Clinical Policy: Leuprolide Acetate (Eligard, Fensolvi, Lupaneta Pack, Lupron Depot, Lupron Depot-PED), Leuprolide Mesylate (Camcevi)

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Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Leuprolide acetate (Eligard®, Fensolvi®, Lupaneta Pack® [with norethindrone acetate tablets], Lupron Depot®, Lupron Depot-Ped®) and leuprolide mesylate (Camcevi™) are gonadotropin-releasing hormone (GnRH) agonists.

FDA Approved Indication(s):
Leuprolide acetate is indicated for:

- Palliative treatment of advanced prostate cancer:
  - Leuprolide acetate injection
  - Eligard
- Treatment of advanced prostate cancer:
  - Lupron Depot (7.5, 22.5, 30, 45)
- Initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms:
  - Lupaneta Pack (3.75, 11.25)

  Limitation(s) of use: Initial treatment course is limited to 6 months and use is not recommended longer than a total of 12 months due to concerns about adverse impact on bone mineral density.
- Management of endometriosis, including pain relief and reduction of endometriotic lesions; In combination with a norethindrone acetate for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms:
  - Lupron Depot (3.75, 11.25)

  Limitation(s) of use: total duration of therapy plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.
- Concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by uterine leiomyomata [fibroids] for whom three months of hormonal suppression is deemed necessary:
  - Lupron Depot (3.75, 11.25)

  Limitation of use: not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.
- Treatment of children with central precocious puberty (CPP):
  - Fensolvi
  - Leuprolide acetate
  - Lupron Depot-Ped (7.5, 11.25, 15, 30)

Camcevi is indicated for the treatment of adult patients with advanced prostate cancer.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Camcevi, leuprolide acetate injection, Eligard, Fensolvi, Lupaneta Pack, Lupron Depot, and Lupron Depot-Ped are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all)**:**

1. Diagnosis of prostate cancer;
2. Request is for one of the following (a, b, c, or d):
   a. Leuprolide acetate injection;
   b. Camcevi;
   c. Eligard;
   d. Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg);
3. Prescribed by or in consultation with an oncologist or urologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a, b, c, or d):*
   a. Leuprolide acetate injection (SC): Dose does not exceed 1 mg per day;
   b. Camcevi (SC): Dose does not exceed 42 mg per 6 months;
   c. Eligard (SC)/Lupron Depot (IM): Dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, 45 mg per 6 months;
   d. Dose is supported by practice guidelines or peer reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Endometriosis (must meet all)**:**

1. Diagnosis of endometriosis;
2. Request is for one of the following (a or b):
   a. Lupron Depot (3.75 mg, 11.25 mg);
   b. Lupaneta Pack (3.75 mg, 11.25 mg);
3. Prescribed by or in consultation with a gynecologist;
4. Age ≥ 18 years;
5. Endometriosis as a cause of pain is one of the following (a or b):
   a. Surgically confirmed;
   b. Both of the following (i and ii):
      i. Clinically suspected;
      ii. Failure of a 3-month trial of one of the following within the last year, unless clinically adverse effects are experienced or all are contraindicated (1, 2, or 3):
         1) A nonsteroidal anti-inflammatory drug *(see Appendix B for examples)*;
         2) An oral or injectable depot contraceptive *(see Appendix B for examples)*;
         3) A progestin *(see Appendix B for examples)*;
6. For members currently receiving treatment with leuprolide, total duration of therapy has not exceeded 12 months;
7. Dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: 6 months

C. Uterine Fibroids (must meet all)**:**

1. Diagnosis of anemia secondary to uterine leiomyomata (fibroids);
2. Diagnosis is confirmed by ultrasound;
3. Request is for Lupron Depot (3.75 mg, 11.25 mg);
4. Prescribed by or in consultation with a gynecologist;
5. Age ≥ 18 years;
6. Prescribed preoperatively to reduce fibroid size and improve hematologic control;
7. For members currently receiving treatment with leuprolide, total duration of therapy has not exceeded 3 months per treatment course;
8. Dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: 3 months

