RX.PA.076.CCH LUTEINIZING HORMONE RELEASING HORMONE (LHRH) AGENTS

The purpose of this policy is to define the prior authorization process for Luteinizing Hormone Releasing Hormone (LHRH) agents.

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

Eligard® (leuprolide) is indicated for the palliative treatment of advanced prostate cancer.

Firmagon® (degarelix) is indicated for the treatment of patients with advanced prostate cancer.

Lupron Depot® (leuprolide) products are indicated for:

- Palliative treatment of advanced prostatic cancer
- Management of endometriosis, including pain relief and reduction of endometriotic lesions; indicated in combination with norethindrone acetate 5 mg daily for the initial management of endometriosis and for the management for recurrence of symptoms
- Concomitant use with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids)

Lupron Depot-Ped® (leuprolide) is indicated for the treatment of children with central precocious puberty.

Supprelin® LA (histrelin) implant is indicated for the treatment of children with central precocious puberty.

Trelstar® (triptorelin) is indicated for the palliative treatment of advanced prostate cancer.

Zoladex® (goserelin) is indicated for:

- Palliative treatment of advanced prostate cancer
- Use for the management of locally confined Stage B2-C prostate cancer (in combination with flutamide)
- Management of endometriosis, including pain relief and reduction of endometriotic lesions (limited to women 18 years of age and older treated for six (6) months)

- Palliative treatment for advanced breast cancer in pre-and peri-menopausal women
- Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The Luteinizing Hormone Releasing Hormone (LHRH) drugs are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Prostate cancer *(for requests out-of-scope for NCH)***
   - Must have a diagnosis of prostate cancer
   - **Camcevi/Zoladex requests ONLY**:
     - Must have a documented trial and failure, contraindication, or intolerance to ALL the following:
       - Firmagon
       - Lupron Depot/Eligard
       - Trelstar

2. **Endometriosis**
   - Must have a diagnosis of moderate endometriosis
     - Must be confirmed by laparoscopy
     - If the diagnosis is not confirmed by surgery, then chart documentation of an adequate work-up and the clinical rationale for the diagnosis must be provided

- Must have tried oral contraceptives and/or progestins for mild endometriosis
    - Covered oral contraceptives and/or progestins covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/
- **Zoladex requests ONLY**:
    - Must have a documented trial and failure, contraindication, or intolerance to Lupron Depot

3. Uterine leiomyomata (fibroids)

- Must have a diagnosis of uterine leiomyomata (fibroids)
- Must be used as a preoperative adjuvant in the surgical management of leiomyoma (e.g., to shrink the fibroid or to maximize preoperative hemoglobin)
    - If not used in the context of a preoperative adjuvant, chart note documentation must be submitted showing the clinical rationale for the use of a GnRH agonist (e.g., short-term treatment of abnormal uterine bleeding/heavy menstrual bleeding, bridge therapy to other medical therapies or menopause)

4. Central precocious puberty

- Must have a diagnosis of central precocious puberty with onset of secondary sexual characteristics earlier than eight (8) years in females and nine (9) years in male
- Must be prescribed by, or in consultation with, a pediatric endocrinologist
- **Fensolvi/leuprolide/Supprelin LA/Triptodur ONLY:** Must be age 2 years or older

5. Breast cancer *(for requests out-of-scope for NCH)*

- Must have a diagnosis of hormone receptor-positive breast cancer

6. Endometrial thinning

- Must have a diagnosis of dysfunctional uterine bleeding
- Must be undergoing (or planning to undergo) endometrial ablation

7. Gender Dysphoria

- Must have a diagnosis of gender dysphoria, as defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) **AND/OR** the International Statistical Classification of Diseases and Related Health Problems (ICD) criteria (*see Table 1 below for criteria)*
- Must be prescribed by, or in consultation with an endocrinologist or other provider experienced in assessing members for hormonal treatment
- For members <16 years of age, must have documentation of pubertal Tanner stage 2 or above (*see Table 2 below for Tanner Stages)*

