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 ≤ 11 years of age or males ≤ 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(R) nasal solution, nafarelin acetate nasal solution. G.D. Searle LLC (per FDA), New York, NY, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
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