Injections: Drugs B 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 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 T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

Baclofen (Intrathecal)

Baclofen is a chemical analog of the inhibitory neurotransmitter gamma-aminobutyric acid and may exert its effects by stimulation of the GABAβ receptor subtype. The precise mechanism of action of baclofen as a muscle relaxant and antispasticity agent is not fully understood. Baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from primary afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect.

Indications

For the treatment of severe spasticity or dystonia of cerebral or spinal origin resulting from diseases or conditions such as but not limited to cerebral palsy, multiple sclerosis, hypoxic/anoxic brain injury, traumatic brain injury, or spinal cord injury.

When treating spasticity due to head injury, it is recommended that a waiting period of one year after injury should elapse before considering intrathecal baclofen therapy.

Not for use in patients younger than four years of age.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement for HCPCS code J0475 (injection, baclofen, 10 mg).

The TAR should document all of the following:

- The patient suffers from one of the indications listed previously.
- The rationale for using intrathecal baclofen over other medication or treatment modalities, including an inadequate response to oral baclofen.
- Failure of physical therapy to relieve spasticity symptoms.
- The patient demonstrates a positive clinical response to a baclofen bolus dose administered intrathecally in a screening trial.

Patients with spasticity due to a cerebral origin need not receive an oral baclofen trial prior to receiving intrathecal baclofen.

Dosage

Establishment of the optimum dose schedule requires that each patient undergoes an initial screening phase with test doses by intrathecal bolus, followed by a very careful individual dose titration prior to maintenance therapy. This is due to the great variability in the effective individual therapeutic dose.

Pump Implantation Maintenance and Filling

Authorization is not required for 1) implantation of the infusion pump and catheter, 2) outpatient refilling and maintenance of the pump or 3) analysis and reprogramming of the pump.

Billing Codes

The following HCPCS codes are used to bill baclofen:

HCPCS Code	Description
J0475	injection, baclofen, 10 mg
J0476	injection, baclofen, 50 mcg for intrathecal trial

Belatacept

Belatacept is a soluble fusion protein consisting of the modified extracellular domain of CTLA-4 fused to a portion (hinge-CH2-CH3 domains) of the Fc domain of a human immunoglobulin G1 antibody. Belatacept is produced by recombinant DNA technology in a mammalian cell expression system.

Belatacept, a selective T-cell (lymphocyte) costimulation blocker, binds to CD80 and CD86 on antigen-presenting cells thereby blocking CD28 mediated costimulation of T lymphocytes. *In vitro*, belatacept inhibits T lymphocyte proliferation and the production of the cytokines interleukin-2, interferon-γ, interleukin-4, and TNF-α. Activated T lymphocytes are the predominant mediators of immunologic rejection.

Indications

Belatacept is indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. It is to be used in combination with basiliximab induction, mycophenolate mofetil and corticosteroids.

Dosage

Belatacept is restricted to patients 18 years of age and older. The maximum daily dosage is 1,300 mg. The recommended dosing schedule is as follows:

Initial Phase Table

Dosage for Initial Phase	Dose
Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose)	10 mg per kg
End of Week 2 and Week 4 after transplantation	10 mg per kg
End of Week 8 and Week 12 after transplantation	10 mg per kg

Maintenance Phase Table

Dosage for Maintenance Phase	Dose
End of Week 16 after transplantation and every four weeks (plus or minus three days) thereafter	510 mg per kg

Required Diagnosis Code

Restricted to ICD-10-CM diagnosis code Z94.0.

Authorization

For doses greater than 1,300 mg per day, an approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS code J0485 (injection, belatacept, 1 mg).

Belimumab (Benlysta)

Benlysta is a BLyS-specific inhibitor that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells. Benlysta does not bind B cells directly, but by binding BLyS, benlysta inhibits the survival of B cells, including autoreactive B cells and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be five years of age or older.

Billing

HCPCS code J0490 (injection, belimumab, 10 mg).

