Cigna Drug and Biologic Coverage Policy

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Subject **Pharmacy Prior Authorization**

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

[Note: Cigna maintains individual and/or group topic Coverage Policies and Pharmacy Benefit Clinical Criteria describing medical necessity criteria under pharmacy benefit plans. Use the Pharmacy Index search box with a specific product name to locate additional coverage policies and clinical criteria.]

Cigna covers drugs and biologics, in accordance with benefit plan specifications, as medically necessary when both of the following criteria are met:

- **One of the following:**
  - Indication for use is approved and listed in the FDA product information (Label) and the dosage, frequency, site of administration, and duration of therapy is not contraindicated or otherwise not recommended in the Label, OR
  - Indication is a supported use, according to the American Hospital Formulary Service (AHFS) compendium and is not contraindicated in the Label.

- **And where available, use of therapeutic alternatives**
  - Unless otherwise specified or clinically inappropriate, prior use of all formulary or covered alternatives meets criteria, unless there are more than five alternatives available, where five will be the maximum required number of alternatives

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature

and adjusted based upon severity, alternative available treatments, and previous response to therapy as applicable.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage

Cigna does not cover the use for any other indication because it is considered experimental, investigational or unproven.

***If you're a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.**

Specific Prior Authorization Criteria:

Drug	Criteria
Clomiphene	For female fertility use: Coverage may be excluded under certain benefit plans. Please review benefit plan for details of specific coverage, including quantity or cycle limitations. For male fertility and any other uses: Cigna does not cover the use for any other indication because it is considered experimental, investigational or unproven.
Evenity™ (romosozumab)	**ALL** of the following: • Treatment of osteoporosis in a postmenopausal woman at high risk for fractures defined as ANY of the following: o History of fragility (non-traumatic) or osteoporotic fracture o Bone mineral density (BMD) T-score less than or equal to -2.5 or lower in the lumbar spine, femoral neck, total hip, and/or 33% (one third) radius [wrist] o T-score between –1.0 and –2.5 if the FRAX® 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3% • Documented **EITHER** of the following: o Failure / Inadequate response to at least **ONE** oral **OR** intravenous bisphosphonate product (for example, osteoporotic fracture while receiving bisphosphonate therapy, ongoing loss of BMD, lack of continued BMD increase) o Contraindication per FDA label, intolerance, inability to take, or not a candidate for oral **AND** intravenous bisphosphonate therapy • Individual will not exceed lifetime maximum of 12 monthly doses of treatment • No concomittant use with any other osteoporosis agent other than a bisphosphonate
Fensolvi®* (leuprolide acetate suspension for subcutaneous injection)	Criteria is met by the following: • Individual is 2 years of age or older • Treatment of children with central precocious puberty (CPP) with onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males • Confirmation of diagnosis as defined by **ONE** of the following: o Pubertal basal level of luteinizing hormone (LH) greater than or equal to 0.3 mIU/ml o Pubertal luteinizing hormone (LH) response to GnRH stimulation testing
Lupaneta Pack™ (leuprolide acetate for depot suspension and norethindrone acetate tablets)	Criteria is met by the following: • Management of endometriosis
Lupron Depot®*	Criteria is met by **EITHER** of the following:

