



Luteinizing Hormone Releasing-Hormone (LHRH) Analogs

Policy Number: M-0039

Zoladex (goserelin acetate)
Supprelin LA/Vantas (histrelin acetate)
Eligard/Lupron/Lupron Depot (leuprolide acetate)
Trelstar/Trelstar Depot/Trelstar LA (triptorelin Pamoate)

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

Goserelin:

FDA

1. Breast cancer, For palliation of advanced disease in pre- and peri-menopausal women
2. Endometriosis
3. Hypoplasia of endometrium
4. Prostate cancer, Advanced (palliative treatment)
5. Prostate cancer, In combination with flutamide for locally confined stage B2-C disease

Off-Label

1. Breast cancer, Adjuvant treatment of hormone receptor-positive, axillary lymph node-positive disease in premenopausal women
2. Carcinoma of pancreas
3. Chronic pelvic pain of female
4. Dysfunctional uterine bleeding
5. In vitro fertilization
6. Ovarian cancer
7. Precocious puberty
8. Prostate cancer
9. Uterine leiomyoma

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Histrelin:

FDA:

1. Carcinoma of prostate, Palliative treatment, advanced disease
2. Central precocious puberty

Off-Label:

1. Acute intermittent porphyria
2. Endometriosis
3. Female infertility; Adjunct
4. Polycystic ovary syndrome
5. Uterine leiomyoma

Leuprolide:

FDA:

1. Anemia - Uterine leiomyoma, Preoperatively, with iron therapy
2. Central precocious puberty
3. Endometriosis
4. Prostate cancer, Advanced (palliative treatment)

Off-Label:

1. ACTH-dependent Cushing's syndrome
2. Amenorrhea, Induction
3. Breast cancer
4. Catamenial pneumothorax
5. Female infertility
6. Growth hormone deficiency
7. Hypersexuality state
8. In vitro fertilization
9. Irritable bowel syndrome
10. Malignant neoplasm of endometrium of corpus uteri
11. Ovarian cancer
12. Premenstrual syndrome



13. Prostate cancer
14. Prostate cancer, Neoadjuvant treatment
15. Uterine leiomyoma

Triptorelin:

FDA

1. Carcinoma of prostate, Palliative treatment, advanced disease

Off-Label

1. Carcinoma of pancreas
2. Central precocious puberty
3. Endometrial hyperplasia
4. Endometriosis
5. Fibrocystic breast changes
6. Growth hormone deficiency
7. Hyperandrogenization syndrome
8. In vitro fertilization
9. Ovarian carcinoma
10. Short stature disorder, Idiopathic
11. Uterine leiomyoma

Coding Information:

HCPCS Code(s)

11981	INSERTION, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
11982	REMOVAL, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
11983	REMOVAL WITH REINSERTION, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
96402	CHEMOTHERAPY ADMINISTRATION, SUBCUTANEOUS OR INTRAMUSCULAR; HORMONAL ANTI-NEOPLASTIC



J1675	INJECTION, HISTRELIN ACETATE, 10 MICROGRAMS
J1950	INJECTION, LEUPROLIDE ACETATE (FOR DEPOT SUSPENSION), PER 3.75 MG
J3315	INJECTION, TRIPTORELIN PAMOATE, 3.75 MG
J9202	GOSERELIN ACETATE IMPLANT, PER 3.6 MG
J9217	LEUPROLIDE ACETATE (FOR DEPOT SUSPENSION), 7.5 MG
J9218	LEUPROLIDE ACETATE, PER 1 MG
J9219	LEUPROLIDE ACETATE IMPLANT, 65 MG
J9225	HISTRELIN IMPLANT (VANTAS), 50 MG
J9226	HISTRELIN IMPLANT (SUPPRELIN LA), 50 MG

ICD-9 Code(s) Note: ICD-9 codes must be coded to the highest level of specificity.

J1950 (Injection, leuprolide acetate (for depot suspension), per 3.75 mg)

174.0 - 174.6	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF AXILLARY TAIL OF FEMALE BREAST
174.8 - 174.9	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST
175.9	MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
218.0 - 218.2	SUBMUCOUS LEIOMYOMA OF UTERUS - SUBSEROUS LEIOMYOMA OF UTERUS
218.9	LEIOMYOMA OF UTERUS UNSPECIFIED

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617.0 - 617.6	ENDOMETRIOSIS OF UTERUS - ENDOMETRIOSIS IN SCAR OF SKIN
617.8 - 617.9	ENDOMETRIOSIS OF OTHER SPECIFIED SITES - ENDOMETRIOSIS SITE UNSPECIFIED
V10.3	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST

J3315 (Injection, triptorelin pamoate, 3.75 mg)

185	MALIGNANT NEOPLASM OF PROSTATE
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

J9202 (Goserelin acetate implant, per 3.6 mg)

174.0 - 174.6	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF AXILLARY TAIL OF FEMALE BREAST
174.8 - 174.9	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST
175.9	MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
185	MALIGNANT NEOPLASM OF PROSTATE
218.0 - 218.2	SUBMUCOUS LEIOMYOMA OF UTERUS - SUBSEROUS LEIOMYOMA OF UTERUS



218.9	LEIOMYOMA OF UTERUS UNSPECIFIED
617.0 - 617.6	ENDOMETRIOSIS OF UTERUS - ENDOMETRIOSIS IN SCAR OF SKIN
617.8 - 617.9	ENDOMETRIOSIS OF OTHER SPECIFIED SITES - ENDOMETRIOSIS SITE UNSPECIFIED
626.8	OTHER DISORDERS OF MENSTRUATION AND OTHER ABNORMAL BLEEDING FROM FEMALE GENITAL TRACT
V10.3	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

J9217 (Leuprolide acetate (for depot suspension), 7.5 mg)

174.0 - 174.6	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF AXILLARY TAIL OF FEMALE BREAST
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617.8 - 617.9	ENDOMETRIOSIS OF OTHER SPECIFIED SITES - ENDOMETRIOSIS SITE UNSPECIFIED
V10.3	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

J9219 (Leuprolide acetate implant, 65 mg) Surgical Implant

185	MALIGNANT NEOPLASM OF PROSTATE
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

J9225 (Histrelin implant, Vantas, 50mg) J9226 (Histrelin implant, Supprelin LA, 50 mg) Surgical Implants

185	MALIGNANT NEOPLASM OF PROSTATE
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

Diagnoses that Support Medical Necessity

Diagnoses listed above.