Prescribing Restrictions

Frequency of billing equals 10 mg/kg every two weeks for three doses, then every four weeks thereafter.

‹‹**Note:** Providers must document the patient's current weight.››

Benralizumab (Fasenra)

Benralizumab is a humanized afucosylated, monoclonal antibody (IgG1, kappa) that directly binds to the alpha subunit of the human interleukin-5 receptor (IL-5Rα) with a dissociation constant of 11 pM. The IL-5 receptor is expressed on the surface of eosinophils and basophils. In an in vitro setting, the absence of fucose in the Fc domain of benralizumab facilitates binding (45.5 nM) to FcγRIII receptors on immune effector cells, such as natural killer (NK) cells, leading to apoptosis of eosinophils and basophils through antibody-dependent cell-mediated cytotoxicity (ADCC). Inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in inflammation. Benralizumab, by binding to the IL-5Rα chain, reduces eosinophils through ADCC; however, the mechanism of benralizumab action in asthma has not been definitively established.

Indications

All FDA-approved indications.

Dosage

All 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 diagnosis of severe asthma with an eosinophilic phenotype and has a blood eosinophil counts equal to or greater than 150 cells/μL.
- 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
  - At least two exacerbations while on high-dosage inhaled corticosteroids and long-acting β2-agonists (LABA) (ICS plus LABA) in the previous year
  - A history of Emergency Department (ED) visits requiring use of oral/systemic corticosteroids and/or hospitalization in the past year
  - Reduced lung function at baseline [pre-bronchodilator FEV1 below 80% in adults, and below 90% 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 antileukotriene agent, tiotropium, or sustained-release theophylline
- Patient will not use Benralizumab as monotherapy.
- Benralizumab will not be used concurrently with mepolizumab, omalizumab, or reslizumab.

Initial approval is for 12 months.

Continued therapy

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

- A significant reduction in OCS dose compared with baseline while maintaining asthma control.
- Reductions in 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, short-acting bronchodilator rescue medication use, 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
- Change From baseline in pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1).
- Improvement in Asthma Control Questionnaire (ACQ6) or Asthma Control Test (ACT) score from baseline.

Reauthorization is for 12 months.

Age Limit

Must be 12 years of age or older.

Billing

HCPCS code J0517 (injection, benralizumab, 1 mg)

One (1) unit of J0517 equals 1 mg of benralizumab

Prescribing Restrictions

Frequency of billing equals 30 mg/30 units every four weeks for the first three doses, then once every eight weeks thereafter.

Maximum billing unit(s) equals 30 mg/30 units.

Required ICD-10-CM Diagnosis Code

J45.50, J45.51, J82.81, J82.82, J82.83, J82.89

Betamethasone Sodium Phosphate and Betamethasone Acetate (Celestone Soluspan)

Betamethasone controls the rate of protein synthesis; depresses the migration of polymorphonuclear leukocytes, fibroblasts; reverses capillary permeability and lysosomal stabilization at the cellular level to prevent or control inflammation.

Indications

All FDA-approved indications.

Dosage

All FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J0702 (injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg)

One (1) unit equals 6 mg of betamethasone (3 mg each of the acetate and sodium phosphate salts)

‹‹Betibeglogene autotemcel (ZYNTEGLO)

ZYNTEGLO adds functional copies of a modified β-globin gene into patients' hematopoietic stem cells (HSCs) through transduction of autologous CD34+ cells with BB305 LVV. After ZYNTEGLO infusion, transduced CD34+ HSCs engraft in the bone marrow and differentiate to produce RBCs containing biologically active βA-T87Q-globin (a modified β-globin protein) that will combine with α-globin to produce functional adult Hb containing βA-T87Q-globin (HbAT87Q). βA-T87Q-globin can be quantified relative to other globin species in peripheral blood using high-performance liquid chromatography. βA-T87Q-globin expression is designed to correct the β/α-globin imbalance in erythroid cells of patients with β-thalassemia and has the potential to increase functional adult HbA and total Hb to normal levels and eliminate dependence on regular pRBC transfusions.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

