

## Commercial/Healthcare Exchange PA Criteria *Effective: March 2005*

**Prior Authorization:** Synarel

**Products Affected:** Synarel (nafarelin) 2 mg/mL Nasal Solution

**Medication Description:** Nafarelin acetate is an intranasally administered synthetic analog of endogenous gonadotropin-releasing hormone (GnRH), also known as luteinizing hormone-releasing hormone (LHRH). Substitution of one amino acid normally found in GnRH leads to sustained activity of this drug that aids in hormonal control; in addition, nafarelin is approximately 200 times more potent than endogenous GnRH. Nafarelin is continuously administered, which leads to down-regulation of the GnRH receptor on the pituitary gland and ultimately decreased production of FSH and LH.

**Covered Uses:**

1. Central precocious puberty (CPP)
2. Management of endometriosis, including pain relief and reduction of endometriotic lesions.

**Exclusion Criteria:**

1. Undiagnosed abnormal vaginal bleeding
2. Use in pregnancy or in women who may become pregnant while receiving Synarel
3. Use in women who are breast-feeding
4. Hypersensitivity to gonadotropin releasing hormone (GnRH), GnRH agonist analogs, nafarelin, or any of the excipients in Synarel

**Required Medical Information:**

1. Diagnosis
2. Past medication trials

**Age Restrictions:**

1. Central precocious puberty (CPP): Females age  $\leq 11$  years of age or males  $\leq 12$  years of age
2. Endometriosis: 18 years of age and older

**Prescriber Restrictions:** N/A

**Coverage Duration:**

1. Central precocious puberty (CPP): 12 months
2. Endometriosis: 6 months of treatment (total)

**Other Criteria:**

**Central precocious puberty (CPP)**

- A. Patient has a confirmed diagnosis of central precocious puberty (CPP)

**Endometriosis**

- A. Patient has a confirmed diagnosis of endometriosis; AND



- B. Patient has had an intolerance to, or treatment failure of oral contraceptives and nonsteroidal anti-inflammatory drugs (NSAIDs).

**References:**

1. Product Information: Synarel<sup>(R)</sup> nasal solution, nafarelin acetate nasal solution. G.D. Searle LLC (per FDA), New York, NY, 2017.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	Update	CCI adoption of EH template and criteria.  CCI P&T Review History: 3/05, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 2/16, 2/17, 1/18	All	October 18, 2019