D. Central Precocious Puberty (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Diagnosis of CPP confirmed by all of the following (i, ii, and iii):
      i. Elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/L (dependent on type of assay used) and/or elevated leuprolide-stimulated LH level > 3.3 - 5 IU/L (dependent on type of assay used);
      ii. Difference between bone age and chronological age was > 1 year (bone age-chronological age);
      iii. Age at onset of secondary sex characteristics (1 or 2):
         1) Female: < 8 years;
         2) Male: < 9 years;
   b. Request is for diagnostic use;
2. Request is for one of the following (a, b or c):
   a. Fensolvi;
   b. Leuprolide acetate;
   c. Lupron Depot Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Member meets one of the following age requirements (a or b):
   a. Female: 2 - 11 years;
   b. Male: 2 - 12 years;
5. Dose does not exceed the following (a, b, c or d):
   a. Diagnostic use: Leuprolide acetate (SC): 20 mcg/kg or as needed;
   b. Therapeutic use: Fensolvi: 45 mg per 6 months;
   c. Therapeutic use: Leuprolide acetate (SC): Initial: 50 mcg/kg per day; titrate dose upward by 10 mcg/kg per day if down-regulation is not achieved (higher mg/kg doses may be required in younger children);
   d. Therapeutic use: Lupron Depot-Ped (IM): 15 mg per month (1 month formulation) or 30 mg per 3 months (3 month formulation) (weight-based dosing).

Approval duration: 12 months

E. Breast and Ovarian Cancer (off-label) (must meet all)**:**
1. Diagnosis of hormone receptor-positive breast cancer or ovarian cancer (including fallopian tube and primary peritoneal cancer);
2. Request is for one of the following (a or b):
   a. Breast cancer: Lupron Depot 3.75;
   b. Ovarian cancer: Lupron Depot 3.75 mg, 7.5 mg, 11.25 mg, 22.5 mg;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a, b, or c):*
   a. Breast or ovarian cancer: Dose does not exceed 3.75 mg per month;
   b. Ovarian cancer: Dose does not exceed 7.5 mg per month, 11.25 mg per 3 months, or 22.5 mg per 3 months;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off- label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

F. Gender Dysphoria, Gender Transition (off-label) (must meet all)**:**
1. Diagnosis of gender dysphoria or request is for gender transition;
2. Request is for a leuprolide product other than Lupaneta Pack;
3. Prescribed by or in consultation with an endocrinologist and a provider with expertise in gender dysphoria and transgender medicine based on a certified training program or

affiliation with local transgender health services (e.g., mental health professional such as psychologist, psychiatrist, see *Appendix D*);
4. Age and pubertal development - meets (a or b):
   a. Member is < 18 years of age and has reached or passed through Tanner Stage 2*;
      **Age ranges approximating Tanner Stage 2 pubertal development extend from 8 to 13 years of age in girls and 9 to 14 years of age in boys.*
   b. Member is ≥ 18 years of age and has failed to achieve physiologic hormone levels with gender-affirming hormonal therapy (e.g., estrogen, testosterone) unless contraindicated or clinically significant adverse effects are experienced;
5. Member demonstrates understanding of expected GnRH analogue treatment outcomes and has given consent for such treatment;
6. If member has a psychiatric comorbidity, member is followed by mental health provider;
7. Psychosocial support will be provided during treatment;
8. Dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

G. Salivary Gland Tumors (off-label) (must meet all)**:**
1. Diagnosis of salivary gland tumors;
2. Disease is androgen receptor positive and recurrent, unresectable, or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Request is for one of the following (a or b):
   a. Eligard;
   b. Lupron Depot (7.5 mg, 22.5 mg);
5. Dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

H. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Prostate Cancer (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving leuprolide acetate, Camcevi, or Eligard/Lupron Depot for prostate cancer and has received this medication for at least 30 days;
2. Request is for one of the following (a, b, c, or d):
   a. Leuprolide acetate injection;
   b. Camcevi;
   c. Eligard;
   d. Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg);
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets any of the following (a, b, c, or d):*
   a. Leuprolide acetate injection (SC): New dose does not exceed: 1 mg per day;
   b. Camcevi (SC): New dose does not exceed 42 mg per 6 months;
   c. Eligard (SC)/Lupron Depot (IM): New dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, or 45 mg per 6 months;
   d. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Endometriosis (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Request is for Lupron Depot/Lupaneta Pack (3.75 mg, 11.25 mg);
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: improvement in dysmenorrhea, dyspareunia, pelvic pain/induration/tenderness, size of endometrial lesions;
4. Total duration of leuprolide therapy has not exceeded 12 months;
5. If request is for a dose increase, new dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: Up to a total treatment duration of 12 months

C. Uterine Fibroids (must meet all)**:**
1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

D. Central Precocious Puberty (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Request is for one of the following (a, b, or c):
   a. Fensolvi;
   b. Leuprolide acetate;
   c. Lupron Depot Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg;
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression;
4. Member meets one of the following age requirements (a or b):
   a. Female: ≤ 11 years;
   b. Male: ≤ 12 years;
5. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. Leuprolide acetate (SC): Initial: 50 mcg/kg per day; titrate dose upward by 10 mcg/kg per day if down-regulation is not achieved (higher mg/kg doses may be required in younger children);
   b. Lupron Depot-Ped (IM): 15 mg per month (1 month formulation) or 30 mg per 3 months (3 month formulation) (dosing is weight-based).
   c. Fensolvi: 45 mg per 6 months.

Approval duration: 12 months

E. Breast and Ovarian Cancer (off-label) (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Lupron Depot for hormone receptor-positive breast or ovarian cancer and has received this medication for at least 30 days;
2. Request is for one of the following (a or b):
   a. Breast cancer: Lupron Depot 3.75 mg;
   b. Ovarian cancer: Lupron Depot 3.75 mg, 7.5, 11.25 mg, 22.5 mg;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. Breast or ovarian cancer: New dose does not exceed 3.75 mg per month;
   b. Ovarian cancer: New dose does not exceed 7.5 mg per month, 11.25 mg per 3 months, or 22.5 mg per 3 months;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

F. Gender Dysphoria, Gender Transition (off-label) (must meet all):
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Request is for a leuprolide product other than Lupaneta Pack;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

G. Salivary Gland Tumors (off-label) (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Eligard or Lupron Depot for salivary gland tumors and has received this medication for at least 30 days;
2. Request is for one of the following (a or b):
   a. Eligard;
   b. Lupron Depot (7.5 mg, 22.5 mg);
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

H. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CPP: central precocious puberty
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
LH: luteinizing hormone
NCCN: National Comprehensive Cancer Network
WPATH: World Professional Association for Transgender Health

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSAIDs*: ibuprofen, naproxen, fenoprofen, ketoprofen, mefenamic acid, meclofenamate, indomethacin, tolmetin, diclofenac, etodolac, diflunisal, meloxicam, piroxicam	Endometriosis Varies – refer to specific prescribing information	Varies – refer to specific prescribing information

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Combined oral estrogen-progesterone contraceptives: ethinyl estradiol + (desogestrel, ethynodiol diacetate, drospirenone, etonogestrel, levonorgestrel, norelgestromin, norethindrone, norgestimate, or norgestrel); estradiol valerate + dienogest; mestranol + norethindrone	Endometriosis 1 tablet PO QD (may vary per specific prescribing information)	1 tablet per day (may vary per specific prescribing information)
Progestin-only oral contraceptives: norethindrone	Endometriosis 0.35 mg PO QD	0.35 mg per day
Depot injection progestin contraceptives: medroxyprogesterone acetate	Endometriosis IM: 150 mg per 3 months (every 13 weeks) SC: 104 mg per 3 months (every 12 to 14 weeks)	See regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Examples provided may not be all-inclusive*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to GnRH, GnRH agonist analogs or any of the components of the individual products (all leuprolide products);
  - Pregnancy (all leuprolide products except Camcevi, Eligard);
  - Lupron 3.75 mg/11.25 mg and Lupaneta Pack:
    - Undiagnosed abnormal vaginal bleeding
    - Breast-feeding
    - If used with norethindrone acetate
      - Thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions;
      - Markedly impaired liver function or liver disease;
      - Known or suspected carcinoma of the breast.
- Boxed warning(s): none reported