Drug	Criteria
(leuprolide acetate for depot suspension)	• Treatment of uterine fibroids or leiomyomata (3.75 mg and 11.25 mg ONLY) • Management of endometriosis (3.75 mg and 11.25 mg ONLY)
Lupron Depot-PED®* (leuprolide acetate for depot suspension)	Criteria is met by the following: • Treatment of central precocious puberty (CPP) with onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males • Confirmation of diagnosis as defined by **ONE** of the following: o Pubertal basal level of luteinizing hormone (LH) greater than or equal to 0.3 mIU/ml o Pubertal luteinizing hormone (LH) response to GnRH stimulation testing
Leuprolide acetate*	Criteria is met by the following: • Use as a stimulation test to confirm a diagnosis of central precocious puberty prior to initiation of treatment
Myalept® (metreleptin)	Criteria is met by **EITHER** of the following: • Documented diagnosis of congenital lipodystrophy as demonstrated by one gene mutation (AGPAT2, BSCL2, CAV1, PTRF) OR • Documented diagnosis of Lawrence Syndrome (acquired lipodystrophy)
Natpara® (parathyroid hormone)	Criteria is met by **BOTH** of the following: • Diagnosis of hypoparathyrodism in an adult (>18 yrs) not well controlled on calcium supplements and active forms of vitamin D, AND • Individual is taking concomitant calcium and vitamin D supplements
Nocdurna® (desmopressin acetate sublingual tablet)	All of the following: • Individual is 18 years of age or older • Documented nocturnal polyuria confirmed by 24-hour urine collection • Awaking at least 2 times per night to void • All underlying causes of nocturia (including medical or pharmacologic induced) have been ruled out or are being treated and, despite documented treatment and treatment failure, symptoms still persist: [for example] Benign Prostatic Hyperplasia, Overactive Bladder, Postmenopausal Genitourinary Syndrome • No concurrent use of loop diuretics or systemic or inhaled glucocorticoids
Noctiva™ (desmopressin acetate nasal spray)	Treatment of nocturia when all of the following are met: • Individual is at least 50 years of age • Documented nocturnal polyuria confirmed by 24-hour urine collection • Awaking at least 2 times per night to void • All underlying causes of nocturia (including medical or pharmacologic induced) have been ruled out or are being treated and, despite documented treatment and treatment failure, symptoms still persist: [for example] Benign Prostatic Hyperplasia, Overactive Bladder, Postmenopausal Genitourinary Syndrome • No concurrent use of loop diuretics or systemic or inhaled glucocorticoids
Northera™ (droxidopa)	Criteria is met by the following diagnosis: • Treatment of symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure associated with one of the following conditions: o Parkinson's disease (PD) o Multiple system atrophy and pure autonomic failure] o Dopamine beta-hydroxylase deficiency o Non-diabetic autonomic neuropathy
Nityr™ (nitisinone)	Criteria is met by the following diagnosis: • Hereditary tyrosinemia type 1
Nuzyra™ (omadacycline)	Criteria is met by the following: • 18 years of age and older • ONE of the following: o Continuation of therapy started in the hospital

Drug	Criteria
	o Treatment of community-acquired bacterial pneumonia (CABP) and documented failure, contraindication, intolerance, or not a candidate for appropriate first-line therapy [a macrolide, doxycycline, moxifloxacin, gemifloxacin, levofloxacin, beta-lactam plus a macrolide] Treatment of acute bacterial skin and skin structure infections (ABSSSI) -AND- documented failure, contraindication, intolerance, or not a candidate for appropriate first-line therapy [ceftriaxone, cefazolin, cephalexin, clindamycin, linezolid, piperacillin-tazobactam, vancomycin]
Orfadin® (nitisinone)	Criteria is met by **BOTH** of the following: • Diagnosis of Hereditary tyrosinemia type 1 • Documented inability to use Nityr (nitisinone tablets).
Otrexup™ (methotrexate)	Criteria is met by the following: • Unable to use generic oral or injectable methotrexate **AND** Rasuvo
Oxandrin® (oxandrolone)	Criteria is met by the following: • Adjunctive therapy to promote weight gain after weight loss: o Following extensive surgery OR o Chronic infections OR o Severe trauma OR o In some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight OR o To offset the protein catabolism associated with prolonged administration of corticosteroid OR o Relief of the bone pain frequently accompanying osteoporosis
Pulmozyme® (dornase alfa)	Criteria is met by the following: • To improve pulmonary function in cystic fibrosis (CF)
Rasuvo™ (methotrexate)	Criteria is met by the following: • Unable to use generic oral or injectable methotrexate
Regranex® (becaplermin)	Criteria is met by the following: • For adjunct treatment of a diabetic neuropathic ulcer of the lower extremity extending into the subcutaneous tissue or beyond
Signifor® (pasireotide)	Criteria is met by **BOTH** of the following: • Documented diagnosis of Cushing's disease in an adult AND • Individual is not candidate for pituitary surgery or previous surgery has not been curative
Signifor LAR® (pasireotide) †may require pre certification if covered under medical benefit OR may require prior authorization if covered under pharmacy benefit	Criteria is met by **BOTH** of the following: • Documented diagnosis of acromegaly in an adult AND • Individual is not candidate for pituitary surgery or response to surgery has been inadequate
Sirturo® (bedaquiline)	Criteria is met by **ALL** of the following: • Individual is an adult (age 18 years and older) • Diagnosis of pulmonary multi-drug resistant tuberculosis • Will be used as part of combination therapy with at least 3 other antimycobacterial drugs • Will be administered by directly observed therapy (DOT)
Somavert® (pegvisomant)	Criteria is met by the following: • Treatment of acromegaly when there is an inadequate response to surgery or radiation therapy, or when these therapies are not appropriate or contraindicated
Syndros® (dronabinol oral solution)	Criteria is met by the following: • Documented inability to use oral dronabinol capsules

