Drug Coverage Policy

Effective Date……5/15/2025
Coverage Policy Number……IP0109
Policy Title……Lupron Depot

Gonadotropin-Releasing Hormone Agonists – Lupron Depot

- Lupron Depot® (leuprolide acetate suspension for intramuscular injection – AbbVie)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

Lupron Depot (3.75 mg intramuscular [IM] injection every month, 11.25 mg IM injection every 3 months) is indicated for the following conditions:[1,2]

- **Anemia caused by uterine leiomyomata** (fibroids), preoperative hematologic improvement in women for whom 3 months of hormonal suppression is deemed necessary. (Lupron Depot in combination with iron therapy).
- **Endometriosis**, including pain relief and reduction of endometriotic lesions (Lupron Depot monotherapy).
- **Endometriosis**, initial management of the painful symptoms of endometriosis and management of recurrence of symptoms (Lupron Depot and norethindrone acetate 5 mg daily).

Lupron Depot (7.5 mg IM injection every month, 22.5 mg IM injection every 3 months, 30 mg IM injection every 4 months, and 45 mg IM injection every 6 months) is indicated for the palliative treatment of **advanced prostate cancer**.[3]

Duration of Treatment:

- Lupron Depot 3.75 mg and 11.25 mg:[1,2]
  - Endometriosis: For the first 6 months of treatment, Lupron Depot may be used as monotherapy or in combination with norethindrone acetate. If retreatment is needed, Lupron Depot must be used in combination with norethindrone acetate (for 6 months). Total duration of treatment is limited to 12 months.
  - Uterine leiomyomata (fibroids): Recommended duration of treatment is up to 3 months.
- Lupron Depot 7.5 mg, 22.5 mg, 30 mg, and 45 mg: Labeling does not specify a treatment duration.

Guidelines

Abnormal Uterine Bleeding/Uterine Leiomyomata (Fibroids)

The American College of Obstetricians and Gynecologists (ACOG) [2021] practice bulletin regarding the management of symptomatic uterine leiomyomas discuss that gonadotropin-releasing hormone (GnRH) agonists (either with or without add-back hormonal therapy) are recommended for bleeding associated with fibroids, uterine enlargement associated with fibroids, and as a bridge to other treatment strategies (such as surgical management, menopause, or other medical therapies).[4] Add-back hormonal therapy (such as low-dose estrogen or progestin, or both) may help mitigate the hypoestrogenic effects of GnRH agonists, such as decreased bone mineral density. The guidelines state that the type, dose, and route of delivery of add-back therapy depend on patient preference and the severity of symptoms.

GnRH agonists can also be used for acute abnormal uterine bleeding with an aromatase inhibitor or antagonist to prevent initial estrogen flare and for the treatment of heavy menstrual bleeding caused by leiomyoma-associated hormonal imbalance.[5] A clinical practice guideline from the Society of Obstetricians and Gynecologists of Canada notes that leuprolide acetate or combined hormonal contraception should be considered highly effective in preventing abnormal uterine bleeding when initiated prior to cancer treatment in premenopausal women at risk of thrombocytopenia.[6] The ACOG committee opinion on options for prevention and management of menstrual bleeding in adolescent patients undergoing cancer treatment states that GnRH agonists are an option for menstrual suppression.[7]

Endometriosis

According to the ACOG practice bulletin on the management of endometriosis (2010, reaffirmed 2018), empiric therapy with a 3-month course of a GnRH agonist is appropriate after an appropriate pretreatment evaluation (to exclude other causes of chronic pelvic pain) and failure of initial treatment with oral contraceptives and nonsteroidal anti-inflammatory drugs.[8] The ACOG committee opinion on dysmenorrhea and endometriosis in the adolescent (2018) notes that patients with

endometriosis who have pain after conservative surgical therapy and suppressive hormonal therapy may benefit from at least 6 months of GnRH agonist therapy with add-back medicine.[9]

Other Uses With Supportive Evidence
ACOG practice guideline (2023) suggests GnRH agonists with adjunctive combined hormonal add-back therapy for adults with severe, refractory premenstrual symptoms.[25] Premenstrual disorders include the conditions of premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD). The symptoms associated with these conditions can be physical and/or affective and may interfere with daily functioning. GnRH agonists are not recommended as first-line therapy and should be reserved for adult patients who have severe symptoms. GnRH agonists are not generally used to treat premenstrual symptoms in adolescents because of the lack of efficacy data in this population and concern for long-term effects on bone health. ACOG recommends selective serotonin reuptake inhibitors for the management of affective premenstrual symptoms and combined oral contraceptives for the management of overall premenstrual symptoms.

