Injections: Drugs T 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 S Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*
- *Immunizations*

Taliglucerase Alfa

Taliglucerase alfa, a hydrolytic lysosomal glucocerebroside-specific enzyme for intravenous infusion, is a recombinant active form of the lysosomal enzyme, β-glucocerebrosidase, which is expressed in genetically modified carrot plant root cells cultured in a disposable bioreactor system. B-glucocerebrosidase is a lysosomal glycoprotein enzyme that catalyzes the hydrolysis of the glycolipid glucocerebroside to glucose and ceramide.

Indications

For use for adults with confirmed diagnosis of Type 1 Gaucher disease.

Authorization

The *Treatment Authorization Request* (TAR) must include a diagnosis of Type 1 Gaucher disease. For other TAR requirements, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E Policy* section in this manual.

Dosage

The recommended dose is 60 units/kg of body weight administered once every two weeks as a 60 thru 120 minute intravenous infusion. The maximum dose is 8,160 mg per day.

Billing

HCPCS code J3060 (injection, taliglucerase alfa, 10 units).

Tbo-Filgrastim

Tbo-filgrastim is a non-glycosylated recombinant methionyl human granulocyte colony-stimulating growth factor (r-metHuG-CSF) manufactured by recombinant DNA technology using the bacterium strain E. coli K802. It binds to G-CSF receptors and stimulates proliferation neutrophils. G-CSF is known to stimulate differentiation commitment and some end-cell functional activation, which increases neutrophil counts and activity.

Indications

To reduce the duration of severe neutropenia in adult patients (18 years of age and older) with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Dosage

The recommended dose of tbo-filgrastim is 5 mcg/kg per day administered as a subcutaneous injection. Administer the first dose of tbo-filgrastim no earlier than 24 hours following myelosuppressive chemotherapy.

Required Codes

Tbo-filgrastim is reimbursable when billed with one of the following ICD-10-CM diagnosis codes:

D70.1	Z51.11
D70.2	Z51.89

Billing

HCPCS code J1447 (injection, tbo-filgrastim, 1 microgram).

Tedizolid Phosphate

Tedizolid phosphate, 1 mg injection (HCPCS code J3090) is restricted to patients 18 years of age and older.

Teplizumab-mzwv (TZIELD™)

Teplizumab-mzwv binds to CD3 (a cell surface antigen present on T lymphocytes) resulting in a partial agonistic signaling and deactivation of pancreatic beta cell autoreactive lymphocytes. Teplizumab-mzwv leads to an increase in the proportion of regulatory T cells and of exhausted CD8+ T cells in peripheral blood.

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 8 years of age or older
- Must be prescribed by or in consultation with an endocrinologist
- Patient has a diagnosis of Stage 2 type 1 diabetes (TID) confirmed by at least two positive pancreatic islet cell autoantibodies:
  - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - Insulin autoantibodies (IAA)
  - Insulinoma-associated antigen 2 autoantibodies (IA-2A)
  - Zinc transporter 8 autoantibodies (ZnT8A)
  - Islet-cell autoantibodies (ICA)

- Patient has dysglycemia (abnormal blood glucose) without overt hyperglycemia defined using an oral glucose tolerance test (OGTT) OR alternative method if appropriate and OGTT is not available:
  - According to the American Diabetes Association (ADA) 2022 Standards of Medical Care in Diabetes, dysglycemia may be diagnosed based on any of the following:
    - ❖ 2-hour plasma glucose (PG) level of 140 to 199 mg/dL (7.8 to 11.0 mmol/L) during OGTT
    - ❖ A fasting plasma glucose (FPG) level of 100 to 125 mg/dL (5.6 to 6.9 mmol/L)
- Patient does not have any of the following:
  - Stage 3 type 1 diabetes
  - Clinical history consistent with type 2 diabetes
  - An active serious infection or chronic infection, including but not limited to Epstein-Barr virus or cytomegalovirus.
  - Serological evidence of past current or past HIV, hepatitis B, or hepatitis C infection
  - Prior treatment with other monoclonal antibody in past one year
- CBC and liver chemistries do not show any of the following lab abnormalities
  - Lymphocyte count less than 1,000 lymphocytes/mcL
  - Hemoglobin less than 10 g/dL
  - Platelet count less than 150,000 platelets/mcL
  - Absolute neutrophil count less than 1,500 neutrophils/mcL
  - Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN

Initial authorization is for three months (14-day treatment course).

