Original Effective Date: 03/01/2016
Current Effective Date: 10/02/2025
Last P&T Approval/Version: 07/30/2025
Next Review Due By: 07/2026
Policy Number: C8756-A

Leuprolide Long Acting (Camcevi, Eligard, Fensolvi, Lupron Depot, Lupron Depot Ped)

PRODUCTS AFFECTED

Camcevi (leuprolide injection emulsion), Eligard (Leuprolide Acetate), Fensolvi (leuprolide acetate), leuprolide acetate (3-month depot), Lupron Depot (leuprolide), Lupron Depot-Ped (leuprolide) Lutrate Depot (leuprolide)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Advanced prostate cancer, Endometriosis, Anemia prior to uterine fibroid surgery, Precocious puberty, Premenopausal ovarian suppression in women with breast cancer, Prevention of chemotherapy induced premature ovarian insufficiency, Ovarian cancer, Transgender health

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

A. ADVANCED PROSTATE CANCER (J9217, J1952, J1954):
1. Documentation of a diagnosis of prostate cancer
AND
2. Documentation the utilization of a Gonadotropin- Releasing Hormone Agonist is recommended for the members stage and disease per NCCN updated guidelines for prostate cancer

B. ENDOMETRIOSIS (J1950 only):
1. Documentation of a diagnosis of endometriosis
AND
2. Documentation member has tried/failed or has an absolute contraindication to ALL of the following:
a) One formulary NSAID (i.e., Ibuprofen, naproxen)
AND
b) One formulary preferred oral estrogen-progestin contraceptive, or medroxyprogesterone, or norethindrone acetate
AND
3. Member is older than 18 years of age

C. UTERINE LEIOMYOMATA (FIBROIDS) (J1950 only):
1. Documentation of uterine leiomyomas confirmed with pelvic imaging
AND
2. Documentation member is symptomatic as evidenced by heavy or prolonged menstrual bleeding, bulk- related symptoms such as pelvic pressure and pain, or reproductive dysfunction (i.e., infertility or obstetric complications)
AND
3. Documentation requested therapy is being used for ONE of the following:
a) As preoperative therapy 3-6 months prior to surgery for ONE of the following reasons: Member has a contraindication to oral iron supplementation to facilitate the procedure and anemia correction is necessary OR Volume reduction is necessary prior to procedure
OR
b) As transitional therapy for members in late perimenopause as they move to menopause
AND
4. Member is older than 18 years of age

D. CENTRAL PRECOCIOUS PUBERTY (J1950, J1951):
1. Documented diagnosis of central precocious puberty and member is currently less than 13 years of age
AND
2. Documentation of an onset of secondary sexual characteristics before one of the following: Females ≤ 8 years of age OR Males ≤9 years of age
AND
3. Confirmation of diagnosis as defined by ONE of the following [DOCUMENTATION REQUIRED]:
a) Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)
b) Pubertal luteinizing hormone in response to a GnRH stimulation test
c) Bone age advanced one year beyond chronological age

E. BREAST CANCER (J9217 or J1950):
1. Documentation of a diagnosis of ONE of the following
(i) Breast cancer in a pre-menopausal or peri-menopausal woman at diagnosis requiring ovarian suppression therapy
OR
(ii) Breast cancer in a man requiring adjuvant endocrine therapy

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

F. PREVENTION OF CHEMOTHERAPY–INDUCED PREMATURE OVARIAN INSUFFICIENCY (Ref 9-17):
1. Documentation member is post puberty
   AND
2. Documentation member is undergoing premenopausal gonadotoxic therapy or gonadotoxic surgery
   AND
3. Prescriber attests member is not a candidate for cryopreservation or is not eligible for cryopreservation [see Other Special Considerations for ASCO recommendations]

G. OVARIAN CANCER: Refer to Standard Oncology Criteria

H. TRANSGENDER HEALTH: N/A
MOLINA REVIEWER NOTE: For California Marketplace, Nevada Marketplace, New Mexico Marketplace, New York Essential Plan, Utah Marketplace, Washington Marketplace, California Medicaid, Nebraska Medicaid, New Mexico Medicaid, New York Medicaid, and Utah Medicaid, please see Appendix.