Drug	Criteria
Thalomid® (thalidomide)	Criteria is met by the following: • For treatment of cutaneous manifestations of erythema nodosum leprosum (ENL)
Tiglutik™ (riluzole)	Criteria is met by **BOTH** of the following: • Documented diagnosis of amyotrophic lateral sclerosis (ALS) Documented intolerance or inability to swallow riluzole tablets
Xenazine® (tetrabenazine)	Criteria is met by **ANY** of the following: • Documented diagnosis of Huntington's disease chorea OR • Documented diagnosis of tardive dyskinesia OR • Documented diagnosis of hyperkinetic movement disorder associated with Tourette's syndrome
Zoladex®** (goserelin)	Criteria is met by **EITHER** of the following: • Use in dysfunctional uterine bleeding • Management of endometriosis

***** *The use of leuprolide (Fensolvi, Lupron Depot) for oncology indications, infertility, and gender dysphoria are addressed in separate coverage policies. Please refer to the related coverage policy links above (Oncology Medications, Infertility Injectables, Treatment of Gender Dysphoria).*
*** The use of goserelin (Zoladex) for oncology indications is addressed in a separate coverage policy. Please refer to the related coverage policy link above (Oncology Medications).*

Therapeutic Categories Requiring Prior Authorization

Therapeutic Categories	Drug	Criteria
Antipsychotic	**Lithobid** (lithium)	Documented failure or intolerance to at least one generic formulation
Blood Thinners	**Coumadin** (warfarin)	Documented failure or intolerance to at least one generic formulation
Cardiovascular	**Lanoxin** (digoxin), **Norpace** (disopyramide phosphate), **Pacerone** (amiodarone), **Rythmol SR** (propafenone HCL ER),**Tikosyn** (dofetilide)	Documented failure or intolerance to at least one generic formulation
Seizure Disorders	**Carbatol, Depakene** (valproic acid), **Depakote, Depakote ER, Depakote sprinkle** (divalproex sodium), **Diastat, Diastat Acudial** (diazepam), **Dilantin, Dilantin-125, Phenytek** (phenytoin), **Felbatol** (felbamate), **Gabitril** (tiagabine hydrochloride), **Keppra, Keppra XR** (levetiracetam), **Klonopin** (clonazepam), **Lamictal, Lamictal XR, Lamictal ODT** (lamotrigine), **Mysoline** (primidone), **Neurontin** (gabapentin), **Tegretol, Tegretol XR** (carbamazepine), **Topamax** (topiramate), **Trileptal** (oxcarbazepine), **Zarontin** (ethosuximide), **Zonegran** (zonisamide)	Documented failure or intolerance to at least one generic formulation

General Background

Drugs intended for human use are evaluated by FDA's Center for Drug Evaluation and Research (CDER) to ensure that drugs marketed in the United States are safe and effective. Biological products are evaluated by FDA's Center for Biologics Evaluation and Research (CBER). Federal law generally requires that prescription drugs in the U.S. be shown to be both safe and effective prior to marketing for all indications or uses. FDA's

review of the applicant's labeling insures that health care professionals and patients have the information necessary to understand a drug product's risks and its safe and effective use.

Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence. This use is called “off-label” and the FDA generally allows an FDA-approved, marketed product used in this manner when the intent is the "practice of medicine".

Employers and health care organizations have an interest in promoting positive patient outcomes. One resource employed to achieve this goal is the medication prior authorization process. This process takes into consideration evidence of a particular medication’s efficacy and safety to promote appropriate utilization and thereby minimize waste and error.

Where Prior Authorization is a part of a pharmacy benefit plan, specific criteria must be met to promote appropriate use:

- Benefit plan coverage parameters, including medical necessity
- FDA approved indication(s) and accepted off-label uses
  - Accepted off-label uses in standard reference compendia (American Hospital Formulary Service Drug Information, AHFS) or
  - Critically appraised, published, peer-reviewed, English-language, biomedical literature supporting both efficacy and safety

The FDA approved indications and accepted off label uses for pharmacy products requiring prior authorization are listed in the table below.