- Must be prescribed for FDA-approved indications and dosages.
- Patient must be 4 to 50 years of age.
  - Patients less than 5 years of age must weigh at least six kg (13.2 lbs) and be able to provide the minimum number of cells required for the manufacturing process.››

- ‹‹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 transfusion-dependent beta thalassemia (TDT) based on one of the following:
  - History of transfusions of at least 100 milliliter per kilogram per year (mL/kg/year) of packed red blood cells (pRBCs) in the prior two years
  - History of eight or more transfusions of pRBCs per year in the prior two years
- Patient has non-β0/β0 genotype (includes ß0/ß+, ß0/ßE, ß+/ß+, and ß+/ßE), β0/β0 genotype and others such as β0/IVS-I-110 or IVS-I-110/IVS-I-110.
- Patient is clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT) and has not had prior HSCT or gene therapy.
- Patient is not pregnant or breastfeeding.
- Patient must not have clinically significant and active bacterial, viral, fungal or parasitic infection active infection.
  - Patient must not have active infection with human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV) or hepatitis C (HCV)
- Patient does not have a known and available Human leukocyte antigen (HLA) matched family donor.
- Patient does not have prior hematopoietic stem cell transplantation (HSCT) or gene therapy.
- Patient does not have any evidence of iron overload.
- Patient does not have cardiac T2 less than 10 msec by MRI, liver iron concentration greater than or equal to 15 mg/g, or advanced liver disease confirmed by MRI.
- Discontinue anti-retroviral medications and/or hydroxyurea one month prior to the planned start of mobilization and conditioning.
- Discontinue iron chelators seven days prior to initiation of myeloablative conditioning.
- Hemoglobin (Hb) greater than or equal to 11 g/dL maintained for at least 30 days prior to mobilization and myeloablative conditioning.››

- Patient will undergo pretreatment hematopoietic stem cell mobilization, apheresis, full myeloablative conditioning with busulfan followed by washout period of at least 48 hours prior to treatment with Zynteglo.

‹‹Authorization is for 12 months (treatment is once in a lifetime).››

Reauthorization

Reauthorization is not approvable.

Age Limits

Must be four to 50 years of age.

Billing

HCPCS code: J3393 (injection, betibeglogene autotemcel, per treatment).

Administration Code

CPT® code 96413 (chemotherapy administration, intravenous infusion; up to one hour, single or initial substance/drug).

Important Instructions for Billing

Due to systems limitations, providers are to take the following steps when submitting claims for Zynteglo:

TAR/SAR Submission Requirements

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific Service Authorization Request (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “3” in the Units box.

‹‹Claim Submission

1. Bill using J3393 (injection, betibeglogene autotemcel, per treatment).
2. Completion of claim forms:

- This billing methodology is restricted to hospital outpatient services and Qualified Treatment Centers (QTCs). Note that pharmacies and clinics cannot bill using this methodology.
- Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
  - On the 837I or *UB-04* claim form, provider must submit three (3) claim lines to represent one (1) service.
    - ❖ Each claim line to represent one unit.
    - ❖ Claims submitted with one or two claim lines will be denied.
  - Provider must submit an invoice for reimbursement.
  - This process will ensure that the total reimbursement paid for the three claim lines is no more than provider submitted invoice paid price.
  - Zynteglo must be billed on its own with no other drug or biologics.

3. Providers are advised to take the following steps in order to ensure that Zynteglo claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Zynteglo “on the “Remarks” section of the *UB-04* claim form (Field 80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006››

- ‹‹Electronic claims may be identified by notation of ‘Zynteglo’ on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.

4. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for Zynteglo shall be one dose (three units) in a lifetime reimbursement under J3393 or any other code (HCPCS, CPT or by NDC).
6. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website,, forms section for completion of 837I and *UB-04* claim forms.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1		N4 11digitNDC	J3393	07/01/2024	1	933,333 33			1
2		N4 11digitNDC	J3393	07/01/2024	1	933,333 33			2
3		N4 11digitNDC	J3393	07/01/2024	1	933,333 34			3
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Figure 1: Betibeglogene autotemcel UB-04 Billing Example

- The total invoice cost of Zynteglo is $2,800,000.
- Note that each provider’s invoice cost may be different.
- If this is split evenly between the three lines, each claim line will have a total of $933,333.33.››

- ‹‹The sum of the three claim lines must equal the paid price on the invoice.

Note: It is not necessary to include the unit of measure qualifier and numeric quantity.

Required ICD-10-CM Diagnosis Codes

D56.1

Prescribing Restrictions

Frequency of billing is one treatment in a lifetime.

Location of Treatment Center

ZYNTEGLO is only available at Qualified Treatment Centers.››

Bevacizumab

Policy for intravitreal bevacizumab (HCPCS code J9035) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Bezlotoxumab (Zinplava™)

Bezlotoxumab is a human monoclonal antibody that binds to Clostridium difficile toxin B and neutralizes its effects.

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 J0565 (injection, bezlotoxumab, 10 mg).

Required ICD-10 Diagnosis Codes

A04.71 and A04.72.

Bimatoprost (Durysta™)

See *Ophthalmology* in the appropriate Part 2 manual for policy pertaining to bimatoprost and its corresponding procedure code.

‹‹Bivalirudin in Sodium Chloride Injection

Clinical Use Parameters

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

TAR Requirement

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

Billing

HCPCS code J0582 (injection, bivalirudin [endo], not therapeutically equivalent to J0583, 1 mg).››

Botulinum Toxins A and B

The botulinum toxins are a family of neurotoxins produced by various toxigenic strains of the gram-positive anaerobic bacterium *Clostridium botulinum* and are comprised of seven antigenically distinct serotypes (A to G). All botulinum neurotoxin serotypes produce their clinical effect of flaccid paralysis by blocking the release of acetylcholine from nerve endings.

Four botulinum toxin products have been approved by the U.S. Food and Drug Administration (FDA).

Three botulinum toxin serotype A products:

I. AbobotulinumtoxinA (Dysport)

II. IncobotulinumtoxinA (Xeomin)

III. OnabotulinumtoxinA (Botox, Botox Cosmetic)

One botulinum toxin serotype B product:

IV. RimabotulinumtoxinB (Myobloc)

A significant difference within botulinum toxin type A serotypes is that the units are not interchangeable between the two FDA-approved products, as there is no common international standard methodology for assaying units within the botulinum toxin serotypes. Therefore, one unit of abobotulinumtoxinA is not equivalent to one unit of onabotulinumtoxinA or incobotulinumtoxinA. Similarly, the units of one botulinum toxin serotype cannot be converted into units of any other botulinum toxin serotype as there is no common international standard methodology for assaying units among the different botulinum toxin serotypes. Consequently, neither the units of abobotulinumtoxinA, onabotulinumtoxinA are interchangeable with rimabotulinumtoxinB. The dosage of any botulinum toxin product must be individualized to each specific patient based upon many factors including, but not limited to, size of the muscles to be injected, the number of muscles to be injected, body weight, the condition being treated, expected patient response, and general health of the patient. Standard doses do not exist.

Authorization

Medical necessity must be established and an approved *Treatment Authorization Request* (TAR) is required for the reimbursement of any of the four botulinum toxins.

Note: The use of botulinum toxins for cosmetics indications is not considered medically necessary and is therefore not a benefit. The least expensive medically necessary option must be used unless supplemental documentation strongly supports the use of the higher cost product.

Billing

Due to the short half-life of the botulinum toxins, Medi-Cal will reimburse the unused portion of the drug only when vials are not split between patients. Scheduling of more than one patient is encouraged to prevent wastage of drug. If a vial is split between two or more patients, the billing must be for the exact amount of drug administered to each individual patient.

