SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-800-750-9692.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization may be delayed.**

Drug Requested: Gonadotropin-releasing Hormone Agonists (GnRH) (PHARMACY)

Preferred Drugs		
❑ **Eligard®** (leuprolide acetate) **7.5 mg (1-month)**	❑ **Eligard®** (leuprolide acetate) **22.5 mg (3-month)**	❑ **Eligard®** (leuprolide acetate) **30 mg (4-month)**
❑ **Eligard®** (leuprolide acetate) **45 mg (6-month)**	❑ **Leuprolide acetate 5 mg/mL SubQ Solution**	❑ **Lupron Depot-Ped®** (leuprolide acetate) **7.5 mg (1-month)**
❑ **Lupron Depot-Ped®** (leuprolide acetate) **11.25 mg (1-month)**	❑ **Lupron Depot-Ped®** (leuprolide acetate) **15 mg (1-month)**	❑ **Lupron Depot-Ped®** (leuprolide acetate) **11.25 mg (3-month)**
❑ **Lupron Depot-Ped®** (leuprolide acetate) **30 mg (3-month)**	❑ **Lupron Depot®** (leuprolide acetate) **3.75 mg (1-month)**	❑ **Lupron Depot®** (leuprolide acetate) **7.5 mg (1-month)**
❑ **Lupron Depot®** (leuprolide acetate) **11.25 mg (3-month)**	❑ **Lupron Depot®** (leuprolide acetate) **22.5 mg (3-month) [syringe kit]**	❑ **Leuprolide acetate 22.5 mg (3-month) [vial]**
❑ **Lupron Depot®** (leuprolide acetate) **30 mg (4-month)**	❑ **Lupron Depot®** (leuprolide acetate) **45 mg (6-month)**	❑ **Trelstar®** (triptorelin pamoate) **3.75 mg (1-month)**
❑ **Trelstar®** (triptorelin pamoate) **11.25 mg (3-month)**	❑ **Trelstar®** (triptorelin pamoate) **22.5 mg (6-month)**	❑ **Zoladex®** (goserelin) **3.6 mg (1-month)**
❑ **Zoladex®** (goserelin) **10.8 mg (3-month)**		
Non-Preferred Drugs		
❑ **Fensolvi®** (leuprolide acetate) **45mg (6-month)**	❑ **Supprelin® LA** (histrelin acetate) **50mg (12-month)**	❑ **Synarel®** (nafarelin acetate) **2mg/ml** (*dosing of 1600 mcg to 1800 mcg per day more than the 400 mcg to 800 mcg per day for endometriosis)
❑ **Triptodur®** (triptorelin) **22.5mg (6-month)**		

(Continued on next page)

(Continued from previous page)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

A. Length of Authorization

- Endometriosis: Coverage will be provided for 6 months and is eligible for conditional renewal
- Uterine leiomyomata (fibroids): Coverage will be provided for 6 months and is eligible for conditional renewal
- Gender Dysphoria: Approval will be indefinite per length of requested treatment, and renewal will not be required
- All other indications: Coverage will be provided for 12 months and may be renewed

B. Quantity Limits:

Drug Name	Strength	Quantity	Day Supply
Leuprolide acetate SubQ solution	5 mg/mL (1 mg/0.2 mL multi-dose vial)	2 vials	28 days
Lupron Depot 1-month	3.75 mg, 7.5 mg	1 injection	28 days
Lupron Depot 3-month	11.25 mg, 22.5 mg	1 injection/vial	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 1-month	7.5 mg, 11.25 mg, 15 mg	1 injection	28 days
Lupron Depot-Ped 3-month	11.25 mg, 30 mg	1 injection	84 days
Eligard 1-month	7.5 mg	1 injection	28 days
Eligard 3-month	22.5 mg	1 injection	84 days
Eligard 4-month	30 mg	1 injection	112 days
Eligard 6-month	45 mg	1 injection	168 days
Fensolvi 6-month	45 mg	1 injection	168 days

(Continued on next page)

Drug Name	Strength	Quantity	Day Supply
Trelstar 1-month	3.75 mg	1 injection	28 days
Trelstar 3-month	11.25 mg	1 injection	84 days
Trelstar 6-month	22.5 mg	1 injection	168 days
Triptodur 6-month	22.5 mg	1 injection	168 days
Supprelin LA	12-month	1 implant	365 days
Synarel	2 mg/mL (200 mcg/spray)	1 bottle (8 mL)	28 days
Zoladex 1-month	3.6 mg	1 implant	28 days
Zoladex 3-month	10.8 mg	1 implant	84 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Diagnosis: Prostate Cancer

