

# LCD for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (L29215)

## Contractor Information

### Contractor Name

First Coast Service Options, Inc.

### Contractor Number

09102

### Contractor Type

MAC - Part B

## LCD Information

### LCD ID Number

L29215

### LCD Title

Luteinizing Hormone-Releasing Hormone (LHRH) Analogs

### Contractor's Determination Number

J1950

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### CMS National Coverage Policy

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50

### Primary Geographic Jurisdiction

Florida

## **Oversight Region**

Region IV

## **Original Determination Effective Date**

For services performed on or after 02/02/2009

## **Original Determination Ending Date**

## **Revision Effective Date**

## **Revision Ending Date**

## **Indications and Limitations of Coverage and/or Medical Necessity**

Leuprolide Acetate (J1950, J9217, J9218 and J9219), goserelin acetate (J9202), triptorelin (J3315) and histrelin acetate implant (J9225) are synthetic luteinizing hormone-releasing hormone (LHRH) agonists, analogs of the naturally occurring gonadotropin-releasing hormone (GnRH).

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. Medical necessity is, however, determined by the Carrier at the local level.

Additional LHRH drugs will be automatically included in this LCD once released and approved by the FDA for the indications listed below.

### ***Indications***

**Leuprolide Acetate** (J1950, J9217, J9218 and J9219) is **FDA approved** for the following indications:

- Anemia due to uterine leiomyomas (treatment): preoperative hematologic improvement of patients with anemia caused by uterine leiomyomas (fibroids), in conjunction with iron supplement therapy,
- Carcinoma, prostatic (treatment): palliative treatment of advanced prostatic cancer, especially as an alternative to orchiectomy or estrogen administration.
- Endometriosis (treatment): management of endometriosis, including pain relief and reduction of endometriotic lesions.

In addition to the **FDA approved** indications, Medicare will cover Leuprolide Acetate for the following **off-labeled indication**:

- Carcinoma, breast (treatment): palliative treatment of advanced breast carcinoma in premenopausal and perimenopausal women.

**Goserelin Acetate (J9202)** is indicated for the following **FDA approved** indications:

- Carcinoma, breast (treatment): as the 3.6mg implant , for the palliative treatment of advanced breast carcinoma in pre- and perimenopausal females.
- Carcinoma, prostatic (treatment): palliative treatment of advanced prostatic carcinoma. Goserelin is indicated for use in combination with radiotherapy and flutamide for the treatment of locally confined Stage T2b-T4 (Stage B2-C) prostatic cancer.
- Endometrial thinning: as the 3.6 mg implant, endometrial thinning agent prior to endometrial ablation
- Endometriosis (treatment): as the 3.6mg implant, management of endometriosis, including treatment of pelvic pain and reduction in the size and number of lesions.

**Triptorelin Pamoate (J3315)** is indicated for the following **FDA approved** indication:

- Carcinoma, prostatic (treatment): palliative treatment of advanced prostatic carcinoma.

**Histrelin Acetate implant (J9225)** is indicated for the following **FDA approved** indication:

- Palliative treatment of advanced prostate cancer

### *Limitations*

**Leuprolide Acetate (J1950, J9217, J9218 and J9219)**

- For anemia due to uterine leiomyomas, some patients respond to iron supplementation alone. A 1-month trial period with iron should be considered prior to initiation of leuprolide therapy. Leuprolide may then be initiated if the response to iron is inadequate.
- Leuprolide Acetate implant (J9219) continually releases Leuprolide Acetate for 12 months. It would not be reasonable to use this drug formulation for a patient whose life expectancy is not at least 12 months.
- If a patient has had any of the other forms of GnRH, implantation of J9219 should be delayed until the therapeutic span of these forms of GnRH has ended. If the patient has had a bilateral orchiectomy, he does not need nor should he get any form of GnRH.
- Leuprolide Acetate, 1mg (J9218) is self administered and therefore not covered.

**Goserelin Acetate (J9202)**

- For treatment of breast cancer, the 10.8mg implant should not be used for this indication because it has not been shown to suppress serum estradiol reliably.
- For the treatment of endometriosis, the 10.8 mg implant should not be used for this indication because it has not been shown to suppress estradiol reliably.

**Histrelin Implant (J9225)**

- The Histrelin Implant (J9225) is designed to release Histrelin continuously for 12 months. It would not be reasonable to use this drug formulation for a patient whose life expectancy is not at least 12 months.

· If a patient has had any of the other forms of GnRH, implantation of J9225 should be delayed until the therapeutic span of these forms of GnRH has ended. If the patient has had a bilateral orchiectomy, he does not need nor should he get any form of GnRH.

Medicare Contractors implement Local Coverage Determinations (LCD) to apply reasonable and necessary standards in situations not covered by specific national policy. Consistent with Social Security Act 1862 (a)(1)(A), if two services are clinically comparable, then Medicare does not cover the additional expense of the more costly service, when this additional expense is not attributable to that part of an item or service that is medically reasonable or necessary. Among the LHRH agonists used for the treatment of prostate cancer and breast cancer there is no demonstrable difference in clinical efficacy. Therefore, Medicare will deny payment for the additional expense of the more costly agent when used for the treatment of prostate cancer (ICD-9 CM code 185) and breast cancer (ICD9-CM codes 174.0-174.9), as not medically reasonable or necessary, and reimburse only to the extent of the least costly drug.

