Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Luteinizing Hormone Releasing Hormone (LHRH) Agents***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***December 2005 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *December 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

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

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.

Lupaneta™ Pack (leuprolide and norethindrone) is indicated for the initial management of the painful symptoms of endometriosis and the management of recurrent symptoms. The initial treatment course is limited to 6 months and use is not recommended for longer than a total of 12 months.

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.

Synarel® (nafarelin) is indicated for:
- Management of endometriosis, including pain relief and reduction of endometriotic lesions
- Treatment of central precocious puberty (gonadotropin-dependent precocious puberty) in children of both sexes

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

Vantas® (histrelin) implant is indicated for the palliative treatment of advanced prostate cancer.

Viadur® (leuprolide) implant 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, 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) drugs are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for the following LHRH products (Eligard, Firmagon, Lupron Depot, Trelstar, and Zoladex) are subject to the preferred medical drug list program **when being used to treat prostate cancer**. Coverage for these products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. Coverage for non-preferred products will continue in situations where the patient is currently receiving treatment.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. LHRH Products

	Products*
Preferred	• Eligard® (leuprolide acetate)
Non-preferred	• Firmagon® (degarelix) • Lupron Depot® (leuprolide acetate for depot suspension) • Trelstar® (triptorelin) • Zoladex® (goserelin acetate)

II. CLINICAL CRITERIA *(Use for ALL Drug Requests)*

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

1. **Prostate cancer**
   - Must have a diagnosis of prostate cancer
     - Coverage for a targeted non-preferred product is provided when the member has a documented hypersensitivity to any of the components of Eligard.
   -

2. **Endometriosis**
   - Must have a diagnosis of 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

3. **Uterine leiomyomata (fibroids)**
   - Must have a diagnosis of uterine leiomyomata (fibroids)
   - Must be used in the treatment for fibroids in the following contexts:
     - Preoperatively to maximize preoperative hemoglobin in patients with documented preexisting anemia (Hemoglobin <11)
     - 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)
   - Must provide clinical rationale for other use of gonadotropin releasing hormone (GnRH) agonist outside of the context of a preoperative adjuvant in the surgical management of leiomyoma

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 males

5. **Breast cancer**
   - Must have a diagnosis of breast cancer

6. **Endometrial thinning**
   - Must have a diagnosis of dysfunctional uterine bleeding
   - Must be undergoing endometrial ablation

7. **Transgender services**

- Refer to RX.PA.434 Transgender Services policy for LHRH coverage criteria

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.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	One (1) year for the following conditions: • Prostate Cancer • Breast Cancer • Central precocious puberty 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	• Same as initial • Endometrial thinning is only approved for a one time, two-month period without reauthorization • Central precocious puberty is only approved up to age 11 in females and age 12 in males

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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4. Lupron Depot – 3 Month 11.25 mg [package insert]. Lake Forest, IL: TAP Pharmaceuticals Inc.; October 2005.
5. Lupron Depot – 3.75 mg [package insert]. Lake Forest, IL: TAP Pharmaceuticals Inc.; October 2005.

6. Lupron Depot-Ped 7.5 mg, 11.25 mg and 15 mg [package insert]. Lake Forest, IL: TAP Pharmaceuticals Inc.; January 2005.
7. Eligard 7.5 mg [package insert]. New York, NY: Sanofi-Synthelabo Inc.; July 2003.
8. Eligard 22.5 mg [package insert]. New York, NY: Sanofi-Synthelabo Inc.; August 2004.
9. Eligard 30 mg [package insert]. New York, NY: Sanofi-Synthelabo Inc.; August 2004.
10. Eligard 45 mg [package insert]. New York, NY: Sanofi-Synthelabo, Inc.; December 2004.
11. UpToDate. Classification and treatment of endometriosis. Accessed December 2005.
12. Lapp T. Practice Guidelines: ACOG Issues Recommendations for the Management of Endometriosis. *Am Fam Physician*. 2000 Sep;62(6):1431.
13. UpToDate. Treatment of uterine leiomyomas. Accessed December 2005.
14. UpToDate. Overview of precocious puberty. Accessed December 2005.
15. Supprelin LA 50mg [package insert]. Lexington, MA: Indevus Pharmaceuticals, Inc; May 2007.
16. Vantas 50mg [package insert]. Lexington, MA: Indevus Pharmaceuticals, Inc; June 2007.
17. Zoladex 3.6 mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; October 2005.
18. Zoladex 10.8 mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; October 2005.
19. Viadur [package insert]. West Haven, CT: Bayer Pharmaceutical Coporation; November 2005.
20. Firmagon [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc: December 2008.
21. Synarel [package insert]. NY, NY: Pfizer Pharmaceuticals, Inc: August 2005.
22. Trelstar [package insert]. Morristown, NJ: Watson Pharma, Inc; March 2010.
23. Lupaneta Pack [package insert]. North Chicago, IL: AbbVie Inc. November 2013.

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.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria update	*12/16*
Preferred Product Update	*12/18*