



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drug: Lupron (leuprolide)

Class: GnRH agonist

Formulary medication: Oral contraceptives

Effective Date: October 1999, updated January 2006, August 2008, August 2009

Policy/Criteria:

1. Lupron may be medically necessary for endometriosis.
 - a. The use of medication is appropriate for the treatment of pelvic pain due to endometriosis and to decrease the size of endometriotic lesions. They may not be prescribed for the sole purpose of infertility treatment, as such is not a MediCal benefit.
 - b. These medications are not considered to be first line therapy of endometriosis and should be used only when other therapies (e.g., oral contraceptives, danazol) have failed or when they cannot be used.
 - c. Once prescribed, the maximum treatment course is for a period of six months.
2. Lupron may be medically necessary if it is used in an attempt to decrease the size of uterine myomata in women in whom myomectomy or hysterectomy are indicated.
 - a. The initial prescription should be for period not to exceed three months. An extension of the treatment period to a maximum of six months will be approved only if there has been a substantial response with the initial therapy and there is a reasonable likelihood of further response.
 - b. Because of a very high recurrence rate, these medications should not be used to decrease uterine volume unless hysterectomy or myomectomy are anticipated.

Clinical Justification:

1. The American College of Obstetricians and Gynecologists (ACOG) recommends medical management of endometriosis using oral contraceptives, progestins, danazol, nonsteroid anti-inflammatory drugs and gonadotropin-releasing hormone (GnRH) agonists.
2. All the recommended medications effectively reduce the size and growth of endometrial tissue.

REFERENCES:

1. ACOG practice bulletin. "Medical management of endometriosis." Number 11, December 1999 (replaces Technical Bulletin Number 184, September 1993). Clinical management guidelines for obstetrician-gynecologists. *Int J Gynaecol Obstet* - 01-Nov-2000; 71(2): 183-96.
2. Schlesselman JJ. "Risk of endometrial cancer in relation to use of combined oral contraceptives: A practitioner's guide to meta-analysis." *Hum Reprod* 1997;12:1851-1863.
3. Sherman ME et al. "Risk factors and hormone levels in patients with serous and endometrioid uterine carcinomas." *Mod Pathol* 1997;10:963-8.
4. Vessey MP et al. "Endometrial and ovarian cancer and oral contraceptives--findings in a large cohort study." *Br J Cancer* 1995;71:1940-2.