Clomiphene
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Clomiphene citrate is indicated for the treatment of ovulatory dysfunction in women desiring pregnancy. AHFS reports that clomiphene citrate has been used alone or in combination with estrogens or menotropins for a variety of conditions including the following: menstrual abnormalities, gynecomastia, fibrocystic breat disease, oligospermia, persistent lactation, endometrial hyperplasia/ anaplasia, and menstrual cycle regulation for rhythm method of contraception. All studies were with limited patients and efficacy has not been estrablished for any of these uses.
FDA Recommended Dosing
Treatment of the selected patient should begin with a low dose, 50 mg daily (1 tablet) for 5 days. The dose should be increased only in those patients who do not ovulate in response to cyclic 50 mg clomiphene citrate. A low dosage or duration of treatment course is particularly recommended if unusual sensitivity to pituitary gonadotropin is suspected, such as in patients with polycystic ovary syndrome (see WARNINGS; Ovarian Hyperstimulation Syndrome). The patient should be evaluated carefully to exclude pregnancy, ovarian enlargement, or ovarian cyst formation between each treatment cycle. If progestin-induced bleeding is planned, or if spontaneous uterine bleeding occurs prior to therapy, the regimen of 50 mg daily for 5 days should be started on or about the 5th day of the cycle. Therapy may be started at any time in the patient who has had no recent uterine bleeding. When ovulation occurs at this dosage, there is no advantage to increasing the dose in subsequent cycles of treatment. If ovulation does not appear to occur after the first course of therapy, a second course of 100 mg daily (two 50 mg tablets given as a single daily dose) for 5 days should be given. This course may be started as early as 30 days after the previous one after precautions are taken to exclude the presence of pregnancy. Increasing the dosage or duration of therapy beyond 100 mg/day for 5 days is not recommended.

The majority of patients who are going to ovulate will do so after the first course of therapy. If ovulation does not occur after three courses of therapy, further treatment with clomiphene citrate is not recommended and the patient should be reevaluated. If three ovulatory responses occur, but pregnancy has not been achieved, further treatment is not recommended. If menses does not occur after an ovulatory response, the patient should be reevaluated. Long-term cyclic therapy is not recommended beyond a total of about six cycles (see PRECAUTIONS).

Evenity

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Limation of Use: The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered

FDA Recommended Dosing

The recommended dose of Evenity is 210 mg administered subcutaneously in the abdomen, thigh or upper arm. Administer Evenity once every month.

Two separate syringes (and two separate subcutaneous injections) are needed to administer the total dose of 210 mg of Evenity. Inject two 105 mg/1.17 mL prefilled syringes, one after the other.

The treatment duration for Evenity is 12 monthly doses.

Patients should be adequately supplemented with calcium and vitamin D during treatment with Evenity.

Evenity should be administered by a healthcare provider.

Lupaneta Pack

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Lupaneta Pack (leuprolide acetate for depot suspension and norethindrone acetate tablets) is indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Limitation of Use: Duration of use is limited due to concerns about adverse impact on bone mineral density. The initial treatment course of Lupaneta Pack is limited to six months. A single retreatment course of not more than six months may be administered after the initial course of treatment if symptoms recur. Use of Lupaneta Pack for longer than a total of 12 months is not recommended.

FDA Recommended Dosing

Lupaneta Pack is a co-packaging of leuprolide acetate for depot suspension for intramuscular use and norethindrone acetate tablets for oral use. Administer as follows:

- 3.75 mg of leuprolide acetate by intramuscular injection once a month for up to six injections(6 months of therapy); to be administered by a healthcare provider
- 5 mg of norethindrone acetate orally once daily for up to 6 months of therapy

The initial course of treatment with leuprolide acetate for depot suspension 3.75 mg in combination with norethindrone acetate 5 mg daily is not to exceed six months.

If the symptoms of endometriosis recur after the initial course of therapy, consider retreatment with Lupaneta Pack for up to another six months. It is recommended that bone density be assessed before retreatment begins.