CONTINUATION OF THERAPY:

A. CENTRAL PRECOCIOUS PUBERTY:
1. Documentation of disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, and improvement in final height prediction
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., convulsions, development or worsening of psychiatric symptoms, etc.)
   AND
3. Member is not currently older than age 12 OR Prescriber has provided contributing factors that may include bone age and height age, predicted height, and discontinuation plan or date.

B. ALL OTHER INDICATIONS:
1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., tumor flare, hyperglycemia/diabetes, cardiovascular disease [myocardial infarction, sudden cardiac death, stroke], QT/QTc prolongation, convulsions, etc.)
   AND
2. Documentation of improvement and/or stabilization of disease due to long-acting leuprolide therapy or member continues on gonadotoxic chemotherapy
   AND
3. FOR ENDOMETRIOSIS:
   a. Documentation that endometriosis symptoms have recurred after initial treatment AND
   b. Leuprolide will be used with norethindrone AND
   c. Treatment duration will not exceed lifetime maximum of 12 months (6 month initial treatment and 6 months for treatment of recurrence)
   AND
4. FOR UTERINE FIBROIDS: Documentation that member's treatment has not exceeded the lifetime maximum of 6 months.

DURATION OF APPROVAL:

ADVANCED PROSTATE CANCER, BREAST CANCER: Initial authorization: 12 months, Continuation of Therapy: 12 months
CENTRAL PRECOCIOUS PUBERTY: Initial authorization: 12 months, Continuation of therapy: 12 months
ENDOMETRIOSIS: Initial authorization: 6 months, Continuation of Therapy: 6 months; Lifetime maximum: 12 months
UTERINE FIBROIDS: Initial authorization: 3 months, Continuation of Therapy: 3 months; Lifetime maximum: 6 months
PREVENTION OF CHEMOTHERAPY–INDUCED PREMATURE OVARIAN INSUFFICIENCY: Initial

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Endometriosis, Uterine Fibroids: Prescribed by or in consultation with a gynecologist or specialist in women's health.
Precocious Puberty: Prescribed by or in consultation with a Pediatric Endocrinologist.
Oncology conditions: Prescribed by or in consultation with an Oncologist or specialist in cancer treatment (e.g., urologist for prostate cancer, etc.).
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests.]

AGE RESTRICTIONS:
Central Precocious Puberty: 2 years of age and older (LUPRON DEPO-PED, FENSOLVI)
Prevention Of Chemotherapy–Induced Premature Ovarian Insufficiency: Member must be post-puberty
All other indications: 18 years of age and older

QUANTITY:
Camcevi 42 mg 1 subcutaneous injection 168 days
Eligard 7.5 mg 1 injection 28 days
Eligard 22.5 mg 1 injection 84 days
Eligard 30 mg 1 injection 112 days
Eligard 45 mg 1 injection 168 days
Fensolvi 45mg 1 injection 168 days
Lupron Depot 1-Month 3.75 mg 1 injection 28 days
Lupron Depot 1-Month 7.5 mg 1 injection 28 days
Lupron Depot 3-Month 11.25 mg 1 injection 84 days
Lupron Depot 3-Month 22.5 mg 1 injection 84 days
Leuprolide Depot 3-Month 22.5 mg 1 injection 84 days
Lupron Depot 4-Month 30 mg 1 injection 112 days
Lupron Depot 6-Month 45 mg 1 injection 168 days
Lupron Depot-Ped 7.5 mg 1 injection 28 days
Lupron Depot-Ped 11.25 mg 1 injection 28 days
Lupron Depot-Ped 3-Month 11.25 mg 1 injection 84 days
Lupron Depot-Ped 15 mg 1 injection 28 days
Lupron Depot-Ped 3-Month 30 mg 1 injection 84 days
Lupron Depot-Ped 6-month 45 mg 1 injection 168 days
Lutrate Depot 3-Month 22.5 mg 1 injection 84 days

Maximum Quantity Limits – Per FDA labeling for products.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous and intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location.