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 codes not listed above

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ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Diagnoses not listed above

Indications and Limitations:

Goserelin acetate (J9202), leuprolide acetate (J9217, J9218, J9219, and J1950), triptorelin (J3315), histrelin implants (J9225, J9226), and histrelin acetate (J1675) are synthetic luteinizing hormone-releasing hormone (LHRH) agonists, analogs of the naturally occurring gonadotropin releasing hormone (GnRH) indicated in one or more of the following:

1. palliative treatment of advanced carcinoma of the prostate
2. carcinoma of the breast
3. certain gynecological conditions
4. precocious puberty

(Note that “advanced” does not necessarily entail either “symptomatic” or “metastatic.”) Some of these offer an alternative treatment for prostatic cancer when neither orchiectomy nor estrogen administration is indicated or acceptable to the patient. Additional GnRH analogs are currently seeking approval, and this LCD will apply to those, once approved.

In order to be covered by Medicare, an injectable drug must be safe and effective, and otherwise reasonable and necessary. Drugs that are used according to FDA approval are considered safe and effective.

Goserelin acetate is administered by a slightly different delivery system than triptorelin and leuprolide acetate. The former is given by injecting drug-containing beads below the abdominal skin and the latter two are given as an intramuscular injection. WPS acknowledges that the differences in administration methods may cause a preference or even, in some isolated cases, a specific need to use one drug rather than the other.

J1950 (Leuprolide acetate for depot suspension)

1. Is indicated for uterine leiomyomas only when it is given “concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata.” (Drug Facts and Comparisons, p 2077.)

J9202 (Goserelin acetate implant, per 3.6 mg)



1. For the indication of dysfunctional uterine bleeding is valid only when J9202 is used as a single injection prior to endometrial ablation.
2. According to the 2004 USP DI, "Goserelin as the 3.6 mg implant is indicated for the palliative treatment of advanced breast cancer in pre- and post menopausal females. The 10.8 mg implant should not be used for this indication because it has not been shown to suppress estradiol reliably."
3. The 2004 USP DL states further, "Goserelin , as the 3.6-mg implant, is indicated for the management of endometriosis, including treatment of pelvic pain and reduction in the size and number of lesions. The 10.8-mg implant should not be used for this indication because it has not been shown to suppress serum estradiol reliably."

J9217 (Leuprolide acetate injection, per 7.5 MG)

1. Indicated for palliative and adjuvant treatment of prostate cancer and is available as an injectable suspension that may be administered subcutaneously, or as a long-acting depot formulation, on a monthly, every three months or every four months basis. The usual dosage of the depot form of leuprolide acetate is 7.5 mg per month, 22.5 mg per three months, or 30 mg per four months, or 45 mg per 6 months.

J9219 (Leuprolide Acetate implant is a once-yearly implant, 65 mg per year)

1. Indicated for palliative and adjuvant treatment of prostate cancer. It is a drug-filled, miniature titanium implant that is placed under the skin, usually in the inner aspect of the upper arm via an in-office surgical procedure. The leuprolide acetate implant delivers approximately 120 micrograms of leuprolide acetate per day over 12 months. After 12 months the implant may be removed or replaced. The physician should reasonably expect the life expectancy of the patient to be longer than one year.

J3315 (Triptorelin pamoate, per 3.75 MG)

1. Indicated in the palliative and adjuvant treatment of prostate cancer. Triptorelin pamoate is administered as an intramuscular injection and is available in the following dosage strengths:
3.75 mg every four (4) weeks
11.25 mg every twelve (12) weeks
22.5 mg every twenty-four (24) weeks

Response to all forms of LHRH analogs should be monitored periodically throughout the 12-month period by measuring serum concentrations of prostate-specific antigen (PSA) and/or testosterone.



Patients who receive an LHRH analog implant should continue to be seen by the managing physician in follow-up at least every three (3) to four (4) months.

J9225 (Histrelin acetate implant, per 50 MG)

1. Indicated for the palliative and adjuvant treatment of prostate cancer. A hydrogel implant containing histrelin is subcutaneously inserted usually in the upper, inner arm and delivers the drug continuously for 12 months. The usual dosage of histrelin acetate in men is 50 mg (implanted subcutaneously) every 12 months. The implant must be removed or replaced after the 12-month treatment. The physician should reasonably expect the life expectancy of the patient to be longer than one year.

Histrelin acetate may also be used of the diagnosis of precocious puberty for children with disability who are covered under Medicare.

Background:

Luteinizing Hormone-Releasing Hormone (LHRH) analogs inhibit and suppress gonadotropin secretion. Upon initial administration, levels of luteinizing hormone (LH) and follicle-stimulating hormone increase (FSH). LH and FSH decrease with continuous administration.

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

1. Eligard[®] [package insert]. Fort Collins, CO: Tolmar, Inc; 2011.
2. Local Coverage Determination for Luteinizing Hormone (LHRH) Analogs (L30479) (Revision X). Available at: <http://www.cms.gov/medicare-coverage-database/details/lcd->

