

## Medical Affairs Policy & Procedure

**Title/Service:** Gonadotropin-Releasing Hormone Agonists (Factrel, Gonadorelin, Goserelin Acetate, Leuprolide Acetate, Lupron, Lutrepulse, Relisorm, Trelstar, triptorelin, Zoladex)

<b>Revised</b>	11/18/11
<b>Reviewed</b>	02/25/00, 04/19/00, 05/05/00, 06/28/02, 07/23/04, 04/28/06, 04/24/09, 04/28/10
<b>Developed</b>	
<b>Policy Committee Approval</b>	11/18/11

### **Description:**

Gonadotropin-Releasing Hormone Agonists are synthetic peptide analogs of naturally occurring gonadotropin-releasing hormone (GnRH or LHRH) which act as potent inhibitors of gonadotropin secretion when given continuously and in therapeutic doses. Chronic stimulation with a GnRH agonist results in "downregulation" of pituitary receptors and consequent suppression of LH and FSH secretion. The end therapeutic result is suppression of ovarian and testicular hormone production. These effects are reversible on discontinuation of drug therapy.

### **Indications of Coverage:**

Gonadotropin-Releasing Hormone Agonists are considered medically necessary for any of the following conditions:

Oncology Indications (refer to NCCN guidelines for specifics):

- Breast Cancer – Invasive
- Ovarian Cancer – Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
- Ovarian Stromal Tumors
- Palliative treatment of prostate carcinoma when orchiectomy is not indicated

Central precocious puberty (the appearance of physical and hormonal signs of pubertal development at an earlier age than is considered normal)

In preparation for surgical treatment of uterine fibroids or leiomyomata (up to three months)

Preparatory to endometrial ablation for dysfunctional uterine bleeding (up to two months)

Endometriosis (up to six months), when a three month trial of agents such as oral contraceptives or Depo-Provera has failed. An additional six months of treatment may be approved if all of the following criteria are met:

Documentation of significant relief of one of the following symptoms:

Menstrual pain with cramping

Pelvic pain or tenderness

Pain with intercourse

Thickening of pelvic tissue

No significant and adverse reactions during the initial six months of treatment are described

The patient has undergone a bone mineral density test with satisfactory results

The patient's second course of Lupron Depot is accompanied by at least 5mg of Norethindrone Acetate daily.

For treatment of infertility (review contract for exclusions and prior authorization or benefit requirements)

**Limitations of Coverage:**

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

**Documentation Required:**

- Office notes

**Rationale:**

Gonadotropin-releasing hormone agonists may be indicated for treatment of specific conditions that are regulated by hormones. These medications are indicated when suppression of estrogen or testosterone is required for disease management.

**References:**

1. ELIGARD 45 mg (leuprolide acetate for injectable suspension). Bridgewater, NJ: sanofi-aventis US. Revised Mar 2007. Available at: [products.sanofi-aventis.us/eligard/eligard\\_45.html](http://products.sanofi-aventis.us/eligard/eligard_45.html). Accessed: 12 Apr 10.
2. Lethaby A, Hickey M, Garry R. Endometrial destruction techniques for heavy menstrual bleeding. *Cochrane Database Syst Rev.* 2005;(4):CD001501.
3. LUPRON DEPOT-PED (leuprolide acetate for depot suspension). Lake Forest, IL: TAP Pharmaceuticals. Dec 2007. Available at: [pitap.abbott.com/lupronpediatric.pdf](http://pitap.abbott.com/lupronpediatric.pdf). Accessed: 12 Apr 10.
4. PierGiorgio Crosignani<sup>1</sup>, David Olive, Agneta Bergqvist and Anthony Luciano. Advances in the management of endometriosis: an update for clinicians. [Hum Reprod Update](#). 2006 Mar-Apr; 12(2): 179-89.
5. Sowter MC, Lethaby A, Singla AA. Pre-operative endometrial thinning agents before endometrial destruction for heavy menstrual bleeding. *Cochrane Database Syst Rev.* 2002;(3):CD001124.
6. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Available at: [http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp). Accessed: Oct 11.

*Approved by the Medical Director*