

Contractor Name

Wisconsin Physicians Service (WPS)

Contractor Number

00951, 00952, 00953, 00954
05101, 05201, 05301, 05401,
05102, 05202, 05302, 05402,
52280

Contractor Type

Carrier
Fiscal Intermediary (FI)
MAC – A
MAC – B

LCD Database ID Number**LCD Version Number****LCD Title**

Luteinizing Hormone-Releasing Hormone (LHRH) Analogs

Contractor's Determination Number

INJ-039

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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 those services that are considered 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.

Title XVIII of the Social Security Act section 1862(a) (1) (D). This section excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act section 1861(t). This section defines coverage of drugs and biologicals.

Title XVIII of the Social Security Act section 1888(e)(20(A)(iii)(11). This section includes chemotherapy and chemotherapy administration services on the list of items excluded from payment to skilled nursing facilities as routine service costs.

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 1, 2.2 Least Costly Alternative (LCA) provision.

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 6: 70.4 Outpatient Observation Services [not to be billed concurrently with chemotherapy].

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 8: 50.5 Drugs and Biologicals [Coverage of SNF services] 70 Medical and Other Health Services Furnished to SNF Patients.

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 12:40.10 Drugs and Biologicals [Coverage of Comprehensive Outpatient Rehabilitation Facility services].

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15: 50-50.1 Drugs and Biologicals. 50.4.5 Unlabeled Use for Anti-Cancer Drugs.

CMS Publication 100-4; Medicare Claims Processing Manual, Chapter 12, 30.5 Medicare Coverage for “Chemotherapy Administration.”

CMS Publication 100-4; Medicare Claims Processing Manual, Chapter 17, 20 Payment Allowance Limits for Drugs and Biologicals.

CMS Publication 100-8, Chapter 13: 5.4 Medicare Program Integrity Manual LCD Requirements That Alternative Service Be Tried First

Primary Geographic Jurisdiction

Intermediary: **Intermediary:** Alaska, Alabama, Arizona, Arkansas, California - Entire State, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri - Entire State, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, Wyoming, District of Columbia, American Samoa, Guam, Northern Mariana Islands, Virgin Islands

Carrier: Wisconsin, Illinois, Michigan, Minnesota

MAC AB: Iowa, Missouri, Nebraska, Kansas

Oversight Region

Region I
Region V
Region VII

Original Determination Effective Date

Revision Effective Date

Indications and Limitations of Coverage and/or Medical Necessity

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. However, 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.

Some patients may have preferences for one form of administration (delivery system) over the other. If the patient signs an appropriate advanced beneficiary notice (ABN) 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. Deductible and co-insurance will still apply.

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 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.”

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. The recommended dose of treorelin pamoate depot is 3.75 mg incorporated in a depot formulation and administered monthly as a single intramuscular injection. The recommended dose of triptorelin pamoate LA is 11.25 mg incorporated in a long acting formulation administered every twelve weeks (approximately 84 days) as a single intramuscular injection.

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.

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.

13x	Hospital-outpatient (HHA-A also) (under OPSS 13x must be used for ASC claims submitted for OPSS payment – eff. 7/00)
21x	SNF – inpatient, Part A
23x	SNF – outpatient (HHA-A also)
85x	Special facility or ASC surgery-rural primary care hospital (eff. 10/94)

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.

Revenue codes only apply to providers who bill these services to the fiscal intermediary or Part A MAC. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or Part B MAC.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

0250	Pharmacy – general classification
0636	Drugs requiring specific identification – detailed coding (eff. 03/92)

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
96402	Chemotherapy administration, subcutaneous or intra-muscular; Hormonal anti-neoplastic
J1675	Injection, Histrelin acetate, 10 micrograms (Note – Non-payable, see Companion Article for details)
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 mg (Note – Non-payable, see Companion Article for details)
J9219	Leuprolide acetate implant, 65 mg
J9225	Histrelin implant (Vantas), 50mg
J9226	Histrelin implant (Supprelin LA), 50 mg