AbobotulinumtoxinA (Dysport)

AbobotulinumtoxinA is an acetylcholine release inhibitor and a neuromuscular blocking agent for intramuscular (IM) injection.

Indication

All FDA-approved non-cosmetic indications.

Dosage

FDA-approved dosages.

Authorization

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

The TAR must include clinical documentation of the following:

- The service is medically necessary.
- Alternative treatments (for example, physical therapy, oral medication[s], etc.) have been tried or considered, have failed and/or are contra-indicated.
- The physician's legible, complete and signed order, treatment plan and/or procedure note for abobotulinumtoxinA.

Billing

HCPCS code J0586 (injection, abobotulinumtoxinA, 5 units).

One (1) unit of J0586 equals five units of abobotulinumtoxinA.

Age Limit

Must be two years of age or older.

Prescribing Restrictions

Frequency of billing equals every 12 weeks.

Maximum billing unit(s) equals 1500 units.

IncobotulinumtoxinA (Xeomin)

IncobotulinumtoxinA is an acetylcholine release inhibitor and neuromuscular blocking agent for intramuscular intraglandular administration.

Indications

All FDA-approved non-cosmetic indications.

Dosage

FDA-approved dosages.

Authorization

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

The TAR must include clinical documentation of the following:

- The service is medically necessary.
- Conservative treatment (for example, physical therapy, oral medication[s], etc.) have been tried or considered, have failed or are contra-indicated.
- A doctor's written order, prescription, treatment plan and/or procedure note for the service requested.

Billing

HCPCS code J0588 (injection, incobotulinumtoxinA, 1 unit).

One (1) unit of J0588 equals 1 Unit of incobotulinumtoxinA.

Age Limit

Must be 18 years of age or older.

Prescribing Restrictions

Frequency of billing equals every 12 weeks.

Maximum billing unit(s) equals 400 units.

OnabotulinumtoxinA (Botox)

OnabotulinumtoxinA is an acetylcholine release inhibitor and a neuromuscular blocking agent for intramuscular, intradetrusor or intradermal administration.

Indication

All FDA-approved non-cosmetic indications.

Dosage

FDA-approved dosages.

Authorization

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

The TAR must establish medical necessity and should clearly state that the patient had been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition.

Age Limits

Must be two years of age or older.

Billing

HCPCS code J0585 (injection, onabotulinumtoxinA, 1 unit)

One (1) unit equals one unit of onabotulinumtoxinA.

Prescribing Restrictions

Frequency of billing equals every 12 weeks.

Maximum billing unit(s) equals 400 units.

RimabotulinumtoxinB (Myobloc)

RimabotulinumtoxinB is an active acetylcholine release inhibitor and neuromuscular blocking agent for intramuscular and intraglandular administration.

Indication

All FDA-approved indications.

Dosage

FDA-approved dosages.

Authorization

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

The TAR must establish medical necessity and it should be made clear that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J0587 (injection, rimabotulinumtoxinB, 100 units).

One (1) unit equals 100 units of rimabotulinumtoxinB.

Prescribing Restriction

Frequency of billing equals every 12 weeks.

Maximum billing unit(s) equals 5000 units.

Brexanolone (Zulresso™)

Zulresso contains brexanolone, a neuroactive steroid gamma-aminobutyric acid (GABA), a receptor positive modulator that is chemically identical to endogenous allopregnanolone. The mechanism of action of brexanolone in the treatment of Postpartum Depression (PPD) in adults is not fully understood but is thought to be related to its positive allosteric modulation of GABAA receptors.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

A TAR may be approved with a diagnosis of postpartum depression and clinical documentation that shows the following:

- For FDA-approved indications and treatment regimens.
- Must be 18 years of age or older.

