Required Codes

Sotalol is reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes:

I48.0 thru I48.4, I48.91, I48.92

Dosage

Starting adult dose is 75 mg administered twice daily. If creatinine clearance is between 60 and 40 mL/min, administer once daily, if less than 40 mg/mL, sotalol is not recommended.

Billing

HCPCS code C9482 (injection, sotalol hydrochloride, 1 mg).

Spesolimab-sbzo (Spevigo®)

Spesolimab-sbzo is a humanized monoclonal immunoglobulin G1 antibody that inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36R. Binding of spesolimab-sbzo to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL-36 α, β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. The precise mechanism linking reduced IL36R activity and the treatment of flares of GPP is unclear.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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 all FDA-approved indications and dosages.
- Patient must have a diagnosis of generalized pustular psoriasis (GPP) flares.
- Must be prescribed by or in consultation with a dermatologist.
- Patient must be 18 years of age or older.
- Patient has no current active infections.
- Patient is not currently on retinoids/methotrexate/cyclosporine prior to initiation of spevigo.

- Documentation of a negative tuberculosis (TB) infection prior to initiating treatment or pretreatment with antituberculosis therapy in patients with latent TB.
- Patient does not have an immediate life-threatening flare of GPP or requiring intensive care treatment.
- Patient does not have SAPHO syndrome (inflammatory bone disorders that may be associated with skin changes.)

Approval is for three months (maximum of two doses one week apart).

Billing

HCPCS code: J1747, (injection, spesolimab-sbzo, 1 mg)

Required ICD-10-CM Diagnosis Codes

L40.1

Prescribing Restriction(s)

Maximum dose: 900 mg/900 units

Frequency of billing: 900 mg/900 units every week for up to two doses

Note: Spevigo is available through the following specialty distributor:
Accredo Specialty Pharmacy
1-800-803-2523

Sutimlimab-jome (Enjaymo™)

Sutimlimab-jome is an immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody (mAb) that inhibits the classical complement pathway (CP) and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4. Sutimlimabjome does not inhibit the lectin and alternative pathways. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of RBCs, resulting in inhibition of hemolysis in patients with cold agglutinin disease (CAD).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Enjaymo 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 olde.r
- Must be prescribed by or in consultation with a hematologist, immunologist or oncologist.

- Patient has a diagnosis of primary cold agglutinin disease (CAD) as defined by all of the following:
  - Evidence of hemolysis (e.g., high reticulocyte count, high LDH, high indirect bilirubin, low haptoglobin)
  - Positive direct antiglobulin (Coombs) test for C3d only (or, in a minority, C3d plus weak IgG)
  - Cold agglutinin titer of equal to or greater than 64 at 4°C
- Patient has had at least one blood transfusion in the previous six months.
- Patient has chronic hemolysis with a hemoglobin (Hgb) level of less than10g/dL.
- Patient has symptomatic anemia or cold-induced ischemic symptoms interfering with daily living (for example, fatigue, dyspnea, acrocyanosis, Reynaud's phenomenon, pain or discomfort in swallowing cold food or liquids, etc.
- Patients has received vaccinations against Neisseria meningitidis, Haemophilus influenzae, and Streptococcus pneumoniae at least two weeks before initiating sutimlimab; if therapy is started urgently, vaccines should be provided as soon as possible.
- Patient does not have cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy.

Initial approval is for six months.

<u>Continued therapy:</u>

- Patient continues to meet initial approval criteria.
- Patient has experienced clinical benefit as evidenced by at least one of the following:
  - Patient did not receive a blood transfusion or achieved transfusion independence
    - Patient's hemoglobin (Hgb) level became equal to or greater than 12 g/dL or Hgb level increased by equal to or greater than 2 g/dL from baseline
  - Patient had a decrease in mean bilirubin and LDH values compared to baseline

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code: J1302, (injection, sutimlimab-jome, 10 mg).

Required ICD-10 Diagnosis Codes

D59.12

Prescribing Restriction(s)

Frequency of billing equals 7,500 mg/750 units weekly for two weeks then every two weeks.

Maximum billing unit(s) equals 7,500 mg/750 units.

Legend

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

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