Does the CPT 30% Rule Apply

No

ICD-9 Codes that Support Medical Necessity

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 female breast
174.8-174.9	Other specified sites of female breast; Breast (female) unspecified
175.0, 175.9	Malignant neoplasm of male breast
218.0-218.2	Uterine leiomyoma
218.9	Uterine leiomyoma, unspecified

617.0-617.6	Endometriosis
617.8-617.9	Endometriosis of other specified sites; Endometriosis, site unspecified
V10.3	History of malignant neoplasm breast

J3315 (Injection, triptorelin pamoate, 3.75 mg)

185	Malignant neoplasm of prostate
V10.46	History of malignant neoplasm, prostate

J9202 (Goserelin acetate implant, per 3.6 mg)

174.0-174.6	Malignant neoplasm of female breast
174.8-174.9	Malignant neoplasm female breast, specified and unspecified
175.0, 175.9	Malignant neoplasm of male breast
185	Malignant neoplasm of prostate
218.0-218.2	Uterine leiomyoma
218.9	Uterine leiomyoma, unspecified
617.0-617.6	Endometriosis
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	History of malignant neoplasm of breast
V10.46	History of malignant neoplasm, prostate

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

174.0-174.6	Malignant neoplasm of female breast
174.8-174.9	Malignant neoplasm female breast, specified and unspecified
175.0, 175.9	Malignant neoplasm of male breast
185	Malignant neoplasm of prostate
218.0-218.2	Uterine leiomyoma
218.9	Uterine leiomyoma, unspecified
617.0-617.6	Endometriosis
617.8-617.9	Endometriosis of other specified sites; Endometriosis, site unspecified
V10.3	History of malignant neoplasm of breast
V10.46	History of malignant neoplasm, prostate

J9219 (Leuprolide acetate implant, 65 mg) Surgical Implant

185	Malignant neoplasm of prostate
V10.46	History of malignant neoplasm, prostate

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

185	Malignant neoplasm of prostate
V10.46	History of malignant neoplasm, prostate

Diagnoses that Support Medical Necessity

Diagnoses listed above.

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 codes not listed above

Diagnoses that DO NOT Support Medical Necessity

Diagnoses not listed above

Documentation Requirements

1. Any administration of the drugs addressed in this policy, in the absence of an acceptable clinical diagnosis, will be denied as not reasonable and necessary.
2. In cases where the provider indicates the more costly agent is medically necessary, the medical record must indicate why it was medically necessary to administer the more costly drug.
3. Documentation must be available to Medicare upon request.

Utilization Guidelines

1. Coverage of leuprolide acetate and histrelin acetate, administered every 12 months in the surgical implant form for treatment of prostate cancer, is considered medically appropriate only for patients having a reasonable expectation of surviving at least 12 months.
2. Surgical implant forms of leuprolide acetate and histrelin acetate hormonal therapy must be removed after twelve months. When a surgical implant is removed, another surgical implant may be inserted to continue therapy.
3. GnRH analogs are covered for the indicated diagnosis, with frequency of administration governed by the duration of action of the previously administered GnRH analog.
4. Drugs discussed within this LCD are paid at the price of the least costly alternative for approved diagnoses.
5. Diagnostic restrictions do not apply to the following CPT/HCPCS codes;

11982	Removal, non-biodegradable drug delivery implant
11983	Removal, with reinsertion, non-biodegradable drug delivery implant
96402	Chemotherapy administration, subcutaneous or intra-muscular; Hormonal anti-neoplastic

6. 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. If the patient has had a bilateral orchiectomy, he does not need and should not receive, any form of GnRH.
7. When administered for treatment of prostate cancer, claims submitted for the more costly drug must have documentation which substantiates the medical necessity for its use, submitted with the claim or upon request. The documentation should include the following information:
 1. History and Physical
 2. Office progress notes documenting medical necessity for the more costly drug.
 3. Letter explaining the medical necessity for the more costly drug
8. If a patient has had a bilateral orchiectomy, he does not need and should not receive any form of GnRH.