The Endocrine Society Guideline (2017) for the Treatment of Gender-Dysphoric/Gender-Incongruent Persons note that persons who fulfill criteria for treatment and who request treatment should initially undergo treatment to suppress physical changes of puberty.[10] Pubertal hormonal suppression should typically be initiated after the adolescent first exhibits physical changes of puberty (Tanner stages G2/B2). However, there may be compelling reasons to initiate hormone treatment before the age of 16 years in some adolescents. The guidelines note suppression of pubertal development and gonadal function can be effectively achieved via gonadotropin suppression using GnRH analogs. Long-acting GnRH analogs are the currently preferred treatment option. An advantage to using a GnRH analog is that the effects can be reversed; pubertal suppression can be discontinued if the individual no longer wishes to transition. Upon discontinuation of therapy, spontaneous pubertal development has been shown to resume. The World Professional Association for Transgender Health (WPATH) Standards of Care (version 8) document also recommends the use of GnRH analogs to suppress endogenous sex hormones in transgender and gender diverse people for whom puberty blocking is indicated.[11] GnRH can also be used in patients during late puberty to suppress the hypothalamic-pituitary-gonadal axis to allow for lower doses of cross-sex hormones.[12] In addition to use in adolescents, GnRH analog therapy is also used in adults, particularly male-to-female patients.[13]

In addition to the approved indications, GnRH agonists such as long-acting leuprolide, have been used for other conditions. The National Comprehensive Cancer Network (NCCN) guidelines address the use of GnRH agonists in a number of guidelines:

- **Adolescent and young adult oncology** (version 2.2025 – September 24, 2024) guidelines note GnRH agonists may be used in (oncology) protocols that are predicted to cause prolonged thrombocytopenia and present a risk for menorrhagia.[14] There are some limited data on GnRH agonists to preserve ovarian function during chemotherapy and some have shown that GnRH agonists may be beneficial for fertility preservation, although the guidelines note further investigation is needed and other fertility preservation modalities should still be pursued.
- **Breast cancer** (version 1.2025 – January 31, 2025) guidelines note that luteinizing hormone-releasing hormone agonists, such as leuprolide, can be used for ovarian suppression.[15] Leuprolide dosing per NCCN includes 3.75 mg to 7.5 mg every 4 weeks or 11.25 mg to 22.5 mg every 12 weeks. The guidelines further note that randomized trials have shown that ovarian suppression with GnRH agonist therapy administered during adjuvant chemotherapy in premenopausal women with breast tumors (regardless of hormone receptor status) may preserve ovarian function and diminish the likelihood of chemotherapy-induced amenorrhea. GnRH analogs plus an aromatase inhibitor is mentioned as a therapy for males with breast cancer.

- **Head and neck cancer** (version 2.2025 – January 17, 2025) guidelines note that 1) leuprolide and 2) abiraterone plus prednisone plus leuprolide can be used for androgen receptor positive salivary gland tumors which are recurrent, unresectable, or metastatic.[16]
- **Ovarian cancer, including fallopian tube cancer and primary peritoneal cancer** (version 3.2024 – July 15, 2024) recommend leuprolide as a hormonal therapy option in various settings (e.g., primary therapy, adjuvant therapy, recurrence).[17]
- **Uterine neoplasm** guidelines (version 2.2025 – January 31, 2025) notes that prescribers may consider GnRH analogs with aromatase inhibitors in patients who are premenopausal and not suitable for surgery for low-grade endometrial stroma sarcoma, adenosarcoma without sarcomatous overgrowth, or hormone receptor positive uterine sarcomas.[18,21]

Coverage Policy

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lupron Depot. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lupron-Depot as well as the monitoring required for adverse events and long-term efficacy, approval for some of the conditions requires Lupron-Depot to be prescribed by or in consultation with a physician who specializes in the condition being treated.

The use of Lupron Depot for infertility is addressed in a separate coverage policy (Fertility Injectables - 1012)

Lupron Depot is considered medically necessary when the following criteria are met:

FDA-Approved Indications

1. **Endometriosis.** Approve Lupron Depot 3.75 mg or 11.25 mg for 1 year if the patient has tried ONE of the following, unless contraindicated (A, B, or C):
   A) A contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems [e.g., Mirena®, Liletta®]), OR
   B) An oral progesterone (e.g., norethindrone tablets), OR
   C) A depo-medroxyprogesterone injection.
   Note: An exception to the requirement for a trial of the above therapies can be made if the patient has previously used a gonadotropin-releasing hormone [GnRH] agonist (e.g., Lupron-Depot) or antagonist (e.g., Orilissa).