Initial Authorization

- ❑ Member is 18 years of age or older
- ❑ Requesting provider is an oncologist or urologist
- ❑ Member has a diagnosis of advanced prostate cancer
- ❑ The quantity (dose) requested is in accordance with FDA-approved labeling, and if applicable or necessary, age and weight conditions are met
- ❑ If requesting a non-preferred drug, the member has failed **ONE** of the preferred formulations noted above

Diagnosis: Breast Cancer

Initial Authorization

- ❑ Member is 18 years of age or older
- ❑ Requesting provider is an oncologist
- ❑ Select **ONE** of the following:
  - ❑ Member is a pre- or peri-menopausal woman
  - ❑ Member is male with suppression of testicular steroidogenesis
- ❑ Member has hormone-receptor positive disease **AND** meets **ONE** of the following:
  - ❑ Medication will be used in combination with adjuvant endocrine therapy
  - ❑ Medication will be used combination with endocrine therapy for recurrent or metastatic disease
  - ❑ Medication will be used as palliative treatment for advanced disease
- ❑ The quantity (dose) requested is in accordance with FDA-approved labeling, and if applicable or necessary, age and weight conditions are met

(Continued on next page)

- ❑ If requesting a non-preferred drug, the member has failed **ONE** of the preferred formulations noted above

Diagnosis: Gender Identity/Gender Dysphoria

Initial Authorization

- ❑ Select **ONE** of the following:
  - ❑ Member is 18 years of age or older and has a diagnosis of gender dysphoria
  - ❑ Member is less than 18 years of age and has a diagnosis of gender dysphoria. Provider please note: parental or legal guardian consent for un-emancipated members is required
- ❑ Provider attests member has the capacity to make informed treatment decisions and has assented to treatment after discussion of the potential benefits and risks
- ❑ Member has been assessed and diagnosed with gender dysphoria according to DSM-V criteria, by **ONE** of the following provider types:
  - ❑ A licensed mental health provider
  - ❑ An endocrinologist
  - ❑ A gender dysphoria-informed hormone prescriber, defined as a provider competent in the assessment of gender dysphoria who practices in conjunction with a multidisciplinary gender dysphoria care team
- ❑ Medication is prescribed by, or in consultation with, a licensed mental health provider, endocrinologist or other medical provider experienced in gender dysphoria hormone therapy
- ❑ Provider attests coexisting behavioral health and medical comorbidities or social problems that may interfere with diagnostic procedures or treatment are being appropriately treated and are not causing symptoms of gender dysphoria
- ❑ Member has experienced puberty development to at least **ONE** of the following:
  - ❑ Tanner stage 2 (stage 2 through 4)
  - ❑ Lab values for Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), and the endogenous sex hormones consistent with at least Tanner stage 2 **(must submit documentation)**
- ❑ If requesting a non-preferred drug, the member has failed **ONE** of the preferred formulations noted above

Diagnosis: Central Precocious Puberty

Initial Authorization

- ❑ Member is less than 13 years of age
- ❑ Onset of secondary sexual characteristics associated with pubertal pituitary gonadotropin activation, occurring earlier than age 8 for girls and age 9 for boys **(submit documentation, progress notes, medical documentation recording physical changes, Tanner staging)**

(Continued on next page)

- ❑ Diagnosis of central precocious puberty is confirmed by **ALL** of the following:
  - ❑ Laboratory documentation of pubertal gonadal sex steroid level
  - ❑ Pubertal luteinizing hormone response simulation by native GnRH **[Laboratory documentation demonstrating basal LH (>0.3 IU/L), and peak stimulated LH (>4-6 IU/L)]**
  - ❑ X-Ray results of the estimated bone age of the non-dominant wrist and hand greater than 2 standard deviations beyond chronological age **(submit laboratory and x-ray documentation)**
- ❑ A tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor)
- ❑ Medication will **NOT** be used in combination with growth hormone therapy
- ❑ The quantity (dose) requested is in accordance with FDA-approved labeling, and if applicable or necessary, age and weight conditions are met
- ❑ If requesting a non-preferred drug, the member has failed **ONE** of the preferred formulations noted above

