Pharmacy Drug Policy Checklist

POLICY NAME	Synarel (nafarelin)	POLICY #	2803P

Criteria

Coverage Criteria for Endometriosis

- ☐ **1.1** Diagnosis of endometriosis
- ☐ **1.2** Documentation that member is not currently pregnant
- ☐ **1.3** Age 18 years or older
- ☐ **1.4** Ordered by or with an obstetrician-gynecologist (women's health doctor)
- ☐ **1.5** Failure to respond, intolerance, or contraindication to systemic contraceptive (birth control) and non- steroidal anti-inflammatory drugs (NSAIDs, such as ibuprofen, naproxen)
- ☐ **1.6** Documentation that member is not concurrently receiving therapy with Lupron, Zoladex, or Orilissa
- ☐ **1.7** Approval Time: One time approval for 6 months of therapy
  - The total duration of therapy should not exceed 6 months due to decreases in bone mineral density; retreatment is not recommended by the manufacturer

Coverage Criteria for Central Precocious Puberty (CPP)

- ☐ **2.1** Onset of symptoms of puberty (breast and genital development, development of pubic hair) before 8 years of age in females or before 9 years of age in males
- ☐ **2.2** Blood tests show a pubertal response with a gonadotropin-releasing hormone (GnRH) agonist
  - luteinizing hormone (LH) and follicle-stimulating hormone (FSH) are measured by blood test
  - LH above 3.3 to 5mIU/ml suggests CPP
  - LH:FSH ratio greater than 0.66 suggests CPP
- ☐ **2.3** Bone age is 2 SD beyond chronological age
- ☐ **2.4** Documented imaging tests to rule out brain tumor or steroid secreting tumors
- ☐ **2.5** If adrenal steroid levels are above thresholds, more tests will be used to rule out non-classical congenital adrenal hyperplasia and adrenal tumors,
  - Threshold for Dehydroepiandrosterone sulfate (DHEAS): 40-135mcg/dL
  - Threshold for testosterone: 35ng/dL
- ☐ **2.6** Approval Time
  - Initial: 12 months
  - Renewal: 12 months if a female and chronological age < 11 or if a male and chronological age < 12, or prescriber submits a statement of medical necessity which indicates the member requires continued therapy to prevent the onset of puberty and the request is approved by a Medical Director CPT Codes HCPCS Codes Criteria Purpose of the Policy