RECOMMEND USE OF J9217, J1952, J1954 FOR ONCOLOGY INDICATIONS, RECOMMEND USE OF J1950, J1951 FOR WOMEN'S HEALTH AND CPP INDICATIONS

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intramuscular, Subcutaneous

DRUG CLASS:
LHRH Analogs, LHRH/GnRH Agonist Analog Pituitary Suppressants

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

FDA-APPROVED USES:

Advanced prostate cancer, Endometriosis and Uterine leiomyomata fibroids, Central precocious puberty

COMPENDIAL APPROVED OFF-LABELED USES:

Breast cancer, Premenopausal ovarian suppression; Recurrent, unresectable, or metastatic salivary gland tumors (with no surgery or RT option) with AR+ tumors (NCCN Head and Neck Cancers SALI-B)

APPENDIX

APPENDIX:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

State Marketplace

California (Source: California Code of Regulations)
Article 15.1 Gender Nondiscrimination in Health Insurance § 2561.2. Discrimination on the Basis of Actual or Perceived Gender Identity. (a) An admitted insurer shall not, in connection with health insurance as defined in subdivision (b) of Insurance Code section I 06, discriminate on the basis of an insured's or prospective insured's actual or perceived gender identity, or on the basis that the insured or prospective insured is a transgender person. The discrimination prohibited by this Section 2561.2 includes any of the following:… (4) Denying or limiting coverage, or denying a claim, for services including but not limited to the following, due to an insured's actual or perceived gender identity or for the reason that the insured is a trans gender person: (A) Health care services related to gender transition if coverage is available for those services under the policy when the services are not related to gender transition, including but not limited to hormone therapy, hysterectomy, mastectomy, and vocal training; or (B) Any health care services that are ordinarily or exclusively available to individuals of one sex when the denial or limitation is due only to the fact that the insured is enrolled as belonging to the other sex or has undergone, or is in the process of undergoing, gender transition. (b) This Section 2561.2 shall have no bearing on the question of whether or not a particular health care service is medically necessary in any individual case."

Nevada (Source: Nevada Legislature)
Senate Bill No. 163 "Section 1. Chapter 689A of NRS is hereby amended by adding thereto the provisions set forth as sections 1.3 and 1.6 of this act.
Sec. 1.3. 1. Except as otherwise provided in this section, an insurer that issues a policy of health insurance shall include in the policy coverage for the medically necessary treatment of conditions relating to gender dysphoria and gender incongruence. Such coverage must include coverage of medically necessary psychosocial and surgical intervention and any other medically necessary treatment for such disorders…
5. When determining whether treatment is medically necessary for the purposes of this section, an insurer must consider the most recent Standards of Care published by the World Professional Association for Transgender Health, or its successor organization."

New Mexico (Source: New Mexico Legislature, Medical Assistance Program Manual)
NM HB007 "BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO: SECTION 1. A new section of Chapter 24 NMSA 1978 is enacted to read: "SHORT TITLE.--This act may be cited as the "Reproductive and Gender-Affirming Health Care Freedom Act"." SECTION 2. A new section of Chapter 24 NMSA 1978 is enacted to read: "DEFINITIONS.--As used in the Reproductive and Gender-Affirming Health Care Freedom Act: A. "gender-affirming health care" means psychological, behavioral, surgical, pharmaceutical and medical care, services and supplies provided to support a person's gender identity;… SECTION 3. A new section of Chapter 24 NMSA 1978 is enacted to read: "PUBLIC BODY PROHIBITED ACTION.-- B. A public body or an entity or individual acting on behalf of or within the scope of the authority of a public body shall not deny, restrict or interfere with a person's HB 7/a Page 3 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 ability to access or provide reproductive health care or gender-affirming health care within the medical standard of care."
State of New Mexico Medical Assistance Program Manual Supplement Number: 24-15 "In the 2023 legislative session, the New Mexico legislature passed House Bill 7 codifying access to both abortion and gender affirming

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

healthcare. This supplement is to provide guidance and clarification as to what constitutes medically necessary gender affirming healthcare.
1. Recipient Eligibility Requirements: MAD will allow and reimburse services for recipients with the following requirements. Requirements and indications must be documented in the member's medical record.
a. Age:
i. Recipients twelve years to seventeen years of age are eligible for hormone therapy only,
ii. Recipients eighteen years of age and older are eligible for hormone therapy, procedural and surgical interventions"