Diagnosis: Gynecological Indications

Initial Authorization

- ❑ Member is 18 years of age or older
- ❑ If requesting a non-preferred drug, the member has failed **ONE** of the preferred formulations noted above
- ❑ Treatment is being prescribed by or in consultation with a specialist in gynecology or reproductive health

Select **ONE** of the following indications for use:

- ❑ **FOR UTERINE LEIOMYOMATA, FIBROIDS** (requires chart notes documenting symptomology/pelvic exam, transvaginal ultrasonography, sono-hysterography):
  - ❑ Member is premenopausal
  - ❑ Member has uterine leiomyomas (fibroids)
  - ❑ Member is using for the management of heavy menstrual bleeding
  - ❑ Member does **NOT** have any contraindications to therapy including osteoporosis, history of thrombotic or thromboembolic disorders, uncontrolled hypertension, or hepatic impairment/disease
  - ❑ Member has history of inadequate response to the following therapies, tried for at least three (3) months each **(must submit chart note documentation of all therapy failures)**:
    - ❑ Oral contraceptives OR a selective progesterone receptor modulator OR intrauterine device
    - ❑ NSAIDs (non-steroidal anti-inflammatory drugs)
    - ❑ tranexamic acid 650 mg

      OR
    - ❑ Member has had surgery for uterine fibroids (i.e. ablation, myomectomy) and has persistent symptoms **(must submit documentation of date/type of surgery or procedure)**

(Continued on next page)

- ❑ The quantity (dose) and administration frequency requested is in accordance with FDA-approved labeling, and if applicable or necessary, age and weight conditions are met

- ❑ **FOR ENDOMETRIOSIS** (requires chart notes detailing and recording treatment plan and/or symptomology of chronic pelvic pain (defined as noncyclical pain lasting 6 or more months that localizes to the anatomic pelvis, anterior abdominal wall at or below the umbilicus, the lumbosacral back, or the buttocks, and is of sufficient severity to cause functional disability or lead to medical care), amenorrhea, preoperative ablation treatment):
  - ❑ Member is premenopausal
  - ❑ Member has a diagnosis of moderate to severe pain associated with endometriosis
  - ❑ Diagnosis of endometriosis has been confirmed by direct visualization during surgery and/or histology
  - ❑ Member does **NOT** have any contraindications to therapy including osteoporosis, severe hepatic impairment/disease, or concomitant use of hormonal contraceptives
  - ❑ Member has history of inadequate response to the following therapies, tried for at least three (3) months each **(must submit chart note documentation of all therapy failures)**:
    - ❑ NSAIDs (non-steroidal anti-inflammatory drugs
    - ❑ Combination (estrogen/progesterone) oral contraceptive
    - ❑ Progestins

    OR
    - ❑ Member has had surgical ablation to prevent recurrence
  - ❑ The quantity (dose) and administration frequency requested is in accordance with FDA-approved labeling, and if applicable or necessary, age and weight conditions are met

REAUTHORIZATION CRITERIA

♦♦♦NOTE: Gender identity/gender dysphoria diagnoses does NOT require reauthorization♦♦♦

Diagnosis: Oncology diagnoses (Please submit chart notes and other supporting documents)

- ❑ Member requires continuation of therapy and is **NOT** experiencing disease progression
- ❑ Ongoing treatment is consistent with FDA-labeling or compendia support
- ❑ Member is **NOT** experiencing an FDA-labeled limitation of use or toxicity
- ❑ The quantity (dose) requested is in accordance with FDA approved labeling

Diagnosis: Central Precocious Puberty (Please submit chart notes and other supporting documents)

- ❑ Member is **NOT** over the age of 13
- ❑ Member has experienced disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction

(Continued on next page)

- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., convulsions, development or worsening of psychiatric symptoms)

Diagnosis: Gynecological Indications (Please submit chart notes and other supporting documents)

- ❑ Total duration of therapy (initial plus re-treatment for symptom recurrence) should not exceed 12 months, **AND** will be used in combination with add-back therapy, unless clinically contraindicated

OR

- ❑ The member's medical history and medical condition's current status requires longer treatment duration than otherwise recommended in published compendia/FDA labeling.

  Please provide an explanation along with any pertinent progress notes of medical condition including recorded recurrence of symptoms, procedure/exam results:

  _____
  _____
  _____
  _____
  _____
  _____

AND

- ❑ Prescriber will order and review a bone density assessment prior to re-treatment

Medication being provided by Specialty Pharmacy - PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.