Appendix D: General Information

- World Professional Association for Transgender Health (WPATH) offers their Global Education Institute (GEI) Certified Training Courses: Best Practices in Transgender Medical and Mental Health Care. Additionally, the following link provides a search tool to locate WPATH member providers: https://www.wpath.org/provider/search
- Transgender Care Therapy Certification Training is also offered by the International Transgender Certification Association (ITCA). Professionals with expertise in transgender care can be located using the following search tool: https://transgendercertification.com/locate-a-professional/
- The draft of WPATH Standards of Care Version 8 are available and open for public comment. These standards of care recommend that adolescents are managed by a multidisciplinary care team that involves both medical and mental health professionals. The list of key disciplines includes but is not limited to: adolescent medicine/primary care, endocrinology, psychology, psychiatry, speech/language pathology, fertility, social work, support staff, and the surgical team. The need to include a healthcare professional with some expertise in mental health does not dictate the inclusion of a psychologist, psychiatrist, or social worker in every assessment. Instead, a general practitioner, nurse, or other qualified clinician could fulfill this requirement as long as they have sufficient expertise to diagnose gender incongruence, recognize mental health concerns, distinguish between these concerns and gender dysphoria, incongruence or diversity,

assist a transgender person in care planning and preparing for gender affirmative medical and surgical treatments, and refer to a mental health professional if needed.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Leuprolide acetate injection Leuprolide acetate (Lupron Depot 7.5, 22.5, 30, 45) Leuprolide acetate (Eligard 7.5, 22.5, 30, 45) Leuprolide mesylate (Camcevi)	Prostate cancer	Camcevi (SC) – 42 mg every 6 months	See regimen
		Leuprolide acetate injection (SC): 1 mg per day	See regimen
		Lupron Depot (IM) - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
		Eligard (SC) - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
Leuprolide acetate (Lupron Depot 3.75, 11.25) Leuprolide acetate (Lupaneta Pack 3.75, 11.25)	Endometriosis	Lupron Depot/Lupaneta Pack (IM) - 3.75 mg per month; 11.25 mg per 3 months	See regimen
Leuprolide acetate (Lupron Depot 3.75)	Uterine fibroids	Lupron Depot (IM) - 3.75 mg/month, 11.25 mg per 3 months	See regimen
Leuprolide acetate injection Leuprolide acetate (Lupron Depot-Ped 7.5, 11.25, 15 [1 mo]; 11.25, 30 [3 mo]) Fensolvi (leuprolide acetate)	CPP	Leuprolide acetate (SC): • Diagnostic: 20 mcg/kg or as needed; • Treatment: Initial: 50 mcg/kg/day; titrate dose upward by 10 mcg/kg/day if down-regulation is not achieved (higher mg/kg doses may be required in younger children).	See regimen
		Lupron Depot-Ped (IM): Monthly administration weight-based starting dose: 7.5 mg (≤ 25 kg), 11.25 mg (> 25 to 37.5 kg), 15 mg (> 37.5 kg) (increase as needed to 15 mg/month); 3-month administration: 11.25 mg or 30 mg	See regimen
		Fensolvi (SC): 45 mg once every six months	See regimen
Leuprolide acetate (Lupron Depot 3.75)	Breast cancer **(off-label)**	Lupron Depot (IM) 3.75 mg per month	See regimen
Leuprolide acetate (Lupron Depot 3.75, 11.25)	Ovarian cancer **(off-label)**	Lupron Depot (IM) 3.75 mg per month, 11.25 mg per 3 months	See regimen