New York (Source: Department of Financial Services)
STATE COMPILATION OF CODES, RULES AND REGULATIONS OF THE STATE OF NEW YORK
TITLE 11. INSURANCE
CHAPTER III. POLICY AND CERTIFICATE PROVISIONS
SUBCHAPTER A. LIFE, ACCIDENT AND HEALTH INSURANCE
PART 52. MINIMUM STANDARDS FOR FORM, CONTENT AND SALE OF HEALTH INSURANCE, INCLUDING STANDARDS OF FULL AND FAIR DISCLOSURE
"52.75 Prohibition on discrimination based on sexual orientation, gender identity or expression, or transgender status.
(a) In addition to the prohibitions against discrimination set forth in section 52.72 of this Part, an insurer shall not discriminate based on an insured's or prospective insured's actual or perceived sexual orientation, gender identity or expression, or transgender status. Discrimination prohibited by this section includes any of the following:
(1) including a policy clause that purports to deny, limit, or exclude coverage based on an insured's sexual orientation, gender identity or expression, or transgender status;
(2) denying, limiting, or otherwise excluding medically necessary services or treatment otherwise covered by a policy on the basis that the treatment is for gender dysphoria; provided further that an insurer shall provide an insured with the utilization review appeal rights required by Insurance Law and Public Health Law articles 49 for gender dysphoria treatment that is denied based on medical necessity;
(3) designating an insured's sexual orientation, gender identity or expression, or transgender status as a pre-existing condition for the purpose of denying, limiting, or excluding coverage; or
(4) denying a claim from an insured of one gender or sex for a service that is typically or exclusively provided to an individual of another gender or sex unless the insurer has taken reasonable steps, including requesting additional information, to determine whether the insured is eligible for the services prior to denial of such claim."

Utah (Source: State of Utah)
S.B. 16 Transgender Medical Treatments and Procedures Amendments "Highlighted Provisions: This bill: defines terms;… requires the Division of Professional Licensing to create a certification for providing hormonal transgender treatments; requires a health care provider to meet certain requirements before providing a hormonal transgender treatment; prohibits a health care provider from providing a hormonal transgender treatment to new patients who were not diagnosed with gender dysphoria before a certain date;…"
MOLINA REVIEWER NOTE: For requests for members <19 years of age, refer to Childhood or Adolescent Gender Dysphoria UT MKP C29291-A.

Washington (Source: State of Washington)
Senate Bill 5313 "Sec. 3. RCW 48.43.0128 and 2020 c 228 s 9 are each amended to read as follows:… (3) For health plans issued or renewed on or after January 1, 2022: (a) A health carrier may not deny or limit coverage for gender affirming treatment when that treatment is prescribed to an individual because of, related to, or consistent with a person's gender expression or identity, as defined in RCW 49.60.040, is medically necessary, and is prescribed in accordance with accepted standards of care."

State Medicaid
California (Source: Department of Health Care Services)
All-Plan Letter 20-018 "MCPs [managed care health plans] are contractually obligated to provide medically necessary covered services to all members, including transgender members. State law defines "medically necessary" as follows: (a) For individuals 21 years of age or older, a service is "medically necessary" or a "medical necessity" when it is reasonable and necessary to protect life, to prevent

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

significant illness or significant disability, or to alleviate severe pain. (b) For individuals under 21 years of age, a service is “medically necessary” or a “medical necessity” if the service corrects or ameliorates defects and physical and mental illnesses and conditions.…Nationally recognized medical experts in the field of transgender health care have identified the following core services in treating gender dysphoria: mental health services; psychotherapy; hormone therapy; and a variety of surgical procedures and treatments that bring primary and secondary gender characteristics into conformity with the individual’s identified gender.”

Nebraska (Source: Legislature of Nebraska)
“Sec. 18. (1) The chief medical officer as designated in section 19 81-3115 shall adopt and promulgate such rules and regulations as are necessary to provide for nonsurgical gender-altering procedures for individuals younger than nineteen years of age, such as puberty-blocking drugs, cross-sex hormones, or both. Such rules and regulations shall be consistent with the Let Them Grow Act…”
MOLINA REVIEWER NOTE: For requests for member’s <19 years of age, refer to Gender Dysphoria Hormone Therapy Molina NE Medicaid C26626-A.