Other Comments

Medicare Contractors implement LCDs to apply the standard of reasonable and necessary in situations not covered by specific national policy. The underlying issue in the application of Social Security Act Section 1862 (a)(1)(A) is that if two services are clinically comparable then Medicare does not cover the additional expense of the more costly one because this additional expense is not attributable to an item or

service that is medically reasonable and necessary. Among the LHRH agonists used for the treatment of prostate cancer, there is no demonstrable difference in clinical efficacy.

Abarelix for the treatment of prostate cancer is not addressed in this LCD. Abarelix is not a gonadotropin releasing hormone analog, but rather is considered a GnRH receptor antagonist. Therefore, Abarelix is not subject to the least costly alternative instructions provided in this LCD. There is a National Coverage Determination (NCD) for the use of Abarelix. To review this NCD go to CMS manual 100-3, section 110.19.

Degarelix, for the treatment of prostate cancer, antagonizes the gonadotropin-releasing hormone (GnRH) receptors and thus is not addressed in this LCD. Therefore, degarelix is not subject at this time, to the least costly alternative instructions provided in this LCD.

For claims submitted to the fiscal intermediary or MAC Part A: This local coverage determination also applies to facilities that have nominated Wisconsin Physician Services to process their claims.

A prior version of Luteinizing Hormone-Releasing Hormone (LHRH) Analogs known as Gonadotropin-Releasing Hormone Analogs was previously in effect for WPS Part B.

* - Unless otherwise indicated, an asterisk indicates a revision to that section of the policy.

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

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 cooperation with advisory groups which include representatives from urology, endocrinology, oncology, gynecology and other specialties.

Sources of Information and Basis for Decision

1. Adaptation of WPS Carrier LCD
2. Other Medicare LCDs

Advisory Committee Meeting Notes

Meeting Date:

Wisconsin:	09/25/2009
Illinois:	09/16/2009
Michigan:	09/09/2009
Minnesota:	09/24/2009
Iowa, Kansas, Missouri, Nebraska	10/08/2009

Start Date of Comment Period

10/08/2009

End Date of Comment Period

11/23/2009

Start Date of Notice Period

(Published)

Revision History Number/Explanation

Last Reviewed On

Related Documents

See companion document titled [Billing and Coding Guidelines for INJ-039, Luteinizing Hormone-Releasing Hormone \(LHRH\) Analogs](#)

Does this LCD contain a "Least Costly Alternative" Provision?

Yes

DRAFT

Coding and Billing Guidelines

Article Type

LCD Companion Article

Article Title

Billing and Coding Guidelines for INJ-039, Luteinizing Hormone-Releasing Hormone (LHRH) Analogs

Effective Date

CMS National Coverage

Title XVIII of the Social Security Act section 1862(a) (1) (A). This section allows coverage and payment for those services that are considered 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.

Title XVIII of the Social Security Act section 1862(a) (1) (D).

CMS Pub. 100-2, Ch.15 §50

CMS Pub. 100-4, Ch. 17

CMS Pub. 100-8, Ch. 13, §5.4

Article Text

The information in this Coding and Billing Article is provided as a supplemental guideline that should be used with Local Coverage Determination (LCD) Leutenizing Hormone-Releasing Hormone (LHRH) Analogs.

Medicare Contractors implement LCDs to apply the standard of reasonable and necessary in situations not covered by specific national policy. The underlying issue in the application of Social Security Act Section 1862 (a)(1)(A) is that if two services are clinically comparable then Medicare does not cover the additional expense of the more costly one because this additional expense is not attributable to an item or service that is medically reasonable and necessary.

Implementation of Least Costly Alternative (LCA)

The least costly alternative (LCA) policy will be applied to Lupron/Zoladex/Trelstar/and other similar drugs for ICD-9-CM codes 185 and V10.46 only. Whereas there are other labeled indications for goserelin acetate implant or leuprolide acetate, they are not affected by the least costly alternative (LCA) provisions of this LCD. That is, LCA pricing will only be applied if the covered diagnosis is related to prostate cancer.