Treatment beyond two six-month courses has not been studied and is not recommended due to concerns about adverse impact on bone mineral density.

leuprolide acetate, Lupron Depot, Lupron Depot-PED, Fensolvi

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

- Central Precocious Puberty (CPP)

Leuprolide acetate injection is indicated in the treatment of children with central precocious puberty. Children should be selected using the following criteria:

1. Clinical diagnosis of CPP (idiopathic or neurogenic) with onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males.
2. Clinical diagnosis should be confirmed prior to initiation of therapy:
   - o Confirmation of diagnosis by a pubertal response to a GnRH stimulation test. The sensitivity and methodology of this assay must be understood.
   - o Bone age advanced 1 year beyond the chronological age.
3. Baseline evaluation should also include:
   - Height and weight measurements.
   - Sex steroid levels.
   - Adrenal steroid level to exclude congenital adrenal hyperplasia.
   - Beta human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor.
   - Pelvic/adrenal/testicular ultrasound to rule out a steroid secreting tumor.
   - Computerized tomography of the head to rule out intracranial tumor.

Fensolvi is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Lupron Depot-PED is indicated in the treatment of children with central precocious puberty (CPP).

CPP is defined as early onset of secondary sexual characteristics (generally earlier than 8 years of age in girls and 9 years of age in boys) associated with pubertal pituitary gonadotropin activation. It may show a significantly advanced bone age that can result in diminished adult height.
Prior to initiation of treatment a clinical diagnosis of CPP should be confirmed by measurement of blood concentrations of luteinizing hormone (LH) (basal or stimulated with a GnRH analog), sex steroids, and assessment of bone age versus chronological age. Baseline evaluations should include height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroid measurements to exclude congenital adrenal hyperplasia.

- Prostate Cancer

Leuprolide acetate injection is indicated in the palliative treatment of advanced prostatic cancer.

Lupron Depot 7.5 mg for 1-month administration, 22.5 mg for 3-month administration, 30 mg for 4-month administration, and 45 mg for 6-month administration (leuprolide acetate) are indicated in the palliative treatment of advanced prostatic cancer.

- Endometriosis

Lupron Depot 3.75 mg and 3 month 11.25 mg are indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot with norethindrone acetate 5 mg daily is also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment or retreatment should be limited to 6 months.

- Uterine Leiomyomata

Lupron Depot 3.75 mg concomitantly with iron therapy is indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron may be added if the response to iron alone is considered inadequate.
Recommended duration of therapy with Lupron Depot 3.75 mg is up to three months. Experience with Lupron Depot in females has been limited to women 18 years of age and older.
Recommended therapy is a single injection of Lupron Depot–3 Month 11.25 mg. This dosage form is indicated only for women for whom three months of hormonal suppression is deemed necessary.

Experience with Lupron Depot–3 Month 11.25 mg in females has been limited to women 18 years of age and older treated for no more than 6 months.

Accepted AHFS Off Label Use - Breast Cancer

FDA Recommended Dosing

CPP: Fensolvi must be administered by a healthcare professional. The dose of Fensolvi is 45 mg administered by subcutaneous injection once every six months. Discontinue Fensolvi treatment at the appropriate age of onset of puberty.

CPP: Lupron Depot-PED is administered as a single intramuscular injection. The starting dose 7.5 mg, 11.25 mg, or 15 mg for 1-month administration is based on the child's weight.

CPP: Lupron Depot-PED is administered as a single intramuscular injection. The doses are either 11.25 mg or 30 mg for 3-month administration.

Refer to Appendix A for weight based dosing detail

Palliative treatment of advanced prostatic cancer:
Lupron Depot 7.5 mg for 1-month administration, given as a single intramuscular injection every 4 weeks.

Lupron Depot 22.5 mg for 3-month administration, given as a single intramuscular injection every 12 weeks.

Lupron Depot 30 mg for 4-month administration, given as a single intramuscular injection every 16 weeks.

Lupron Depot 45 mg for 6-month administration, given as a single intramuscular injection every 24 weeks.

Endometriosis:
Lupron Depot 3.75mg

Uterine leiomyomata: Lupron Depot 3.75mg

Myalept

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.
Limitations of use:
The safety and effectiveness of Myalept for the treatment of complications of partial lipodystrophy have not been established. The safety and effectiveness of Myalept for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH) have not been established. Myalept is not indicated for use in patients with HIV-related lipodystrophy. Myalept is not indicated for use in patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy.