New Mexico (Source: New Mexico Legislature, Medical Assistance Program Manual)
NM HB007 “BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO: SECTION 1. A new section of Chapter 24 NMSA 1978 is enacted to read: "SHORT TITLE.--This act may be cited as the "Reproductive and Gender-Affirming Health Care Freedom Act"." SECTION 2. A new section of Chapter 24 NMSA 1978 is enacted to read: "DEFINITIONS.--As used in the Reproductive and Gender-Affirming Health Care Freedom Act: A. "gender-affirming health care" means psychological, behavioral, surgical, pharmaceutical and medical care, services and supplies provided to support a person's gender identity;… SECTION 3. A new section of Chapter 24 NMSA 1978 is enacted to read: "PUBLIC BODY PROHIBITED ACTION.-- B. A public body or an entity or individual acting on behalf of or within the scope of the authority of a public body shall not deny, restrict or interfere with a person's HB 7/a Page 3 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 ability to access or provide reproductive health care or gender-affirming health care within the medical standard of care.”
State of New Mexico Medical Assistance Program Manual Supplement Number: 24-15 “In the 2023 legislative session, the New Mexico legislature passed House Bill 7 codifying access to both abortion and gender affirming healthcare. This supplement is to provide guidance and clarification as to what constitutes medically necessary gender affirming healthcare.
1. Recipient Eligibility Requirements: MAD will allow and reimburse services for recipients with the following requirements. Requirements and indications must be documented in the member’s medical record.
a. Age:
i. Recipients twelve years to seventeen years of age are eligible for hormone therapy only,
ii. Recipients eighteen years of age and older are eligible for hormone therapy, procedural and surgical interventions”

New York (Source: New York Codes, Rules and Regulations)
Title 18 Section 505.2 – Physicians’ services.
“…(l) Gender dysphoria treatment.
(l) As provided in this subdivision, payment is available for medically necessary hormone therapy and/or gender reassignment surgery for the treatment of gender dysphoria.
(2) (i) Hormone therapy, whether or not in preparation for gender reassignment surgery, shall be covered as follows:
(a) treatment with gonadotropin-releasing hormone agents (pubertal suppressants), based upon a determination by a qualified medical professional that an individual is eligible and ready for such treatment, i.e., that the individual:
(1) meets the criteria for a diagnosis of gender dysphoria;
(2) has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;
(3) does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
(4) has adequate psychological and social support during treatment; and
(5) demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment;

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

(b) treatment with cross-sex hormones for patients who are sixteen years of age and older, based upon a determination of medical necessity made by a qualified medical professional; patients who are under eighteen years of age must meet the applicable criteria set forth in clause (a).
(ii) Notwithstanding the requirement in clause (b) of subparagraph (i) of this paragraph that an individual be sixteen years of age or older, payment for cross-sex hormones for patients under sixteen years of age who otherwise meet the requirements of clause (b) of subparagraph (i) of this paragraph shall be made in specific cases if medical necessity is demonstrated and prior approval is received."

Utah (Source: State of Utah)
S.B. 16 Transgender Medical Treatments and Procedures Amendments "Highlighted Provisions: This bill: defines terms;… requires the Division of Professional Licensing to create a certification for providing hormonal transgender treatments; requires a health care provider to meet certain requirements before providing a hormonal transgender treatment; prohibits a health care provider from providing a hormonal transgender treatment to new patients who were not diagnosed with gender dysphoria before a certain date;…"
MOLINA REVIEWER NOTE: For requests for members <19 years of age, refer to Gonadotropin-Releasing Hormone (GnRH) MHUT C24948-A or Hormone Therapy for Gender Dysphoria MHUT C24947-A.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Leuprolide is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone or luteinizing hormone-releasing hormone (GnRH or LHRH), which possesses greater potency compared with the natural hormone (generally considered a GnRH agonist). It acts as a potent inhibitor of gonadotropin secretion when administered continuously in therapeutic doses. Following initial stimulation of gonadotropins, chronic administration of leuprolide leads to suppression of ovarian and testicular steroidogenesis. These effects are reversible after drug discontinuation.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Leuprolide long acting are considered experimental/ investigational and therefore, will follow Molina's Off-Label policy. Contraindications to leuprolide include: hypersensitivity to GnRH, GnRH agonist analogs, or any of the excipients in the preparation, undiagnosed abnormal uterine bleeding, and pregnancy.

Exclusions/Discontinuation:
Requested use is for In vitro fertilization or infertility, hirsutism or menstrual migraine.

OTHER SPECIAL CONSIDERATIONS:
FERTILITY PRESERVATION:
Fertility Preservation in People with Cancer: American Society of Clinical Oncology Guideline Update 2025
Fertility preservation in females
Recommendation 4.1 Embryo cryopreservation: Embryo cryopreservation should be offered as it is an established fertility preservation method, and it has routinely been used for storing embryos after in vitro fertilization.