Reauthorization is not approvable.

Age Limit

Must be eight years of age or older.

Billing

HCPCS code J9381 (injection, teplizumab-mzwv, 5 mcg).

Required ICD-10-CM Diagnosis Codes

E10.8, E10.9

Prescribing Restrictions

Frequency of billing is one treatment in a lifetime.

Teprotumumab-trbw (Tepezza)

Teprotumumab's mechanism of action in patients with thyroid eye disease has not been fully characterized. Teprotumumab binds to insulin-like growth factor-1 receptor inhibitor and blocks its activation and signaling.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Teprotumumab-trbw will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Patient must have a clinical diagnosis of Grave's disease associated with active thyroid eye disease (TED) with a clinical activity score (CAS) of greater than or equal to 4 for the most severely affected eye or patient has moderately to severely active TED, associated with at least one of the following:
  - Lid retraction equal to or greater than 2 mm
  - Moderate or severe soft tissue involvement
  - Proptosis equal to or greater than 3 mm
  - Diplopia
  - Corneal exposure
- Patient must be euthyroid or with mild hypo- or hyperthyroidism defined as free thyroxine and free triiodothyronine levels less than 50 percent above or below the normal limits.
- Must be prescribed by or in consultation with an ophthalmologist, endocrinologist or a physician who specializes in treatment of thyroid eye disease.
- Patient does not require surgical ophthalmological intervention.
- Patient must not have poorly controlled diabetes.
- Diabetic patient must have well controlled disease (defined as HgbA1c less than 9.0 percent at most recent clinic visit).
- Patient has a contraindication, intolerance, or lack of response to glucocorticoids or a documented justification why the use of glucocorticoids is not appropriate.

Authorization is for 12 months (a maximum of eight infusions).

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J3241 (injection, teprotumumab-trbw, 10 mg).

Suggested ICD-10-CM Diagnosis Codes

E05.00

Prescribing Restrictions

Frequency of billing equal to 10 mg/kg initial dose, then 20 mg/kg every three weeks for seven additional doses.

Tezepelumab-ekko (Tezspire™)

Tezepelumab-ekko is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2λ that binds to human TSLP with a dissociation constant of 15.8 pM and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade.

Airway inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes, ILC2 cells) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in airway inflammation. Blocking TSLP with tezepelumab-ekko reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, FeNO, IL-5, and IL-13; however, the mechanism of tezepelumab-ekko action in asthma 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

Must submit clinical documentation to substantiate the following:

- Must be used for FDA- approved indications and dosages.
- Patient must be 12 years of age or older.
- Patient has a physician-diagnosed asthma for at least 12 months.
- Must be prescribed by or in consultation with a pulmonologist, allergist or immunologist.
- Patient is adherent on medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller (such as long acting beta2 agonist (LABA), with or without oral corticosteroids (OCS).
- Patient has persistent uncontrolled asthma as defined by at least one of the following:
  - An Asthma Control Questionnaire (ACQ6) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline.
  - A history of at least 2 asthma exacerbation events within prior 12 months.
  - A history of at least 1 severe asthma exacerbation resulting in hospitalization within prior 12 months.
  - Reduced lung function at baseline [pre-bronchodilator FEV1 below 80% in adults, and below 90 percent in adolescents] despite regular treatment with high dose inhaled corticosteroid (ICS) or with medium or high dose ICS plus a LABA with or without oral corticosteroids (OCS) and additional asthma controller medications such as leukotriene receptor inhibitors, long-acting anti-muscarinics (LAMA), or sustained-release theophylline.
- Patient will not use tezepelumab-ekko as monotherapy.

Initial approval is for 12 months.

Continued therapy:

Patient has experienced improvement in asthma control as evidenced by at least one of the following:

- Reductions in Annual Asthma Exacerbation Rate as shown by any of the following:
  - Improvement in patient's Forced Expiratory Volume in 1 Second (FEV1), peak expiratory flow, nighttime awakenings, or any other symptoms that would require an increase in OCS dose
  - Reduction in ED visits requiring use of oral/systemic corticosteroids and/or hospitalization
  - Reduction in use of short-acting bronchodilator rescue medications
- Improvement from baseline in Asthma Control Questionnaire-6(ACQ-6) or Asthma Control Test (ACT) score

Reauthorization is for 12 months.

