

# **LCD for Gonadotropin Releasing Hormone Analogs (L26657)**

## **Contractor Information**

### **Contractor Name**

Wisconsin Physicians Service Insurance Corporation

### **Contractor Number**

05102, 05202, 05302, 05402

### **Contractor Type**

MAC - Part B

## **LCD Information**

### **LCD ID Number**

L26657

### **LCD Title**

Gonadotropin Releasing Hormone Analogs

### **Contractor's Determination Number**

INJ-539

### **AMA CPT / ADA CDT Copyright Statement**

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### **CMS National Coverage Policy**

Title XVIII of the Social Security Act, Section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

CMS Pub. 100-2, Ch. 15, §50

CMS Pub. 100-4, Ch. 17

CMS Pub. 100-8, Ch. 13, §5.4

CMS Pub. 100-9, Ch. 16

## **Oversight Region**

Region I  
Region X

## **Original Determination Effective Date**

For services performed on or after 02/01/2008

## **Original Determination Ending Date**

## **Revision Effective Date**

For services performed on or after 08/01/2009

## **Revision Ending Date**

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

Goserelin acetate (J9202), leuprolide acetate (J9217, J9218, J9219, and J1950), triptorelin (J3315) and histrelin implant (J9225) 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: palliative treatment of advanced carcinoma of the prostate, carcinoma of the breast, certain gynecological conditions, and precocious puberty. (Note that "advanced" does not necessarily entail either "symptomatic" or "metastatic.") Some of these offer an alternative or supplemental 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, provided "incident to" a physician's service, and otherwise reasonable and necessary. Drugs that are used according to FDA approval are considered safe and effective.

Goserelin acetate and histrelin implant are administered by a slightly different delivery system than triptorelin and leuprolide acetate. The former are given by injecting drug-containing beads below the abdominal skin and the latter two are given as an intramuscular injection. Although we acknowledge 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, clinical evidence and FDA indications do not support differential effectiveness of one over the other. Therefore, for approved clinical indications, Medicare will pay for the dosage administered for any of these drugs only at the rate approved for the lowest-priced drug approved for the given indication.

It is understood that patients may have preferences for one form of administration (delivery system) over the other. If the patient desires the more expensive medication, and if the patient signs an appropriate advanced beneficiary notice explaining the partial payment of the more expensive drug, and the claim is submitted with the appropriate modifier (currently GA), then the patient may be charged for the difference between the reimbursement of the more expensive medication and the reimbursement of the less expensive medicine. Deductible and co-insurance will still apply.

WPS acknowledges that there may be true medical indications requiring the use of a more expensive drug. In such cases, payment will be made so long as a statement giving the circumstances supporting the determination of medical necessity for the use of the more expensive drug is documented on each claim.

J1950 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.)

For J9202, the indication of dysfunctional uterine bleeding is valid only when J9202 is used as a single injection prior to endometrial ablation.

Per 2006 USP DI, "Goserelin, as the 3.6 mg implant, is indicated for the palliative treatment of advanced breast cancer in pre- and perimenopausal females. The 10.8 mg implant should not be used for this indication because it has not been shown to suppress estradiol reliably."

The 2006 USP DI. 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."

Because the one-year implants (for the patient with advanced prostate cancer) would be inappropriate for a patient with less than a one-year life expectancy, NAS will allow payment for this implant only if a reasonable assessment determines the patient's life expectancy is at least one year. NAS previously published a guideline for determining if a patient with prostate cancer is terminal (having a life expectancy of less than six months) and, so, eligible for Hospice Care. (See Medicare B News, Issue 192, dated October 22, 2001) Clearly, a patient meeting the criteria for Hospice Care, is not eligible for a one-year implant.

If a patient has previously received a GnRH analog, a subsequent injection or implantation should be delayed until the therapeutic span of the earlier GnRH analog has ended.

The patient who has had a bilateral orchiectomy, does not need and should not receive, any form of GnRH.

This policy specifically does not address the use of J0128, Injection, abarelix, 10 mg. Abarelix is not a gonadotropin releasing hormone analog, but rather is considered a GnRH receptor antagonist. Coverage of abarelix is based on CMS' Change Request 3775, Transmittals 34 and 532 Abarelix for the Treatment of Prostate Cancer.

Coverage of an injection and coverage of an injected drug are each allowable under Medicare only if the drug is furnished and administered by the physician or by auxiliary personnel under the direct supervision of the physician in the office or in the patient's home. Any drug which is self-administered and any drug administered by a family member or "caretaker" is not a covered benefit under Medicare Part B.

Drugs which have been determined to be usually self-administered by the patient are listed on the WPS website as Usually Self Administered Drugs and are not a covered benefit under Medicare Part B.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

### **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.**

### **CPT/HCPCS Codes**

Note: Codes 11981 – 11983 are used only for non-biodegradable drug delivery implants (including only J9219 and J9225 implants in this policy). This is not the appropriate code to use for the pellet-type implant of J9202 (which is bio-degradable). Code 96402 is to be used for injections of J9202.

11981	INSERTION, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
11982	REMOVAL, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
11983	REMOVAL WITH REINSERTION, NON-BIODEGRADABLE DRUG DELIVERY IMPLANT
96372	THERAPEUTIC, PROPHYLACTIC, OR DIAGNOSTIC INJECTION (SPECIFY SUBSTANCE OR DRUG); SUBCUTANEOUS OR INTRAMUSCULAR
96402	CHEMOTHERAPY ADMINISTRATION, SUBCUTANEOUS OR INTRAMUSCULAR; HORMONAL ANTI-NEOPLASTIC
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
J9219	LEUPROLIDE ACETATE IMPLANT, 65 MG
J9225	HISTRELIN IMPLANT (VANTAS), 50 MG

### **ICD-9 Codes that Support Medical Necessity**

Note: The following two drugs are excluded from Medicare coverage as Usually Self-Administered Drugs and are included here only to assure these HCPCS codes are not used inappropriately:

J1675 histrelin acetate, 10 mcg  
J9218 leuprolide acetate, per 1 mg

The indications listed above are the only ICD-9-CM codes that support medical necessity. For each drug, WPS will cover use for an approved diagnosis at the price of the least costly alternative (LCA) in widespread use: (Note: Diagnoses allowed for CPT/HCPCS codes 11981, 11982, 11983, 90772 and 96402 are broader than those listed in this LCD.)

