

LCD for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (L30479)

Future

Please note: This is a Future LCD.

Contractor Information

Future

Future

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

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

Contractor Type

Carrier – MAC – FI

LCD Information

Future

Future

LCD ID Number

L30479

LCD Title

Luteinizing Hormone-Releasing Hormone (LHRH) Analogs

Contractor's Determination Number

INJ-039

AMA CPT / ADA CDT Copyright Statement

CPT codes, descriptions and other data only are copyright 2009 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. Current Dental Terminology, (CDT) (including procedure codes, nomenclature, descriptors and other data contained therein) is copyright by the American Dental Association. © 2002, 2004 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.

CMS National Coverage Policy

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

Oversight Region

Region V

Original Determination Effective Date

For services performed on or after 03/18/2010

Original Determination Ending Date

Revision Effective Date

For services performed on or after 03/18/2010

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

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 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. 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.

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.

13x	Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS 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:

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 3/92)

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 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 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 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
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, 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 that Support Medical Necessity
Diagnoses listed above.

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity
ICD-9 codes not listed above

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

Diagnoses that DO NOT Support Medical Necessity

Diagnoses that DO NOT Support Medical Necessity
Diagnoses not listed above

General Information



Documentation Requirements

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.

Appendices

Utilization Guidelines

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 entitled Gonadotropin-Releasing Hormone Analogs was previously in effect for WPS Part B.

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

* - 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

Sources of Information and Basis for Decision

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

Advisory Committee Meeting Notes

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

Open Meeting: 08/19/2009

Start Date of Comment Period

10/08/2009

End Date of Comment Period

11/23/2009

Start Date of Notice Period

02/01/2010

Revision History Number

x

Revision History Explanation

x

Reason for Change

Last Reviewed On Date

01/06/2010

Related Documents

This LCD has no Related Documents.

LCD Attachments

[Coding and Billing \(PDF - 33,691 bytes\)](#)

All Versions



Updated on 01/13/2010 with effective dates 03/18/2010 - N/A

Updated on 01/13/2010 with effective dates 03/18/2010 - N/A