I. POLICY

It is the policy of UPMC 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, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

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

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization Process for Luteinizing Hormone Releasing Hormone (LHRH) agonists.

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. PROCEDURE

Lupron Depot® products are indicated for the following:
- 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® is indicated for the treatment of children with central precocious puberty.

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

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

Vantus® implant is indicated for the palliative treatment of advanced prostate cancer.

Viadur® implant is indicated for the palliative treatment of advanced prostate cancer.

Trelstar Depot® and Trelstar LA® are indicated for the palliative treatment of advanced prostate cancer.

Zoladex ® is indicated for the following:
- 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.
- For use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.

Initial Authorization Criteria:
Based upon diagnosis, the following criteria must be met:

1. For the diagnosis of prostate cancer:

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• Member must have a diagnosis of prostate cancer.
• The following strengths will be approved:
  • Lupron Depot®: 30mg IM q 4 months, 22.5 mg IM q 3 months, or 7.5 mg IM q month.
  • Eligard®: 45 mg IM q 6 months, 30mg IM q 4 months, 22.5 mg IM q 3 months, or 7.5 mg IM q 1 month.
  • Viadur® Implant (65mg of leuprolide) SC in inner area of upper arm q 12 months; must be removed after 12 months and replaced to continue therapy.
  • Vantus® implant (50mg of histrelin acetate) SC in the inner area of the upper arm q 12 months; must be removed after 12 months and replaced to continue therapy.
  • Trelstar Depot®: 3.75mg IM q 1 month.
  • Trelstar LA®: 11.25mg IM q 84 days (3months).
  • Zoladex® Implant:
    - Prostate cancer: 3.6mg SC q 28 days or 10.8mg SC q 12 weeks into anterior abdominal wall below the naval line.
    - Treatment of locally confined Stage B2-C prostate cancer (in combination with flutamide): therapy should be started eight (8) weeks prior to initiating radiotherapy and continue during radiation therapy
      - Treatment regimen using 3.6mg SC eight (8) weeks before radiotherapy followed in 28 days by 10.8mg SC can be administered; OR
      - Alternatively, four 3.6mg SC at twenty-eight (28) day intervals, two depots preceding and two during radiotherapy.

2. For the diagnosis of endometriosis:
• Member must have a diagnosis of endometriosis
  - Must be confirmed by laparoscopy; OR
  - 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.
• For mild endometriosis, the member must have tried oral contraceptives and/or progestins.
• The following strengths will be approved:
  - Lupron Depot®: 11.25mg IM q 3 months, or 3.75 mg IM q month.
  - Zoladex® Implant 3.6mg SC q 28 days into anterior abdominal wall below the naval line (limited to women 18 years of age and older treated for six (6) months).

3. For the diagnosis of uterine leiomyomata (fibroids):
• Member must have a diagnosis of uterine leiomyomata (fibroids).
• The use of GnRh (gonadotropin-releasing hormone) agonist can be used in the treatment for fibroid in the following contexts:
  1. It may be used preoperatively to maximize preoperative hemoglobin in patients with documented preexisting anemia (Hemoglobin < 11).
  2. It may be used preoperatively to decrease the size of the fibroid uterus, so a less invasive route of hysterectomy can be attempted. (i.e. from an abdominal hysterectomy to a vaginal hysterectomy or a laparoscopic hysterectomy).
• Clinical rationale for other use of GnRh agonist outside of the context of preoperative adjuvant in the surgical management of leiomyoma must be provided.
• The following strengths will be approved:
  ▪ Lupron Depot®: 11.25mg IM q 3 months, or 3.75 mg IM q month.

4. For the diagnosis of central precocious puberty:
• Member 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 males.
• The following strengths will be approved:
  ▪ Lupron Depot Ped®: 15mg IM q month, 11.25mg IM q month, or 7.5 mg IM q month.
  ▪ Supprelin LA® implant: 50mg of histrelin acetate SC in the inner area of the upper arm q 12 months; must be removed after twelve (12) months and replaced to continue therapy.

5. For the diagnosis of breast cancer:
• Member must have a diagnosis of breast cancer.
• The following strength will be approved:
  ▪ Zoladex ® Implant 3.6mg SC q 28 days into anterior abdominal wall below the naval line.

6. For endometrial thinning:
• Member must have a diagnosis of dysfunctional uterine bleeding.
• Member must be undergoing endometrial ablation.
• The following strength will be approved:
  ▪ Zoladex ® Implant 3.6mg SC q twenty-eight (28) days into anterior abdominal wall below the naval line; one or two depots given four (4) weeks apart.
    • When one depot is administered, surgery should be performed at four (4) weeks.
    • When two depots are administered, surgery should be performed within two (2) to four (4) weeks following administration of second depot.
The medication will be approved based upon the above criteria for an initial period of one (1) year for the following conditions:

- Prostate Cancer
- Breast Cancer
- Central Precocious Puberty

The medication will be approved based upon the above criteria for an initial period of six (6) months for the following condition:

- Endometriosis

The medication will be approved based upon the above criteria for an initial period of three (3) months for the following condition:

- Uterine leiomyomata

The medication will be approved based upon the above criteria for a period of two (2) months for the following condition:

- Endometrial thinning

**Reauthorization Criteria:**

1. All prior authorization renewals will be 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 disease has improved based upon the prescriber’s assessment while on therapy.

2. If the above reauthorization criteria is met, the medication will be approved for an additional three (3) months, six (6) months or one (1) year of therapy, depending upon diagnosis.

3. Endometrial thinning will only be approved for a one (1) time two (2) month period without reauthorization.

**Limitations:**

If a member does not meet the above approval criteria, the prior authorization request will be sent for review by a UPMC Health Plan Medical Director.
VI. BIBLIOGRAPHY