- Must be equal to or less than six months postpartum.
- Onset of symptoms was in the third trimester or within four weeks of delivery.
- Must be diagnosed with moderate to severe postpartum depression confirmed by Hamilton Rating Scale for Depression (HAM-D) equal to or greater than 20, or other comparable standardized rating scale.
- An adequate trial of at least two anti-depressants from two separate drug classes at an adequate dose and treatment duration was shown to be ineffective or produced untoward effects when used by the patient; or
- Must document why other alternatives are not adequate, effective or have been deemed to be clinically contraindicated for the individual patient.
  - Alternatives indicated for PPD include selective serotonin reuptake inhibitor (SSRI), serotonin-norepinephrine reuptake inhibitor (SNRI), tricyclic antidepressant (TCA), bupropion, or mirtazapine
- Must not have active psychosis.

Duration of Approval is for 30 days. Limited to one time use per pregnancy.

REMS Program

Zulresso is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zulresso REMS because excessive sedation or sudden loss of consciousness can result in serious harm.

Requirements of the Zulresso REMS include the following:

- Healthcare facilities must enroll in the program and ensure that Zulresso is only administered to patients who are enrolled in the Zulresso REMS.
- Pharmacies must be certified with the program and must only dispense Zulresso to healthcare facilities who are certified in the Zulresso REMS.
- Patients must be enrolled in the Zulresso REMS prior to administration of Zulresso.
- Wholesalers and distributors must be registered with the program and must only distribute to certified healthcare facilities and pharmacies.

Further information, including a list of certified healthcare facilities, is available at *www.zulressorems.com* or 1-844-472-4379.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1632 (injection, brexanolone,1 mg).

Prescribing Restrictions

Frequency of billing equals one time per pregnancy.

Bumetanide Injection

Bumetanide inhibits the reabsorption of sodium and chloride in the ascending loop of Henle and proximal renal tubule, which interferes with the chloride-binding cotransport system. This mechanism increases the excretion of water, magnesium phosphate, sodium chloride, magnesium phosphate, and calcium. It decreases both free water clearance and solute free water reabsorption increases sodium chloride excretion to the distal tubule (natriuresis), calciuria, phosphaturia, and minimal bicarbonaturia.

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 J1939 (injection, bumetanide, 0.5 mg).

Prescribing Restriction(s)

Frequency of billing equals 10 mg/20 units per day.

Maximum billing unit(s) equals 10 mg/20 units.

Bupivacaine Hydrochloride

Bupivacaine blocks the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination, and conduction velocity of affected nerve fibers. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone.

Epinephrine is a vasoconstrictor added to bupivacaine to slow absorption into the general circulation and thus prolong maintenance of an active tissue concentration.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code: J0665 (injection, bupivicaine, not otherwise specified, 0.5 mg).

‹‹Bupivacaine Liposome Injectable Suspension

Local anesthetics block the generation and the conduction of nerve impulses presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be six years of age or older.

Billing

HCPCS code J0666, (injection, bupivacaine liposome, 1 mg).

Prescribing Restriction(s)

Maximum billing unit(s) is equal to 266mg/266 units.››

Bupivacaine Solution (Posimir)

Bupivacaine blocks both the initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to sodium ions, which results in inhibition of depolarization with resultant blockade of conduction.

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 or older.
- Patient is scheduled for elective outpatient procedure.
- Patient is not undergoing a soft tissue procedure.
- Patient is not undergoing obstetrical paracervical block anesthesia.
- Patient is not a pregnant or lactating female.
- Patient is not on a long-term opioid or other analgesic therapy.
- Patient does not have a known hypersensitivity to local anesthetic agents (for example, lidocaine, bupivacaine, etc.).

Authorization is for three months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS Code: C9144, (injection, bupivacaine (posimir), 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 660 mg/660 units as a single dose.

Maximum billing unit(s) equals 660 mg/660 units.

Buprenorphine (BRIXADI™)

BRIXADI contains buprenorphine, a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor.

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 codes:

J0577 (injection, buprenorphine extended release [brixadi], less than or equal to 7 days of therapy).

J0578 (injection, buprenorphine extended-release [brixadi], greater than 7 days and up to 28 days of therapy).