Age Limit

Must be 12 years of age or older.

Billing

HCPCS code: J2356, (injection, tezepelumab-ekko, 1 mg).

Required ICD-10 Diagnosis Codes

J45.50, J45.51.

Prescribing Restriction(s)

Frequency of billing equals 210 mg/210 units every four weeks.

Maximum billing unit(s) equals 210 mg/210 units.

Thyrotropin Alfa

Thyrotropin alfa is reimbursable for use in the following groups: (1) as a diagnostic tool for serum thyroglobulin testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer and (2) as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

Dosage

A two-injection regimen is recommended. The two-injection regimen is thyrotropin alfa 0.9 mg intramuscularly (IM) followed by a second 0.9 mg IM injection 24 hours later.

For imaging or remnant ablation, radioiodine administration should be given 24 hours following the final thyrotropin alfa injection. A post-ablation scan should be performed three to five days after radioiodine administration. A diagnostic serum thyroglobulin with or without scanning should be performed 48 hours after radioiodine administration.

Authorization

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

Billing

HCPCS code J3240 (injection, thyrotropin alpha, 0.9 mg) provided in 1.1 mg vial.

Tigecycline

Tigecycline inhibits protein translation in bacteria by binding to the 30S ribosomal subunit and blocking entry of amino-acyl tRNA molecules into the A site of the ribosome. This prevents incorporation of amino acid residues into elongating peptide chains. In general, tigecycline is considered bacteriostatic; however, tigecycline for injection has demonstrated bactericidal activity against isolates of Streptococcus pneumoniae and Legionella pneumophila.

Safety warning

All-cause mortality was higher in patients treated with tigecycline than comparators in a meta-analysis of clinical trials. Tigecycline should be reserved for use in situations when alternative treatments are not suitable.

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 (J3244 only. No age restriction on J3243).

Billing

HCPCS codes:

J3243 (injection, tigecycline, 1 mg).

J3244 (injection, tigecycline [accord] not therapeutically equivalent to J3243, 1 mg).

Prescribing Restriction(s)

Frequency of billing equals100 mg/100 units, followed by 50 mg /50 units every 12 hours.

Maximum billing unit(s) equals 100 mg/100 units.

Tildrakizumab-asmn

Tildrakizumab-asmn is an interleukin-23 antagonist in solution for subcutaneous (SQ) use.

Indications

Tildrakizumab-asmn is used to treat patients with moderate-to-severe chronic plaque psoriasis (i.e., extensive and/or disabling disease) who are candidates for phototherapy or systemic therapy and when other systemic therapies are medically less appropriate.

Age Limit

Must be 18 years of age and older.

Dosage

100 mg SQ injection administered at weeks zero and four, and every 12 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 to treat moderate-to-severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate.
- Alternative psoriasis therapies (e.g., phototherapy, oral agents, etc.) have been tried or considered, have failed, or are contra-indicated.
- The physician’s legible, complete, and signed treatment plan/order for tildrakizumab-asmn.

Billing

HCPCS code J3245 (injection, tildrakizumab-asmn, 1 mg)
One (1) unit of J3245 equals 1 mg of tildrakizumab-asmn solution.

Tocilizumab

Tocilizumab is an interleukin-6 (IL-6) receptor antagonist for intravenous (IV) or subcutaneous (SQ) administration.

Indications

Tocilizumab is used to treat the following conditions:

- Rheumatoid Arthritis
- Giant Cell Arteritis
- Polyarticular Juvenile Idiopathic Arthritis
- Systemic Juvenile Idiopathic Arthritis
- Cytokine Release Syndrome

Age Limit

Must be two years of age and older.

Dosage

The recommended dosage varies based on the patient's treatment condition, age, laboratory measurements, and response to therapy.

Authorization

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

The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for tocilizumab.

Billing

HCPCS code J3262 (injection, tocilizumab, 1 mg)
One (1) unit equals 1 mg of tocilizumab.