   Dosing. Approve ONE of the following dosing regimens (A or B):
   A) 3.75 mg IM once every month; OR
   B) 11.25 mg IM once every 3 months.

2. **Prostate Cancer.** Approve for 1 year if the patient meets ALL of the following (A and B):
   A. Prescribed by or in consultation with an oncologist.
   B. Preferred product criteria is met for the product(s) as listed in the below table(s)

Employer Plans:

Product	Criteria

Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg (leuprolide acetate)	**Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg is considered medically necessary when the following are met:** A. **ONE** of the following (i or ii): i. Patient has tried **ONE** of the following (a or b): a. **Eligard** [may require prior authorization] b. **Firmagon** [may require prior authorization] ii. Patient is currently receiving Lupron Depot

Individual and Family Plans:

Product	**Criteria**
Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg (leuprolide acetate)	**Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg is considered medically necessary when the following are met:** A. **ONE** of the following (i or ii): i. Patient has tried **ONE** of the following (a or b): a. **Eligard** [may require prior authorization] b. **Firmagon** [may require prior authorization] ii. Patient is currently receiving Lupron Depot

Dosing. Approve ONE of the following dosing regimens (A, B, C, or D):
A) 45 mg IM once every 6 months; OR
B) 30 mg IM once every 4 months; OR
C) 22.5 mg IM once every 3 months; OR
D) 7.5 mg IM once every month.

3. **Uterine Leiomyomata (fibroids).** Approve for 3 months.

   Dosing. Approve ONE of the following dosing regimens (A or B):
   A) 3.75 mg IM once every month; OR
   B) 11.25 mg IM once every 3 months.

Other Uses with Supportive Evidence

4. **Abnormal Uterine Bleeding.** Approve for 6 months.

   Dosing. Approve ONE of the following dosage regimens (A or B):
   A) 3.75 IM once every month; OR
   B) 11.25 IM once every 3 months.

5. **Breast Cancer.** Approve for 1 year if prescribed by or in consultation with an oncologist.

   Dosing. Approve ONE of the following dosage regimens (A or B):
   A) 3.75 mg or 7.5 mg IM once every month; OR
   B) 11.25 mg or 22.5 mg IM once every 3 months.

6. **Gender Dysphoric/Gender-Incongruent Persons; Persons Undergoing Gender Reassignment (Female-To-Male [FTM] or Male-to-Female [MTF]).** Approve for 1 year if prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.

Dosing. Approve ONE of the following dosage regimens (A, B, C, or D):
A) 3.75 or 7.5 mg IM once every month; OR
B) 11.25 or 22.5 mg IM once every 3 months; OR
C) 30 mg IM once every 4 months; OR
D) 45 mg IM once every 6 months.

7. **Head and Neck Cancer – Salivary Gland Tumors.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, and C):
   A) Patient has recurrent, unresectable, or metastatic disease; AND
   B) Patient has androgen receptor-positive disease; AND
   C) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve ONE of the following dosage regimens (A or B):
   A) 3.75 mg or 7.5 mg IM every month; OR
   B) 11.25 mg or 22.5 mg IM once every 3 months.

8. **Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer.** Approve for 1 year if prescribed by or in consultation with an oncologist.

   Dosing. Approve ONE of the following dosage regimens (A or B):
   A) 3.75 mg or 7.5 mg IM every month; OR
   B) 11.25 mg or 22.5 mg IM once every 3 months.

9. **Premenstrual Disorders, including Premenstrual Syndrome and Premenstrual Dysphoric Disorder.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) According to the prescriber, the patient has severe, refractory premenstrual symptoms; AND
   C) Patient has tried ONE of the following therapies (i or ii):
      i. A selective serotonin reuptake inhibitor (SSRI); OR
      Note: Examples of SSRI include citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline.
      ii. A combined oral contraceptive.

   Dosing. Approve ONE of the following dosage regimens (A or B):
   A) 3.75 mg IM once every month; OR
   B) 11.25 mg IM once every 3 months.

10. **Preservation of Ovarian Function/Fertility in Patients undergoing Chemotherapy.** Approve for 1 year if prescribed by or in consultation with an oncologist.

    Dosing. Approve ONE of the following dosage regimens (A or B):
    A) 3.75 mg IM once every month; OR
    B) 11.25 mg IM once every 3 months.

