



# **SUMMACARE**

## Health Plan

### **Guidelines for Medication Use:**

#### **GNRH Analogues**

#### **Lupron, Lupron-Depot Zoladex**

##### **Background:**

Lupron/Lupron-Depot (leuprolide) and Zoladex (goserelin) are synthetic analogues of gonadotropin releasing hormone (GnRH), also known as luteinizing releasing hormone (LRH). The principal effect of these agents during long-term administration is inhibition of gonadotropin secretion and suppression of testicular and ovarian hormone formation. In males, Lupron/Lupron-Depot and Zoladex reduce serum concentrations of testosterone and dihydrotestosterone to levels typically seen after surgical castration. In females, Lupron/Lupron-Depot and Zoladex suppress production of ovarian estrogen and androgens as well as luteinizing hormone and follicle-stimulating hormone.

Because of their significant effect on testicular and ovarian hormone formation, Zoladex and Lupron/Lupron-Depot inhibit the growth of hormone-dependent tumors and are effective in the treatment of conditions dependent on circulating gonadal hormones.

##### **Administration:**

Lupron-Depot 3 Month, Lupron-Depot 4 Month, Lupron-Depot Ped and Zoladex should be administered by a health care professional.

Zoladex (goserelin) is administered in the form of a subcutaneous pellet every one to three months, depending on the product used.

Lupron (leuprolide acetate) is administered by subcutaneous injection on a daily basis.

Lupron-Depot (leuprolide acetate for suspension) is administered intramuscularly every one to four months, depending on the product used.

##### **Note:**

GnRH analogues do not require authorization when billed to SummaCare for one of the following diagnoses:

- Stage D prostate cancer.
- Palliative treatment of advanced breast cancer in premenopausal and perimenopausal women.

##### **Criteria for approval:**

GnRH analogues may be authorized for the treatment of the following conditions:

- Precocious puberty (Lupron/Lupron-Depot Ped only).
- Symptomatic endometriosis, as an alternative to surgical intervention.
- In cases of moderate to severe symptomatic uterine leiomyomata (fibroids) as a pre-operative agent to reduce surgical and vascular complications of hysterectomy or myomectomy. Iron replacement therapy should also be initiated. Therapy should be authorized for up to 90 days. **Note:** rapid fibroid regrowth should be expected after discontinuation of GNRH agents. Lupron Depot or Zoladex should not be considered as a replacement for surgery.
- As an endometrial thinning agent prior to endometrial ablation or hysterectomy.

**Note:** When used in the treatment of symptomatic endometriosis, prior to surgery for uterine fibroids, or as an endometrial thinning agent prior to surgical intervention, the dose of Lupron Depot should be 3.75mg per month or 11.25mg per 3 months. Doses averaging more than 3.75mg per month require documentation of need prior to approval.

**Authorization Procedure:**

- 1) Unless otherwise dictated by plan design, Lupron/Lupron-Depot and Zoladex are covered under the SummaCare medical benefit. Lupron for daily injection may be self-administered and is therefore covered under the SummaCare prescription drug benefit.
- 2) When obtained from a SummaCare specialty provider, Lupron, Lupron-Depot, and Zoladex require authorization.
- 3) **Length of authorization:**
  - Precocious puberty: 12 months
  - Symptomatic endometriosis: 6 months. One additional 6-month course may be authorized if symptoms recur. Manufacturer recommendations cannot support additional courses of therapy. Other therapeutic modalities should be approached.
  - When used to reduce fibroid size prior to surgery or as an endometrial thinning agent prior to uterine ablation/hysterectomy, therapy may be authorized for up to 3 months.
- 4) Lupron-Depot and Zoladex are not intended for self-administration and should be administered by qualified personnel in an ambulatory setting. Claims for Lupron-Depot and Zoladex are paid as a medical benefit. Lupron for self-administration may be obtained from a network pharmacy or specialty pharmacy. The Pharmacy Authorization staff will receive and review requests for Lupron and Zoladex to be provided by a pharmacy or specialty provider. Pharmacy Authorization Staff will enter the appropriate authorizations and exceptions into the pharmacy system and Amysis system.
- 5) Pharmacy Management staff will notify the prescriber and provider of authorization or denial of services following the procedures set forth in department policies and procedures.

**Revised and Approved: March 2, 2000, September 4, 2003**

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Medical Director

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Pharmacy Director

## References

Astra-Zeneca Pharmaceuticals. *Zoladex Product Literature*. October 2001.

TAP Pharmaceuticals Inc. *Lupron Product Literature*. April 1996.

TAP Pharmaceuticals Inc. *Lupron Depot Product Literature*. July 1997.

American Society of Health-System Pharmacists. Leuprolide Acetate. ASHP Drug Information 1998. 1998: 873-82.

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