FDA Recommended Dosing

The recommended daily dosages are:
Body weight 40 kg or less: starting dose 0.06 mg/kg/day, increase or decrease by 0.02 mg/kg to a maximum daily dose of 0.13 mg/kg.
Males greater than 40 kg body weight: starting dose 2.5 mg/day, increase or decrease by 1.25 mg to 2.5 mg/day to a maximum dose of 10 mg/day.

Natpara

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.
Limitations of Use:
Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone.

Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations
Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

FDA Recommended Dosing

The starting dose of Natpara is 50 mcg injected once daily in the thigh. When starting, decrease dose of active vitamin D by 50%, if serum calcium is above 7.5 mg/dL.

Nocdurna

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Nocdurna is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

In the Nocdurna clinical trials nocturnal polyuria was defined as night-time urine production exceeding one-third of the 24-hour urine production.

Before starting Nocdurna:

- Evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and address other treatable causes of nocturia.
- Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.

FDA Recommended Dosing

The recommended Nocdurna dosage in:

- Women is 27.7 mcg once daily, one hour before bedtime, administered sublingually without water.
- Men is 55.3 mcg once daily, one hour before bedtime, administered sublingually without water.

The recommended dose for women is lower than for men because women are more sensitive to the effects of Nocdurna and had a higher risk of hyponatremia with the 55.3 mcg dose in clinical trials.

Noctiva

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Noctiva is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Nocturnal polyuria was defined in the Noctiva clinical trials as night-time urine production exceeding one-third of the 24-hour urine production.

Before starting Noctiva:

- Evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and optimize the treatment of underlying conditions that may be contributing to the nocturia.
- Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.

Limitation of Use: Noctiva has not been studied in patients less than 50 years of age.

FDA Recommended Dosing

For patients younger than 65 years of age who are not at increased risk for hyponatremia:

- The recommended dose is one spray of Noctiva 1.66 mcg in either the left or right nostril approximately 30 minutes before going to bed.

For patients 65 years of age, or younger patients at increased risk for hyponatremia:

- The recommended starting dose is one spray of Noctiva 0.83 mcg in either the left or right nostril approximately 30 minutes before going to bed.
- After at least 7 days of treatment, the dose can be increased to 1.66 mcg, if needed, provided the serum sodium is within the normal range during treatment with the 0.83 mcg dose.
- The 0.83 mcg dose did not meet all prespecified efficacy endpoints in clinical trials but may have a lower risk of hyponatremia

Northera

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure [Parkinson's disease (PD), multiple system atrophy and pure autonomic failure], dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assessed periodically

FDA Recommended Dosing

Starting dose is 100 mg three times during the day.
Titrate by 100 mg three times daily, up to a maximum dose of 600 mg three times daily

Nityr

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

NITYR is indicated for the treatment of patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

FDA Recommended Dosing

Starting Dosage The recommended starting dosage of NITYR is 0.5 mg/kg orally twice daily. Round up to the nearest dosage that can be administered using the available tablet strengths

Titrate the dosage for individual patients, as needed based on biochemical and/or clinical response.

Dosage Titration

- Monitor plasma and/or urine succinylacetone concentrations, liver function parameters and alphafetoprotein levels.
- If succinylacetone is still detectable one month after the start of nitisinone treatment, increase the nitisinone dosage to 0.75 mg/kg twice daily. A maximum dosage of 1 mg/kg orally twice daily may be needed based on the evaluation of all biochemical parameters. Round up to the nearest dosage that can be administered using the available tablet strengths.
- If the biochemical response is satisfactory, the dosage should be adjusted only according to body weight gain.
- During the initiation of therapy or if there is a deterioration in the patient's condition, it may be necessary to follow all available biochemical parameters more closely (i.e., plasma succinylacetone, urine 5-aminolevulinate (ALA) and erythrocyte porphobilinogen (PBG)-synthase activity).

Nuzyra

FDA Approved Indication/Accepted AHFS Off Label Uses (if available)

Community-Acquired Bacterial Pneumonia (CABP)
Nuzyra is indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
Nuzyra is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae.

Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Nuzyra and other antibacterial drugs, Nuzyra should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of

such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

FDA Recommended Dosing

Infection	Loading Doses	Maintenance Dose
CABP	Day 1: 200 mg by intravenous infusion over 60 minutes OR 100 mg by intravenous infusion over 30 minutes twice	100 mg by intravenous infusion over 30 minutes once daily OR 300 mg orally once daily
ABSSSI	Day 1: 200 mg by intravenous infusion over 60 minutes OR 100 mg by intravenous infusion over 30 minutes twice OR	100 mg by intravenous infusion over 30 minutes once daily OR 300 mg orally once daily
ABSSSI (Nuzyra tablets only)	Day 1 and Day 2: 450 mg orally once daily	300 mg orally once daily

- CABP and ABSSSI: Treatment duration is 7 to 14 days.
- Fast for at least 4 hours and then take Nuzyra tablets with water. After oral dosing, no food or drink (except water) is to be consumed for 2 hours and no dairy products, antacids, or multivitamins for 4 hours.
- See full prescribing information for the preparation of NUZYRA IV and other administration instructions.

Orfadin

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

ORFADIN is indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

FDA Recommended Dosing

Starting Dosage

The recommended starting dosage of ORFADIN is 0.5 mg/kg administered orally twice daily

Maintenance Regimen

In patients 5 years of age and older who have undetectable serum and urine succinylacetone concentrations after a minimum of 4 weeks on a stable dosage of nitisinone, the total daily dose of ORFADIN may be given once daily (e.g., 1 to 2 mg/kg once daily)

Otrexup

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), or children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).

Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis “flare” is not due to an undiagnosed concomitant disease affecting immune responses.
Limitations of Use:
Otrexup is not indicated for the treatment of neoplastic diseases.

FDA Recommended Dosing

Recommended starting doses of methotrexate:
Adult RA: 7.5 mg once weekly

pJIA: 10 mg/m2 once weekly

Psoriasis: 10 to 25 mg once weekly of an oral, intramuscular, subcutaneous, or intravenous formulation

Adjust dose gradually to achieve an optimal response

Oxandrin
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Indicated as adjunctive therapy to promote weight gain after weight loss: • following extensive surgery • chronic infections • severe trauma • in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight • to offset the protein catabolism associated with prolonged administration of corticosteroid • relief of the bone pain frequently accompanying osteoporosis
FDA Recommended Dosing
The daily adult dosage is 2.5mg to 20 mg given in 2 to 4 divided doses. For children the total daily dosage is ≤0.1 mg per kilogram body weight or ≤0.045 mg per pound of body weight.
Pulmozyme
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Daily administration of Pulmozyme in conjunction with standard therapies is indicated in the management of cystic fibrosis (CF) patients to improve pulmonary function. In patients with a forced vital capacity (FVC) >40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics. Safety and efficacy of daily administration have not been demonstrated in patients for longer than 12 months.
FDA Recommended Dosing
The recommended dosage is one 2.5 mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration.
Rasuvo
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), or children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose nonsteroidal anti-inflammatory agents (NSAIDs). Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis “flare” is not due to an undiagnosed concomitant disease affecting immune responses. Limitations of use” Rasuvo is not indicated for the treatment of neoplastic diseases.
FDA Recommended Dosing
Recommended starting dose of methotrexate: Adult RA: 7.5 mg once weekly of an oral or subcutaneous formulation pJIA: 10 mg/m2 once weekly Psoriasis: 10 to 25 mg once weekly of an oral, intramuscular, subcutaneous, or intravenous formulation Adjust dose gradually to achieve an optimal response
Signifor
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Indicated for the treatment of adult patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative

Accepted AHFS Off Label Use - In combination with other medical therapies for treatment of Cushing's disease

FDA Recommended Dosing

Recommended initial dosage is either 0.6 mg or 0.9 mg by subcutaneous injection twice a day; recommended dosage range is 0.3 mg to 0.9 mg twice a day.

Signifor LAR

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.

FDA Recommended Dosing

The recommended initial dose is 40 mg administered by intramuscular injection once every 4 weeks (every 28 days).

Sirturo

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Sirturo is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in the treatment of adults (18 years and older) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided. Administer Sirturo by directly observed therapy (DOT).

This indication is approved under accelerated approval based on time to sputum culture conversion [see *Clinical Studies (14)*]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitations of Use:

- Do not use SIRTURO for the treatment of:
  - Latent infection due to *Mycobacterium tuberculosis*
  - Drug-sensitive tuberculosis
  - Extra-pulmonary tuberculosis
  - Infections caused by non-tuberculous mycobacteria
- The safety and efficacy of Sirturo in the treatment of HIV infected patients with MDR-TB have not been established as clinical data are limited [see *Clinical Studies (14)*].