Recommendation 4.2. Mature oocyte cryopreservation: Cryopreservation of unfertilized oocytes should be offered as it is an established fertility preservation method and may be especially well suited to females who do not have a male partner, do not wish to use donor sperm, or have religious or ethical objections to embryo freezing. Oocyte cryopreservation should be performed in centers with the necessary expertise.. Qualifying statement: Flexible ovarian stimulation protocols for oocyte collection are available. Timing of this procedure no longer depends on the menstrual cycle in most cases, and stimulation can be initiated with less delay compared with older protocols. Thus, oocyte harvesting for the purpose of oocyte or embryo cryopreservation is now possible on a cycle day–independent schedule. Of special concern in estrogen-sensitive breast and gynecologic malignancies is the possibility that these fertility preservation interventions (e.g., ovarian stimulation regimens that increase estrogen levels) may increase the risk of cancer

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

progression or recurrence. Aromatase inhibitor–based stimulation protocols are now well established and may alleviate these concern. In particular, there is no increased cancer recurrence risk as a result of aromatase inhibitor– supplemented ovarian stimulation.

Recommendation 4.3. Post-treatment setting: Embryo and oocyte cryopreservation for fertility preservation may be offered in the post-treatment setting to patients who did not undergo fertility preservation before their cancer treatment but are at risk of primary ovarian insufficiency or infertility. They may also be offered to survivors who previously underwent fertility preservation but may not have enough cryopreserved tissue to meet their desired family size, as well as for those who want or need to delay childbearing and consequently face the risk of age-related fertility decline, which may be accelerated in cancer survivors.

Recommendation 4.4. In vitro maturation (IVM): IVM of oocytes may be offered as an emerging FP method.

Recommendation 4.5. Ovarian transposition: Ovarian transposition (oophoropexy) may be offered to reproductive-aged patients when pelvic irradiation is required. However, because of radiation scatter, ovaries are not always protected, and patients should be aware that this technique is not always successful. Because of the risk of remigration of the ovaries, this procedure should be performed as close to the time of radiation treatment as possible.
Qualifying Statement: Ovarian transposition is not suitable for patients with a moderate or high risk of ovarian metastasis, or those receiving concomitant gonadotoxic chemotherapy.

Recommendation 4.6. Uterine transposition: Uterine transposition in reproductive-aged patients remains experimental and should be offered only as part of a clinical trial or approved experimental protocols.

Recommendation 4.7. Conservative gynecologic surgery: For patients with stage IA2 to IB1 cervical cancer, radical trachelectomy may be offered to preserve fertility if the tumor diameter is <2 cm and invasion depth is <10 mm. For patients with well-differentiated (grade 1) endometrial tumors with minimal myometrial invasion, as confirmed by magnetic resonance imaging, fertility-sparing surgery may be offered. Hormonal therapy using progestins, either orally or via an intrauterine device, is the primary fertility-preserving option for early-stage endometrial cancer. Patients with stage IA grade 1 epithelial ovarian cancer after thorough staging may be offered fertility-sparing surgery. Uterine preservation may be considered in other stages and grades to enable future use of assisted reproductive technologies. In other gynecologic malignancies, less radical surgeries may be offered to spare reproductive organs when clinically appropriate.

Recommendation 4.8. Ovarian suppression: Gonadotropin-releasing hormone agonists (GnRHa) should not be used in place of established fertility preservation methods such as oocyte, embryo, or ovarian tissue cryopreservation. GnRHa may be offered as an adjunct to females with breast cancer. Beyond breast cancer, the potential benefits and risks of GnRHa warrant further investigation, and trials are encouraged.

Recommendation 4.9. Ovarian suppression: For patients with oncologic emergencies requiring urgent chemotherapy, GnRHa may be offered and can provide benefits such as menstrual suppression.

Recommendation 4.10. Ovarian tissue cryopreservation and transplantation: Ovarian tissue cryopreservation (OTC) for the purpose of future transplantation may be offered to patients with cancer as an established fertility preservation method. As it does not require ovarian stimulation, it can be performed immediately in those unable to delay chemotherapy. In addition, it does not require sexual maturity and hence may be the only method available in prepubertal patients. This method may also be offered as an emerging method to restore global ovarian function. While this option may be offered as an alternative to embryo or oocyte cryopreservation, it may also serve as an adjunct option. Proceeding with OTC should be guided by patient preferences, clinical considerations, and individual circumstances including future flexibility, success rates, and legal considerations.