11. **Prophylaxis or Treatment of Uterine Bleeding or Menstrual Suppression in Patients with Hematologic Malignancy, or Undergoing Cancer Treatment, or Prior to Bone Marrow/Stem Cell Transplantation (BMT/SCT).** Approve for 1 year if prescribed by or in consultation with an oncologist.

    Dosing. Approve ONE of the following dosage regimens (A or B):
    A) 3.75 mg IM once every month; OR

B) 11.25 mg IM once every 3 months.

12. Uterine Cancer. Approve for 1 year if prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following dosage regimens (A, B, C, or D):
A) 7.5 mg IM once every month; OR
B) 22.5 mg IM once every 3 months; OR
C) 30 mg IM once every 4 months; OR
D) 45 mg IM once every 6 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Lupron Depot for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Menstrual Migraine**. A review article notes that GnRH analogs are effective in eliminating menstrual migraines, but their use is limited due to the significant adverse effects of estrogen deficiency, including severe vasomotor symptoms, sleep disruption, and a marked reduction in bone density.[21,22]

2. **Polycystic Ovarian Syndrome (PCOS)**. Review articles do not recommend GnRH agonists as a treatment modality. [24,25] Additionally, the International Evidence-based Guideline for the Assessment and Management of Polycystic Ovary Syndrome (2018) only mention GnRH products as they relate to infertility and assisted reproductive technology procedures.[26]

Coding Information

1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J3490[†]	Unclassified drugs
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J1954	Injection, leuprolide acetate for depot suspension (Cipla), 7.5 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg

[†]Note: May be considered for coverage when used to report Lupaneta Pack

References

1. Lupron Depot – 3.75 mg [prescribing information]. North Chicago, IL: AbbVie; October 2023.

2. Lupron Depot –11.25 mg [prescribing information]. North Chicago, IL: AbbVie; October 2023.
3. Lupron Depot – 1 Month 7.5 mg, 3 Month 22.5 mg, 4 Month 30 mg, 6 Month 45 mg [prescribing information]. North Chicago, IL: AbbVie; March 2024.
4. The American College of Obstetricians and Gynecologists (ACOG) practice bulletin No. 228: Management of Symptomatic Uterine Leiomyomas. June 2021. Available at: https://www.acog.org/. Accessed on February 10, 2025.
5. Bradley LD, Gueye NA. The medical management of abnormal uterine bleeding in reproductive-aged women. Gynecology Expert Reviews. *Am J Obstet Gynecol*. 2016;214:31-44.
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8. Management of Endometriosis. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists. Number 114. 2010 (reaffirmed 2018). *Obstet & Gynecol*. 2010;116(1):223-236.
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18. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2025. Search term: leuprolide, lueprolide depot.
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25. Management of Premenstrual Disorders. ACOG Clinical Practice Guideline. No. 7. December 2023. Available at www.acog.org/. Accessed on February 10, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Name Change: Updated** Policy Name from "Leuprolide – Long Acting" to "Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products for Non-Oncology and Non-infertility Indications." **Premenstrual Disorders, including Premenstrual Syndrome and Premenstrual Dysphoric Disorder: Added** as a new coverage condition for Lupron Depot 3.75 mg and 11.25 mg. **Medical Necessity Criteria: Removed** Stimulation Test to Confirm a Diagnosis of Central Precocious Puberty Prior to Initiation of Treatment - (leuprolide acetate only). **Added** dosing information for all FDA approved indications. **Conditions Not Covered: Removed** the conditions "Hirsutism" and "Premenstrual Syndrome (PMS)."	06/15/2024
Selected Revision	**Updated HCPCS Coding:** **Added:** J3490, J1950, J1954, J9217	12/1/2024
Annual Revision	**Updated** the name of the policy **from** "Gonadotropin-Releasing Hormone Agonists – Injectable Long Acting Products for Non-Oncology and Non-infertility Indications" **to** "Gonadotropin-Releasing Hormone Agonists – Lupron Depot" **Removed** Lupaneta Pack (obsolete). **Added** criteria for Prostate Cancer, Breast Cancer, Head and Neck Cancer – Salivary Gland Tumors, Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer, Preservation of Ovarian Function/Fertility in Patients undergoing Chemotherapy, Prophylaxis or Treatment of Uterine Bleeding or Menstrual Suppression in Patients with Hematologic Malignancy, or Undergoing Cancer Treatment, or Prior to Bone Marrow/Stem Cell Transplantation (BMT/SCT), Uterine Cancer.	5/15/2025

The policy effective date is in force until updated or retired.