‹‹Tocilizumab-bavi (Tofidence™)

Tocilizumab products bind to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R), and has been shown to inhibit IL-6-mediated signaling through these receptors.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Tofidence™ will be considered medically necessary when all of the following criteria is met:

Universal Criteria:

1. Must be used for all FDA approved indications and dosages.
2. Must be prescribed by or in consultation with a rheumatologist.
3. Test and monitor patients for latent and active TB initially and during treatment.
4. Routine monitoring of patients for the development of signs and symptoms of infection during and after treatment with Tofidence.
5. Tofidence is not used in combination with etanercept (Enbrel), adalimumab (Humira), infliximab (Remicade), rituximab (Rituxan), abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), or golimumab (Simponi)
6. The absolute neutrophil count (ANC) is above 2000 per mm3, platelet count is above 100,000 per mm3.
7. ALT or AST is not more than 1.5 times the upper limit of normal (ULN).
8. Live vaccines must not be administered during therapy with Tofidence **and**››

‹‹**Initial Authorization:**

Rheumatoid Arthritis (RA):

1. Patient is at least 18 years of age.
2. Diagnosis of moderately to severely active rheumatoid arthritis.
3. Unless contraindicated, patient has tried and failed one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs) (e.g., methotrexate, leflunomide, hydroxychloroquine, etc.) **or**
4. Unless contraindicated, patient has tried and failed at least one tumor necrosis factor (TNF alpha) (e.g., Enbrel, Humira).

Polyarticular Juvenile Idiopathic Arthritis (PJIA):

1. Patients is two years of age or older.
2. Diagnosis of active polyarticular juvenile idiopathic arthritis.
3. Unless contraindicated, patient has tried and failed at least one oral Disease-Modifying Anti-Rheumatic Drugs (DMARDs) (e.g., methotrexate, leflunomide, hydroxychloroquine, etc.) **or**
4. Unless contraindicated, patient has tried and failed at least one tumor necrosis factor (TNF alpha) (e.g. Enbrel, Humira).

Systemic Juvenile Idiopathic Arthritis (SJIA):

1. Patient is 2 years of age or older.
2. Diagnosis of active systemic juvenile idiopathic arthritis.
3. Unless contraindicated, patient has tried and failed NSAIDs or corticosteroids.

Initial authorization is for 12 months.››

‹‹**Universal Re-Authorization:**

4. Patient continues to meet the initial approval criteria.
5. Normal lab results as documented by routine laboratory monitoring (neutrophils, platelets, lipids, and liver function tests)
6. Lack of unacceptable toxicities (serious infections, hepatotoxicity, GI perforation, etc.) and documentation of positive clinical outcome (percent improvement in JIA ACR core set, physical global assessment, functional ability, etc.)

Re-authorization is for 12 months.

Age Limits

Must be two years of age or older (PJIA and SJIA).

Must be 18 years of age or older (RA).

Billing

HCPCS code Q5133 (injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg).

One (1) unit equals 1 mg of tocilizumab-bavi.››

Tofersen (QALSODY)

Tofersen is an antisense oligonucleotide that causes degradation of SOD1 mRNA through binding to superoxide dismutase 1 (SOD1) mRNA, which results in a reduction of SOD1 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:

- 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 neurologist with expertise in ALS.
- Patient has weakness attributable to ALS, and a confirmed diagnosis of ALS (definite or clinically probable) based on revised El Escorial World Federation of Neurology criteria, Awaji or Gold Coast criteria.
- Patient has a confirmed mutation in the superoxide dismutase 1 (SOD1) gene.
- Baseline documentation of functional ability prior to initiating treatment (e.g., muscle strength, respiratory strength, walking, climbing stairs, etc).
- Patient does not depend on invasive ventilation or tracheostomy.
- Patient was not previously treated for ALS with cellular therapies or gene therapies.

Initial authorization is for six months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Positive clinical response as evidenced by documentation of less functional decline from baseline, reduction in decline in respiratory strength, or reduction in decline in muscle strength, etc.
- Patient does not depend on invasive ventilation or tracheostomy.
- Patient has an absence of unacceptable toxicity from the drug, for example, serious myelitis and/or radiculitis, papilledema, aseptic meningitis, etc.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1304 (injection, tofersen, 1 mg).

Required ICD-10-CM Diagnosis Codes

G12.21

Prescribing Restrictions

Frequency of billing equals 100 mg/100 units every 14 days for three doses followed by 100 mg/100 units every 28 days.

Maximum billing units equals 100 mg/100 units.

Treprostinil

Treprostinil, 1 mg, (HCPCS code J3285) is reimbursable for patients 16 years of age or older with pulmonary hypertension. Claims require authorization.