Drug Name	Indication	Dosing Regimen	Maximum Dose
Leuprolide acetate (Lupron Depot 7.5, 22.5) Leuprolide acetate (Eligard 7.5, 22.5, 30, 45)	Salivary Gland tumors **(off-label)**	Lupron Depot (IM) - 7.5 mg per month; 22.5 mg per 3 months. Eligard (SC) - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen

VI. Product Availability

Drug Name	Availability
Leuprolide acetate injection (generic)	Kit: 2.8 mL multi-dose vial (1 mg/0.2 mL)
Leuprolide acetate (Eligard 7.5, 22.5, 30, 45)	Kit: 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month)
Leuprolide acetate (Lupron Depot 7.5, 22.5, 30, 45)	Prefilled syringe: 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month)
Leuprolide acetate and norethindrone acetate tablets (Lupaneta Pack 3.75, 11.25)	Pack: 3.75 mg leuprolide acetate syringe (1 month) with 5 mg norethindrone tablets Pack: 11.25 mg leuprolide acetate syringe (3 month) with 5 mg norethindrone tablets
Leuprolide acetate (Lupron Depot 3.75)	Prefilled syringe: 3.75 mg (1 month)
Leuprolide acetate (Lupron Depot 11.25)	Prefilled syringe: 11.25 mg (3 month)
Leuprolide acetate (Lupron Depot-Ped 7.5, 11.25)	Prefilled syringe: 7.5 mg (1 month), 11.25 mg (1 month), 15 mg (1 month) Prefilled syringe: 11.25 mg (3 month), 30 mg (3 month)
Leuprolide mesylate (Camcevi)	Injection emulsion: 42 mg

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Gender Dysphoria

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: no significant changes; for oncology, summarized NCCN and FDA-approved uses for improved clarity (limited to diagnosis) and added specialist involvement in care; references reviewed and updated.	08.07.18	11.18
Addition of gender dysphoria as off-label use.	07.16.19	08.19
4Q 2019 annual review: Prostate cancer – removed Eligard redirection as it is on the formulary with similar placement to alternatives, added urologist specialist option; references reviewed and updated.	08.01.19	11.19
Added Fensolvi (new dosage form) to the policy for Central Precocious Puberty; added off-label NCCN indication and criteria for salivary gland tumor; references reviewed and updated.	05.07.20	08.20
4Q 2020 annual review: no significant changes; references reviewed and updated.	09.10.20	11.20
3Q 2021 annual review: for endometriosis and uterine fibroid indications added requirements for total duration of therapy per prescribing information; for uterine fibroids continuation of therapy revised to restrict re-authorization and require use of initial approval criteria as each preoperative treatment course would be evaluated individually; revised salivary gland tumor to allow continuity of care; for gender dysphoria continuation of therapy added requirement that request is not for Lupaneta Pack to align with initial approval criteria; for ovarian cancer added Lupron Depot 7.5 mg and 22.5 mg strengths per NCCN; references reviewed and updated.	04.13.21	08.21
4Q 2021 annual review: RT4: added Camcevi, a new dosage form of existing product [Lupron Depot] with same indication for prostate cancer; added gender transition to gender dysphoria criteria set; clarified breast cancer should be hormone receptor-positive; references reviewed and updated.	07.08.21	11.21
For gender dysphoria or gender transition, modified prescriber requirements to allow experts in transgender medicine based on a certified training program or affiliation with local transgender health services; added general information Appendix D with resources for transgender provider search tools and examples of training programs.	12.06.21	02.22
4Q 2022 annual review: for CPP added diagnostic use as an approvable use; for Lupron Depot (7.5, 22.5, 30, 45); updated FDA-approved indication to include non-palliative treatment of advanced prostate cancer; for endometriosis removed “If request is for Lupaneta Pack, medical justification supports inability to use Lupron Depot”; references reviewed and updated.	07.21.22	11.22

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.