Table 1: Diagnostic Criteria

	Diagnostic Criteria
DSM-5-TR Adolescents & Adults	• A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six month's duration, as manifested by at least two of the following: o A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics) o A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics) o A strong desire for the primary and/or secondary sex characteristics of the other gender o A strong desire to be of the other gender (or some alternative gender different from one's assigned gender) o A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender) o A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender) **AND** • The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
DSM-5-TR Children	• A marked incongruence between one's experienced/expressed gender and assigned gender, lasting at least 6 months, as manifested by at least **SIX** of the following (one of which must be the first criterion): o A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender) o In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing o A strong preference for cross-gender roles in make-believe play or fantasy play o A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender o A strong preference for playmates of the other gender

	○ In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities ○ A strong dislike of one's sexual anatomy ○ A strong desire for the physical sex characteristics that match one's experienced gender **AND** • The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning
ICD-10 Codes	• F64 Gender identity disorders ○ F64.0 Transsexualism ○ F64.1 Dual role transvestism ○ F64.2 Gender identity disorder of childhood ○ F64.8 Other gender identity disorders ○ F64.9 Gender identity disorder, unspecified

Table 2: Tanner Stages (Sexual Maturity Rating)

Tanner Stage	Boys – Development of External Genitalia	Girls – Breast Development	Boys and Girls – Pubic Hair
Stage 1	Prepubertal		
Stage 2	Enlargement of scrotum and testes; scrotal skin reddens and changes in texture	Breast bud stage with elevation of breast and papilla; enlargement of areola	Sparse growth of long, slightly pigmented hair, straight or curled, at base of penis or along labia
Stage 3	Enlargement of penis (length at first); further growth of testes	Further enlargement of breast and areola; no separation of their contour	Darker, coarser and more curled hair, spreading sparsely over junction of pubes
Stage 4	Enlargement of penis (length at first); further growth of testes	Areola and papilla form a secondary mound above level of breast	Hair adult in type, but covering smaller area than in adult; no spread to medial surface of thighs
Stage 5	Adult genitalia	Mature stage: projection of papilla only, related to recession of areola	Adult female in type and quantity, with horizontal upper border

Reauthorization Criteria:

All prior authorization renewals are reviewed every three (3) months, six (6) months or one (1) year, depending upon diagnosis, to determine the Medical Necessity for continuation of therapy based on chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

- Members with a diagnosis of dysfunctional uterine bleeding and is using requested drug for endometrial thinning are not eligible for reauthorization
- Members with endometriosis are eligible for a 1-time reauthorization (for 6 months) ONLY if using Lupron

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	**One (1) year for the following conditions:** • Prostate Cancer • Breast Cancer • Central precocious puberty • Gender Dysphoria **Six (6) months for the following condition:** • Endometriosis **Three (3) months for the following condition:** • Uterine leiomyomata **Two (2) months for the following condition:** • Endometrial thinning
Reauthorization	**One (1) year for the following conditions:** • Prostate Cancer · • Breast Cancer · • Central precocious puberty (only up to age 11 in females and age 12 in males) • Gender Dysphoria **Six (6) months for the following condition:** • Endometriosis (Lupron ONLY; other products are not eligible for reauthorization)

	Three (3) months for the following condition: • Uterine leiomyomata **Endometrial thinning is NOT eligible for reauthorization**

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Code

HCPCS code	Brand	Description
J1950	Lupron	Injection, leuprolide acetate, 3.75mg
J1952	Camcevi	Leuprolide injectable, camcevi, 1 mg
J3315	Trelstar	Injection, triptorelin pamoate, 3.75mg
J3316	Trelstar	Injection, triptorelin, extended release, 3.75mg
J9155	Firmagon	Injection, degarelix, 1mg
J9218	-	Injection, leuprolide acetate, 1mg
J9217	Eligard Lupron Depot	Injection, leuprolide acetate, 7.5mg
J9202	Zoladex	Goserelin acetate implant, 3.6mg
J9226	Supprelin LA	Histrelin implant (Supprelin LA), 50 mg

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial review	XX/XX

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.