FDA Recommended Dosing

Administer Sirturo by directly observed therapy (DOT).

Recommended Dosage in Combination Therapy

Only use Sirturo in combination with at least 3 other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, Sirturo treatment may be initiated in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible. Refer to the prescribing information of the drugs used in combination with Sirturo.
The recommended dosage of Sirturo is 400 mg orally once daily for the first two weeks, followed by 200 mg orally three times per week (with at least 48 hours between doses) for 22 weeks (total duration of 24 weeks).

Somavert

FDA Approved Indication /Accepted AHFS Off Label Uses (if available)

Somavert is indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.

FDA Recommended Dosing

The recommended loading dose of Somavert is 40 mg given subcutaneously, under healthcare provider supervision. On the next day following the loading dose, instruct patients or their caregivers to begin daily subcutaneous injections of 10 mg of Somavert.

Titrate the dosage to normalize serum IGF-I concentrations (serum IGF-I concentrations should be measured every four to six weeks). The dosage should not be based on growth hormone (GH) concentrations or signs and symptoms of acromegaly. It is unknown whether patients who remain

symptomatic while achieving normalized IGF-I concentrations would benefit from increased Somavert dosage. • Increase the dosage by 5 mg increments every 4-6 weeks if IGF-I concentrations are elevated. • Decrease the dosage by 5 mg decrements every 4-6 weeks if IGF-I concentrations are below the normal range. The recommended dosage range is between 10 to 30 mg given subcutaneously once daily and the maximum daily dosage is 30 mg given subcutaneously once daily.
Tiglutik
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Indicated for the treatment of amyotrophic lateral sclerosis (ALS).
FDA Recommended Dosing
The recommended dosage for Tiglutik is 50 mg (10 mL) taken orally twice daily, every 12 hours. Tiglutik should be taken at least 1 hour before or 2 hours after a meal
Xenazine
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Indicated for the treatment of chorea associated with Huntington's disease Accepted AHFS Off Label Use - Other hyperkinetic movement disorders including tardive dyskinesia and limited experience in Tourette's syndrome
FDA Recommended Dosing
Individualization of dose with careful weekly titration is required. The 1st week's starting dose is 12.5 mg daily; 2nd week, 25 mg (12.5 mg twice daily); then slowly titrate at weekly intervals by 12.5 mg to a tolerated dose that reduces chorea. Maximum recommended single dose not to exceed 25 mg.
Zoladex
FDA Approved Indication /Accepted AHFS Off Label Uses (if available)
Stage B2-C Prostatic Carcinoma Zoladex is indicated for use in combination with flutamide for the management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate. Treatment with ZOLADEX and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy. Prostatic Carcinoma Zoladex is indicated in the palliative treatment of advanced carcinoma of the prostate. Endometriosis Zoladex is indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with ZOLADEX for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months. Endometrial Thinning Zoladex is indicated for use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. Advanced Breast Cancer Zoladex is indicated for use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women. The estrogen and progesterone receptor values may help to predict whether Zoladex therapy is likely to be beneficial.
FDA Recommended Dosing
Zoladex 3.6 mg should be administered subcutaneously every 28 days

Coding/Billing Information

Note: Drugs in the above table are typically covered under pharmacy benefit plans. Certain prescription drugs require an authorization for coverage to ensure that appropriate treatment regimens are followed. Medical drug coding and diagnosis codes, however, are generally not required for pharmacy claims submissions therefore this section is not in use.

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Covered when medically necessary when used to report Signifor LAR (pasireotide) under the medical benefit:

HCPCS Codes	Description
J2502	Injection, pasireotide long acting, 1 mg

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APPENDIX A
Lupron Depot PED

Body Weight	Recommended Dose
≤25 kg	7.5 mg
>25-37.5 kg	11.25 mg
>27.5 kg	15 mg

Regranex

The amount of Regranex Gel to be applied will vary depending upon the size of the ulcer area. To calculate the length of gel to apply to the ulcer, measure the greatest length of the ulcer by the greatest width of the ulcer in either inches or centimeters. To calculate the length of gel in inches or centimeters, use the formula shown below :

Tube Size	Formula
15 g tube	Inches= length X width X 0.6
15 g tube	Centimeters= length X width ÷ 4