Fertility preservation in children

Recommendation 5.1. Clinicians should offer established methods of fertility preservation (e.g., semen or oocyte cryopreservation) in children and adolescents who have initiated puberty, with patient assent and parent or guardian consent. For prepubertal children, the only fertility preservation options are ovarian and

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

testicular cryopreservation, the latter of which is currently investigational.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg
J1952	Leuprolide injectable, camcevi, 1 mg
J1954	Injection, leuprolide acetate for depot suspension (Cipla), 7.5 mg
J1954	Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg

AVAILABLE DOSAGE FORMS:
Prostate cancer:
Eligard KIT 7.5MG
Eligard KIT 22.5MG
Eligard KIT 30MG
Eligard KIT 45MG
Lupron Depot (1-Month) KIT 7.5MG
Lupron Depot (3-Month) KIT 22.5MG
Lupron Depot (4-Month) KIT 30MG
Lupron Depot (6-Month) KIT 45MG
RECOMMEND USE OF J9217 FOR MEDICAL BILLING

Prostate cancer:
Camcevi 42 MG
RECOMMEND USE OF J1952 FOR MEDICAL BILLING

Prostate cancer:
Leuprolide Acetate INJ 22.5MG (3 Month)
Lutrate Depot INJ 22.5MG (3 Month)
RECOMMEND USE OF J1954 FOR MEDICAL BILLING

Endometriosis and Uterine leiomyomata fibroids:
Lupron Depot (1-Month) KIT 3.75MG
Lupron Depot (3-Month) KIT 11.25MG
RECOMMEND USE OF J1950 FOR MEDICAL BILLING

Central Precocious puberty:

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Lupron Depot-Ped (1-Month) KIT 11.25MG
Lupron Depot-Ped (1-Month) KIT 15MG
Lupron Depot-Ped (1-Month) KIT 7.5MG
Lupron Depot-Ped (3-Month) KIT 11.25MG (Ped)
Lupron Depot-Ped (3-Month) KIT 30MG (Ped)
Lupron Depot-Ped (6-month) KIT 45MG (Ped)
RECOMMEND USE OF J1950 FOR MEDICAL BILLING

Central Precocious puberty:
Fensolvi (6 Month) KIT 45MG (Ped)
RECOMMEND USE OF J1951 FOR MEDICAL BILLING