· There will be two LCA policies implemented for this LCD. The short acting LHRH agents (J1950, J3315, J9217 and J9202) will be grouped together in one LCA and the two 12-month LHRH implants (J9219 and J9225) will be grouped together in another LCA. For the approved indications, Medicare will pay for the dosage administered at the allowed amount of the lower-priced medication for each group.

As with any submitted charge that is not considered medically reasonable and necessary, the beneficiary can be held liable for the denied charge if an Advanced Beneficiary Notice (ABN) is signed before each injection. The beneficiary's liability, however, must not exceed the difference in Medicare allowance between the two medications.

If there are true medical necessity indications requiring the use of the more costly agent (e.g. allergy), Medicare will consider payment for the difference in cost if documentation of the medical indication that requires the use of the more costly drug accompanies the claim. Please see the documentation requirement section of this LCD for specific documentation that must accompany a claim. Patient or physician preference for route of administration does not constitute medical necessity.

### **Coding Information**

#### **Bill Type Codes:**

**Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.**

#### **Revenue Codes:**

**Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.**

99999

Not Applicable

### CPT/HCPCS Codes

11981	INSERTION, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
11982	REMOVAL, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
11983	REMOVAL WITH REINSERTION, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
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

### ICD-9 Codes that Support Medical Necessity

#### For J1950 the following ICD-9 CM codes are covered

218.0 - 218.9	SUBMUCOUS LEIOMYOMA OF UTERUS - LEIOMYOMA OF UTERUS UNSPECIFIED
280.0	IRON DEFICIENCY ANEMIA SECONDARY TO BLOOD LOSS (CHRONIC)
285.1	ACUTE POSTHEMORRHAGIC ANEMIA
617.0 - 617.9	ENDOMETRIOSIS OF UTERUS - ENDOMETRIOSIS SITE UNSPECIFIED

#### For J9217 the following ICD-9 CM codes are covered

174.0 - 174.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0 - 175.9	

	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
185	MALIGNANT NEOPLASM OF PROSTATE
218.0 - 218.9	SUBMUCOUS LEIOMYOMA OF UTERUS - LEIOMYOMA OF UTERUS UNSPECIFIED
233.0	CARCINOMA IN SITU OF BREAST
233.4	CARCINOMA IN SITU OF PROSTATE
280.0	IRON DEFICIENCY ANEMIA SECONDARY TO BLOOD LOSS (CHRONIC)
285.1	ACUTE POSTHEMORRHAGIC ANEMIA
617.0 - 617.9	ENDOMETRIOSIS OF UTERUS - ENDOMETRIOSIS SITE UNSPECIFIED
V10.3	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

**For J9219 the following ICD-9 CM codes are covered**

185	MALIGNANT NEOPLASM OF PROSTATE
233.4	CARCINOMA IN SITU OF PROSTATE
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

**For J9202 the following ICD-9 CM codes are covered**

174.0 - 174.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0 - 175.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
185	MALIGNANT NEOPLASM OF PROSTATE
218.0 - 218.9	SUBMUCOUS LEIOMYOMA OF UTERUS - LEIOMYOMA OF UTERUS UNSPECIFIED
233.0	CARCINOMA IN SITU OF BREAST
233.4	CARCINOMA IN SITU OF PROSTATE
280.0	IRON DEFICIENCY ANEMIA SECONDARY TO BLOOD LOSS (CHRONIC)
285.1	ACUTE POSTHEMORRHAGIC ANEMIA

617.0 - 617.9	ENDOMETRIOSIS OF UTERUS - ENDOMETRIOSIS SITE UNSPECIFIED
V10.3	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

**For J3315 the following ICD-9 CM codes are covered**

185	MALIGNANT NEOPLASM OF PROSTATE
233.4	CARCINOMA IN SITU OF PROSTATE
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

**For J9225 the following ICD-9 CM codes are covered**

185	MALIGNANT NEOPLASM OF PROSTATE
233.4	CARCINOMA IN SITU OF PROSTATE
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

**Diagnoses that Support Medical Necessity**

See ICD-9 –CM codes that support medical necessity

**ICD-9 Codes that DO NOT Support Medical Necessity**

Any diagnosis that does not appear in the ICD-9 codes that support medical necessity section of this LCD and specifically for the following:

**J9218 (this HCPCS is non-covered as it is self administered)**

185	MALIGNANT NEOPLASM OF PROSTATE
233.4	CARCINOMA IN SITU OF PROSTATE
V10.46	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

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

## **Diagnoses that DO NOT Support Medical Necessity**

See ICD-9 codes that do not support medical necessity

### **General Information**

#### **Documentation Requirements**

Medical record documentation maintained by the physician must indicate the medical necessity for using any of these drugs. Documentation of the symptoms, the administration and dosage of the drug should be found in the patient's medical record. This information is usually found in the history and physical and/or office/progress notes. This documentation must be available upon request.