Triamcinolone Acetonide Extended-Release Injectable Suspension (Zilretta)

Triamcinolone acetonide extended-release injectable suspension is a microsphere formulation of triamcinolone acetonide, a corticosteroid, to be administered by intra-articular injection.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Authorization

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

Triamcinolone acetonide extended-release injection is considered medically necessary when the following criteria are met:

- For FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Patients must have a diagnosis of osteoarthritis of the knee; and
- Patient must have inadequate response, intolerance or contraindication to at least two of the following:
  - Acetaminophen
  - Oral NSAIDs
  - Topical NSAIDs; and

- Patient must have treatment failure, intolerance or contraindication to short-acting, intra-articular steroid injections or adequate pain control but with drug-induced hyperglycemia.
- Approval will be granted for a maximum of one dose (32 mg) of triamcinolone acetonide extended-release injection per knee per lifetime.

One approval will be granted for a duration of six months. The TAR is not renewable.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J3304 (injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg)

Must use modifiers RT, LT for applicable knee(s).

Prescribing Restrictions

Frequency of billing equals no repeat administration.

Maximum billing unit(s) equals 32 mg equals 32 units each knee.

Triamcinolone Acetonide for Suprachoroidal Use (Xipere™)

Policy for triamcinolone acetonide injection for suprachoroidal use (HCPCS code J3299) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Triferic AVNU®

Triferic AVNU contains iron in the form of ferric pyrophosphate citrate. Iron binds to transferrin for transport to erythroid precursor cells to be incorporated into hemoglobin.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Authorization

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

Triferic Avnu is considered medically necessary when all of the following criteria are met:

- Patient must be 18 years of age or older.
- Patient must have a diagnosis of hemodialysis-dependent chronic kidney disease (HDD-CKD)
  - The diagnosis of HDD-CKD is four or more months and patient requires hemodialysis at least three times per week
- Patient has serum ferritin less than or equal to 200 ng/mL.
- Patient has Serum Transferrin Saturation (TSAT) less than or equal to 20 percent.
- Patient has Hemoglobin less than 10 grams per deciliter (g/dL) or is being treated with an Erythropoiesis-Stimulating Agent (ESA) to maintain Hemoglobin at target and a TSAT of 30 percent or less and ferritin less than or equal to 500 ng/mL.
- Patient is not receiving peritoneal dialysis.
- Patient is not receiving home hemodialysis.

Initial authorization is for three months.

Continued treatment:

- Patient is monitored and continues to meet initial approval criteria.
- Patient has positive clinical response evidenced by mean change in hemoglobin from baseline.

Reauthorization is for three months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1445 (injection, ferric pyrophosphate citrate solution [triferic avnu], 0.1 mg of iron)

Important Billing Instructions:

Due to systems limitations, only whole numbers in units can be processed. Providers must bill for 68 units rather than 67.5 units.

Suggested ICD-10-CM Diagnosis Codes

N18.5, N18.6.

Prescribing Restriction(s)

Frequency of billing equals 6.75 mg/67.5 units at each hemodialysis session.

Maximum billing unit(s) equals 6.75 mg/67.5 units.

Triptorelin XR

Triptorelin extended-release (XR) is a gonadotropin-releasing hormone (GnRH) for intramuscular (IM) administration.

Indications

Triptorelin XR is used for the treatment of pediatric patients with central precocious puberty.

Age Limit

Two to 12 years of age.

Dosage

The recommended dose is 22.5 mg IM injection given once every 24 weeks.

Authorization

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

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

- A diagnosis of central precocious puberty (idiopathic or neurogenic) as defined by the onset of secondary sexual characteristics before the age of 8 years in girls and age 9 years in boys.
- The clinical diagnosis is confirmed by a pubertal basal level of luteinizing hormone (LH) based on the laboratory reference ranges, a pubertal response to a GnRH stimulation test, and the child's bone age is advanced one year or more beyond the child's chronologic age.
- Alternate etiologies of precocious puberty have been considered, evaluated, and ruled-out by baseline evaluation and testing such as height, weight, and height velocity; a brain MRI; gonadal and adrenal ultrasound imaging; serum levels of estrogen or testosterone; and adrenal steroids and beta human chorionic gonadotropin levels.

Required Codes

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

- E22.8 (Other hyperfunction of pituitary gland [central precocious puberty]).

Billing

HCPCS code J3316 (injection, triptorelin extended-release, 3.75 mg)
One (1) unit of J3316 equals 3.75 mg triptorelin extended-release injection solution.

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.