REFERENCES

1. Lupron Depot (leuprolide acetate for depot suspension) for intramuscular injection[prescribing information]. North Chicago, IL: AbbVie Inc; March 2024.
2. Lupron Depot 3.75mg (leuprolide acetate for depot suspension) for injection, for intramuscular use [prescribing information]. North Chicago, IL: AbbVie Inc; October 2023.
3. Lupron Depot 11.25mg (leuprolide acetate for depot suspension) for injection, for intramuscular use [prescribing information]. North Chicago, IL: AbbVie Inc; October 2023.
4. Lupron Depot-Ped (leuprolide acetate for depot suspension) for intramuscular use [prescribing information]. North Chicago, IL: AbbVie Inc; April 2023.
5. Leuprolide Acetate Injection Depot (leuprolide acetate for depot suspension) 22.5mg for intramuscular injection [prescribing information]. Warren, NJ: Cipla USA, Inc.; August 2024.
6. Camcevi (leuprolide) injectable emulsion, for subcutaneous use [prescribing information]. Durham, NC: Accord BioPharma Inc., February 2025.
7. Fensolvi (leuprolide acetate) for injectable suspension, for subcutaneous use [prescribing information]. Fort Collins, CO: Tolmar; October 2024.
8. Lutrate Depot (leuprolide acetate), for depot suspension 22.5mg for intramuscular injection [prescribing information]. New Jersey: Avyxa Pharma, LLC; November 2024.
9. Peccatori FA, Azim HA Jr, Orecchia R, et al: Cancer, pregnancy and fertility: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol 24:vi160-vi170, 2013(suppl 6)
10. Loren AW, Mangu PB, Beck LN, et al: Fertility preservation for patients with cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol 31:2500-2510, 2013
11. Blumenfeld Z, Katz G, Evron A: 'An ounce of prevention is worth a pound of cure': The case for and against GnRH-agonist for fertility preservation. Ann Oncol 5:1719-1728, 2014
12. Blumenfeld Z, von Wolff M: GnRH-analogues and oral contraceptives for fertility preservation in women during chemotherapy. Hum Reprod Update 14: 543-552, 2008
13. Lambertini M, Ceppi M, Poggio F, et al: Ovarian suppression using luteinizing hormone releasing hormone agonists during chemotherapy to preserve ovarian function and fertility of breast cancer patients: A meta-analysis of randomized studies. Ann Oncol 26:2408-2419, 2015
14. Blumenfeld, Z. (2018). Fertility Preservation by Endocrine Suppression of Ovarian Function Using Gonadotropin-Releasing Hormone Agonists: The End of the Controversy? Journal Of Clinical Oncology, 36(19), 1895-1897. doi: 10.1200/jco.2018.78.9347
15. Oktay K, Harvey BE, Partridge AH, et al. Fertility Preservation in Patients with Cancer: ASCO Clinical Practice Guideline Update. J Clin Oncol 2018;36:1994.
16. Ethics Committee of the American Society for Reproductive Medicine. Electronic address: ASRM@asrm.org. Fertility preservation and reproduction in patients facing gonadotoxic therapies: an Ethics Committee opinion. Fertil Steril 2018; 110:380.
17. Su, H. I., Lacchetti, C., Letourneau, J., Partridge, A. H., Qamar, R., Quinn, G. P., … Loren, A. W. (2025). Fertility Preservation in People With Cancer: ASCO Guideline Update. Journal of Clinical Oncology, 43(12). https://doi.org/10.1200/jco-24-02782
18. National Comprehensive Cancer Network Guidelines Version 2.2018. Breast Cancer.www.nccn.org. Accessed 04/2019.
19. National Comprehensive Cancer Network Guidelines Version 4.2018. Prostate Cancer. www.nccn.org. Accessed 04/2019.

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

20. National Comprehensive Cancer Network. 2023. Breast Cancer (Version 4.2023). [online] Available at: <breast.pdf (nccn.org)> [Accessed 17 May 2023].
21. National Comprehensive Cancer Network. 2023. Prostate Cancer (Version 1.2023). [online] Available at: <prostate.pdf (nccn.org)> [Accessed 17 May 2023].
22. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. (2021). Obstetrics & Gynecology, 137(6), e100–e115. https://doi.org/10.1097/aog.0000000000004401
23. National Comprehensive Cancer Network. 2024. Breast Cancer (Version 3.2024). [online] Available at: <breast.pdf (nccn.org)> [Accessed 27 June 2024].
24. National Comprehensive Cancer Network. 2024. Prostate Cancer (Version 4.2024). [online] Available at: <prostate.pdf (nccn.org)> [Accessed 27 June 2024].
25. Kaplowitz, P., Bloch, C., & Endocrinology, the S. O. (2016). Evaluation and Referral of Children With Signs of Early Puberty. Pediatrics, 137(1). https://doi.org/10.1542/peds.2015-3732
26. National Comprehensive Cancer Network. 2025. Head and Neck Cancers (Version 4.2025). [online] Available at: < head-and-neck.pdf (nccn.org)> [Accessed 22 June 2025].
27. National Comprehensive Cancer Network. 2025. Breast Cancer (Version 4.2025). [online] Available at: <breast.pdf (nccn.org)> [Accessed 22 June 2025].
28. National Comprehensive Cancer Network. 2025. Prostate Cancer (Version 2.2025). [online] Available at: <prostate.pdf (nccn.org)> [Accessed 22 June 2025].

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Quantity Drug Class	Q3 2025
Compendial Approved Off-Labeled Uses Contraindications/Exclusions/ Discontinuation Other Special Considerations Coding/Billing Information Available Dosage Forms References	
REVISION- Notable revisions: Continuation of Therapy Duration of Approval References	Q3 2024
REVISION- Notable revisions: Continuation of Therapy Duration of Approval References	Q1 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Quantity Place of Administration Appendix Coding/Billing Information Available Dosage Forms References	Q3 2023

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

REVISION- Notable revisions: Products Affected Required Medical Information Prescriber Requirements Quantity Coding/Billing Information Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file

Molina Healthcare, Inc. confidential and proprietary © 2025
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.