Suggested ICD-10-CM Diagnosis Codes

F11.20, F11.21, F11.220, F11.221, F11.222, F11.229, F11.23, F11.24, F11.250, F11.251, F11.259, F11.281, F11.282, F11.288, F11.29

Prescribing Restrictions

Frequency of billing:

- J0577: 3 syringes (up to 32 mg total dose)/3 units per week.
- J0578: 2 syringes (up to 128 mg total dose)/2 units per month.

Maximum billing units:

- J0577: 3 syringes (up to 32 mg total dose).
- J0578: 2 syringes (up to 128 mg total dose).

Buprenorphine Extended Release

Buprenorphine extended-release injection is a partial opioid agonist for subcutaneous (SQ) administration. The extended-release formulation delivers buprenorphine at a controlled rate over a one-month period.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Authorization

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

Note: Sublocade is available only through a restricted distribution program called the Sublocade Risk Evaluation and Mitigation Strategy (REMS) Program because of the risk of serious harm or death that could result from intravenous self-administration. This requires that all healthcare settings and pharmacies that dispense it must be certified in the REMS program. Healthcare providers, healthcare settings, and pharmacies must obtain Sublocade through a restricted distribution program and the medication should never be dispensed directly to a patient.

Required ICD-10-CM Code

F11.20 (opioid dependence, uncomplicated).

F11.21 (opioid dependence, in remission).

Billing

HCPCS code Q9991 (injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg).

One (1) unit of Q9991 equals 100 mg or less of buprenorphine extended-release solution.

HCPCS code Q9992 (injection, buprenorphine extended-release (sublocade), greater than 100 mg).

One (1) unit of Q9992 equals greater than 100 mg of buprenorphine extended-release solution.

Burosumab-twza (Crysvita®)

Burosumab-twza is a fibroblast growth factor 23 (FGF23) blocking antibody. X-linked hypophosphatemia is caused by excess fibroblast growth factor 23 (FGF23) which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D. Burosumab-twza binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Crysvita will be considered medically necessary if the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens.
- Patient must be six months of age or older for XLH or two years and older for TIO.
- Patient must have a diagnosis of X-linked hypophosphatemia (XLH) confirmed by:
  - Genetic testing (PHEX mutation) of patient or family member with X-linked inheritance; or
  - Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL; or
- Patient must have a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized.
- Must confirm baseline fasting serum phosphorus level is below the reference range for patient age before initiating burosumab.
- Must not be given in combination with oral phosphate and calcitriol or other activated vitamin D metabolites (paricalcitol, doxercalciferol, calcifediol, or alfacalcidol).
- Patient must not have severe renal impairment (defined as glomerular filtration rate (GFR) of less than 30 mL/min.
- Patient must discontinue oral phosphate and/or active vitamin D analogs (for example., calcitriol, paricalcitol, doxercalciferol, calcifediol) at least one week prior to treatment.
- Provider to monitor serum 25-hydroxy vitamin D levels; and supplement with cholecalciferol or ergocalciferol to maintain levels in the normal range for age as necessary.

Initial approval is for 12 months.

Continued therapy:

- Patient continues to meet the initial approval criteria.
- Patient has shown a clinically significant improvement in serum phosphate level.
- Patient's serum phosphorus level is not above the upper limit of the laboratory normal reference range.
- Patient has shown a positive clinical response or stabilization of disease.

Reauthorization is for 12 months.

Age Limit

Must be six months of age or older for XLH or two years and older for TIO.

Billing

HCPCS code J0584 (injection, burosumab-twza, 1 mg)

Suggested ICD-10-CM Diagnosis Codes

E83.31

Prescribing Restriction(s)

Frequency of billing equals 180 mg/180 units every two weeks.

Maximum billing unit(s) equals 180 mg/180 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.
*	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
∞	Represents a majority of authorized networks of full-line wholesalers that are eligible to inventory Cabenuva provided they service eligible class of trade.