Medicare will not cover the excess cost for the more expensive of these medications that have the same overall clinical response as another. The patient will not be responsible for the difference in price between the two drugs without an acceptable Advanced Beneficiary Notice (ABN).. The medical record must document the medical necessity (e.g. allergy) for using the more costly treatment. This documentation could include and is not limited to the following:

- History and physical
- Office/progress note
- Medical evidence for the indication that requires the use of the higher priced drug

For the two drugs that are delivered over a 12-month period (J9219 and J9225), the medical record must document and justify the physician's belief that the patient's life expectancy is at least 12 months.

For patients being treated for pre-operative hematologic improvement of anemia caused by uterine leiomyomas (fibroids) in conjunction with oral iron supplement therapy: The FDA label states that a one-month trial of oral iron should be considered prior to initiation of leuprolide therapy. For this LCD, Medicare would expect the provider to take into consideration the condition of the patient (e.g., degree of anemia, size of the fibroid etc..) and clearly document in the medical record the rationale for why the one month trial of oral iron would or would not be medically reasonable.

## **Appendices**

### **Utilization Guidelines**

#### **Frequency and Dosing**

Leuprolide Acetate (for depot suspension) (J1950), for the treatment of endometriosis and uterine leiomyomas. 3.75mg monthly or 11.25mg once every 3 months.. Treatment should not exceed three months for anemia due to uterine leiomyomas and six months for endometriosis. Retreatment is not recommended.

Leuprolide Acetate Implant (J9219) for the treatment of carcinoma of the prostate. Subcutaneous implant, one implant per 12 months (120mcg/day). When one implant is removed another may be inserted.

Leuprolide Acetate (for depot suspension) (J9217) for the treatment of prostate cancer, intramuscular 7.5mg once a month, 22.5mg once every three months (eighty four days), or 30 mg every four months or 45mg once every 6 months. Leuprolide acetate (J9218) 1mg/day for the treatment of prostate cancer is non-covered as this drug is self-administered.

Triptorelin pamoate (J3315) for the treatment of prostate cancer. Give 3.75mg monthly or 11.25 mg once every three months (12 weeks). Goserelin acetate implant (J9202) for the treatment of prostate cancer, breast cancer and endometriosis, 3.6 mg once every 28 days.

Goserelin acetate implant (J9202) for the treatment of prostate cancer, 10.8mg once every 3 months (12 weeks). Histrelin implant (J9225) for the treatment of prostate cancer. 50mg once a year. When one implant is removed another implant may be inserted.

### **Sources of Information and Basis for Decision**

Mahutte, N., Aydin, A. (2003). Medical management of endometriosis-associated pain. *Obstetrics and Gynecology Clinics*, 30(1), W.B. Saunders Company. Retrieved from <http://home.mdconsult.com> on 12/16/2005.

Other Intermediaries Local Coverage Determinations.

Package insert for Viadur<sup>®</sup> (leuprolide acetate implant). Retrieved from [www.drugs@FDA.gov](http://www.drugs@FDA.gov)

Package insert for Vantas<sup>®</sup> (histrelin acetate implant). Retrieved from <http://www.vantasimplant.com> and <http://www.drugs.com> on 12/12/2005.

The Association of Community Cancer Centers (2005). Leuprolide (systemic); Goserelin (systemic); Triptorelin (systemic). Retrieved from <http://www.acc-cancer.org> on 10/27/2005.

Rivera, J.A., Christopoulos, S., Small, D. and Trifiro, M. (2004). Clinical Case Seminar. Hormonal manipulation of benign metastasizing leiomyomas: report of two cases and review of literature. *Journal of Clinical Endocrinology and Metabolism*, 89 (7). The Endocrine Society. Retrieved from <http://home.mdconsult.com> on 12/16/2005.

Zelnak, A., O'Regan, R. (2004). Goserelin was as effective as chemotherapy±goserelin for treatment of ER-positive, but not ER-negative, breast cancer. *Evidence-based Obstetrics & Gynecology*,

### **Advisory Committee Meeting Notes**

This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.

### **Start Date of Comment Period**

**End Date of Comment Period****Start Date of Notice Period**

12/04/2008

**Revision History Number**

Original

**Revision History Explanation**

Revision Number:Original

Start Date of Comment Period:N/A

Start Date of Notice Period:12/04/2008

Revised Effective Date:02/02/2009

LCR B2009-  
December 2008 Bulletin

This LCD consolidates and replaces all previous policies and publications on this subject by the carrier predecessors of First Coast Service Options, Inc. (Triple S and FCSO).

For Florida (00590) this LCD (L29215) replaces LCD L5769 as the policy in notice. This document (L29215) is effective on 02/02/2009.

**Reason for Change****Last Reviewed On Date****Related Documents**

This LCD has no Related Documents.

**LCD Attachments**

Coding Guidelines (HTM - 10,643 bytes)

**All Versions**

Updated on 11/30/2008 with effective dates 02/02/2009 - N/A