- A. WPS will reimburse the LCA known for J9217, J3315 and J9202 for diagnoses 185 and V10.46.
 - B. WPS will reimburse the LCA known for J9225, *J9226 and J9219 for diagnoses 185 and V10.46.
1. Pricing is set quarterly by Medicare's drug pricing schedule.

2. Pricing will be crosswalked only among similar **interval** drugs; e.g. one month pricing will not be crosswalked to 1/12 of one-year pricing.
3. In some cases, the ASP-based price of an established drug may govern the WAC based price of a recently introduced drug.

Reasons for Denial

1. All other indications not listed in the "indications and Limitations of Coverage and/or Medical Necessity" section of the related policy.
2. The medical record does not verify that the service described by the HCPCS code was provided.
3. J9218 (leuprolide acetate [Lupron®], per 1 mg) is non-covered since this formulation is usually self administered.
4. J1675 (histrelin) acetate [Supprelin ®], 10 mg) is non-covered since this formulation is usually self-administered and/or is being used in lieu of a medication that normally is self-administrated.

Coding and Billing Guidelines

1. If the more costly medication is provided, use the -GA modifier to indicate that the advance beneficiary notice is on file for the difference in cost of the two drugs.
2. For the 10.8 mg dose of goserelin, bill J9202, three units. For the 11.25 dose of leuprolide, bill J1950, three units.
3. For the 22.5, 30 or 45 mg doses of leuprolide, bill J9217 three, four or six units respectively.
4. CPT codes 11981-11983 and 96402 may be used for clinical reasons other than administration of GnRH and are not assigned to any diagnosis included in INJ-039.
5. The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedent over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.
6. An advance beneficiary notification (ABN) may be used for outpatient services which are likely to be non-covered, whether for medical necessity or for other reasons. Refer to CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 30, for complete instructions.

For claims submitted to the carrier or Part B MAC:

All services/procedures performed on the same day for the same beneficiary by the physician/provider should be billed on the same claim

Claims for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs services are payable under Medicare Part B in the following places of service:

Office (11), home (12), assisted living facility (13), group home (14), custodial care facility (33), and independent clinic (49). When administered in hospital inpatient (21), hospital outpatient (22) or skilled nursing facility (31), these drugs are covered and paid for under the Part A benefit and not billable to Part B.

When the leuprolide or histrelin implants are administered to a patient in a facility (POS = 21, 22, 24, 31, 51), the physician should bill only the surgical implant codes and not the drug. Administration, by injection, of an LHRH agonist to a patient in a facility (POS= 21, 22, 24, 31, 51) is considered not to be a physician service (it can be administered by the facility staff) and CPT code 96402 should **not** be billed. The drug also may **not** be billed.

Hospital Inpatient Claims:

- The hospital should report the patient's principal diagnosis in Form Locator (FL) 67 of the UB-04. *The principal diagnosis is the condition established after study to be chiefly responsible for this admission.*
- *The hospital enters ICD-9-CM codes for up to eight additional conditions in FLs 67A-67Q if they co-existed at the time of admission or developed subsequently, and which had an effect upon the treatment or the length of stay. It may not duplicate the principal diagnosis listed in FL 67.*
- For inpatient hospital claims, the admitting diagnosis is required and should be recorded in FL 69. (See CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 25, Section 75 for additional instructions.)

Hospital Outpatient Claims:

- *The hospital should report the full ICD-9-CM code for the diagnosis shown to be chiefly responsible for the outpatient services in FL 67. If no definitive diagnosis is made during the outpatient evaluation, the patient's symptom is reported. If the patient arrives without a referring diagnosis, symptom or complaint, the provider should report an ICD-9-CM code for Persons Without Reported Diagnosis Encountered During Examination and Investigation of Individuals and Populations (V70-V82).*
- *The hospital enters the full ICD-9-CM codes in FLs 67A-67Q for up to eight other diagnoses that co-existed in addition to the diagnosis reported in FL 67.*

Other Comments:

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

Published:

Revision History/Explanation