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
259.1	PRECOCIOUS SEXUAL DEVELOPMENT AND PUBERTY NOT ELSEWHERE CLASSIFIED
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
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
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, 50mg) \*Surgical Implant

185

MALIGNANT NEOPLASM OF PROSTATE

V10.46

PERSONAL HISTORY OF MALIGNANT  
NEOPLASM OF PROSTATE

### **Diagnoses that Support Medical Necessity**

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

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

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

## **General Information**

### **Documentation Requirements**

Medicare will not cover the excess cost for the more expensive of these medications that have the same overall clinical response as another already in widespread use. The lowest-priced drug approved for the given indication will be determined separately for the one-year duration formulations. The patient will not be responsible for the difference in price between the two drugs without an acceptable advanced beneficiary notification (ABN).

There may be true medical indications requiring the use of a more expensive drug. In such cases, payment will be made so long as a statement giving the circumstances supporting the determination of medical necessity for the use of the more expensive drug is documented on each claim.

Any administration of these drugs in the absence of an acceptable clinical diagnosis (see above section) will be denied as not reasonable and necessary

The manufacturers strongly recommend that the provider should attempt to adhere closely to the schedule (every four weeks, 12 weeks, etc.), though they note that a delay of a few days is permissible.

Because CPT codes 11981-11983 may be used for implants other than J9219 and J9225, WPS will not limit these procedures to just these two HCPCS codes and the diagnoses in this LCD. Similarly, 96372 and 96402 will be allowed for indicated diagnoses beyond those in this LCD.

Chart documentation must support the diagnosis on the claim, and be made available to Medicare upon request.

For one-year implants, the chart must document and justify the clinician's belief that the patient's life expectancy is at least one year.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

## **Appendices**

### **Utilization Guidelines**

GnRH analogs will be covered for the indicated diagnoses with a frequency governed by the duration of action of a previously administered GnRH analog.

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

This policy does not reflect the sole opinion of the contractor or contractor medical director. Although the final decision rests with the contractor, this policy was developed in consideration of the active LCDs maintained by the preceding Medicare contractors for Jurisdiction 5.

This policy is subject to the reasonable and necessary guidelines and the limitation of liability provision

"Relative Effectiveness and Cost-Effectiveness of Methods of Androgen Suppression in the Treatment of Advanced Prostatic Cancer." Summary, Evidence Report/Technology Assessment: Number 4, January 1999. Agency for Health Care Policy and Research, Rockville, MD. <http://www.ahrp.gov/clinic/prosumm/html>.

"Most Testosterone-Suppressing Treatments for Advanced Prostate Cancer Produce Similar Outcomes." Press Release, January 12, 1999. Agency for Health Care Policy and Research, Rockville, MD.

<http://www.ahrp.gov/news/press/pr1999/prospr.html>

Ellis, William; Higano, Celestia S.; Lange, Paul H; Russell, Kenneth. Preliminary Communication; "Intermittent Androgen Suppression with Leuprolide and Flutamide for Prostate Cancer: A Pilot Study"; Division of Oncology, Department of Medicine, Department of Urology and Department of Radiation Oncology, University of Washington, Seattle; July 29, 1996.

Technology Advisory Committee, February 4-5, 1997.

Other Contractors' Medical Policies

FDA-Approved Product Inserts

Carrier Advisory Committee recommendations

Drug Facts and Comparisons, 57th ed, St. Louis, Wolters Kluwer, 2002

## **Advisory Committee Meeting Notes**

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

### **End Date of Comment Period**

### **Start Date of Notice Period**

05/01/2009

### **Revision History Number**

2

### **Revision History Explanation**

07/30/2009: Restored accidental removal of contract number 05392 (WPS Part B MAC Eastern Missouri), effective 01/01/09. Correctly removed contract number 05392 effective 8/1/2009, as it is being combined with contractor number 05302 (WPS Part B MAC Missouri - Entire State.)

06/30/2009 The contractor number 05392 will no longer be valid as of 8/1/2009 as it will be joining with the W MO number.

CPT code 90772 deleted and replaced with CPT code 96372, effective 01/01/2009

### **Reason for Change**

### **Last Reviewed On Date**

05/01/2009

### **Related Documents**

This LCD has no Related Documents.

### **LCD Attachments**

[Billing and Coding Guidelines \(PDF - 14,481 bytes\)](#)

Updated on 07/30/2009 with effective dates 08/01/2009 - N/A

Updated on 07/30/2009 with effective dates 01/01/2009 - 07/31/2009

Updated on 07/17/2009 with effective dates 01/01/2009 - N/A

Updated on 04/24/2009 with effective dates 01/01/2009 - N/A

Updated on 05/23/2008 with effective dates 03/01/2008 - 12/31/2008

Updated on 03/28/2008 with effective dates 03/01/2008 - N/A

Updated on 03/07/2008 with effective dates 03/01/2008 - N/A

Updated on 01/25/2008 with effective dates 02/01/2008 - 02/29/2008

Updated on 12/07/2007 with effective dates 02/01/2008 - N/A