Reference number(s)
2984-A, 3157-A, 3158-A

Supplemental Specialty Prior Authorization (SSPA) Synarel

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Synarel	nafarelin acetate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Synarel is indicated for:

- Treatment of central precocious puberty (CPP) (gonadotropin-dependent precocious puberty) in children of both sexes.
- Management of endometriosis, including pain relief and reduction of endometriotic lesions. Experience with Synarel for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months.

Compendial Uses

- Uterine leiomyomata (fibroids)[13,14]
- Hirsutism[13,15,16]

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- Preservation of ovarian function in patients with cancer[9,10]
- Prevention of recurrent menstrual related attacks in acute porphyria[11,12]
- Inhibition of premature luteinizing hormone (LH) surges in women undergoing assisted reproductive technology[17-21]
- Triggering of follicle maturation and ovulation in assisted reproductive technology cycle[17-21]

All other indications are considered experimental/investigational and are not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: For central precocious puberty initial requests, laboratory report or medical record documentation of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal basal level of luteinizing hormone (LH) on a third-generation LH assay.

Prescriber Specialties[11,12]

For prevention of recurrent menstrual related attacks in acute porphyria, this medication must be prescribed by or in consultation with a provider experienced in the management of porphyrias.

Coverage Criteria

Central Precocious Puberty (CPP)[1-8]

Authorization of 12 months may be granted for treatment of CPP when all of the following criteria are met:

- The diagnosis of CPP has been confirmed by either of the following criteria based on laboratory reference range:
  - A pubertal response to a gonadotropin releasing hormone (GnRH) agonist test
  - A pubertal basal level of luteinizing hormone (LH) on a third-generation LH assay
- The assessment of bone age versus chronological age supports the diagnosis of CPP.
- The member meets either of the following criteria:
  - The member is a female and was less than 8 years of age at the onset of secondary sexual characteristics.
  - The member is a male and was less than 9 years of age at the onset of secondary sexual characteristics.
- The pathologic cause of CPP has been assessed (e.g., imaging screening for intracranial tumors, genetic testing for familial CPP [e.g., MKRN3 or DLK1 variants]).

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Endometriosis[1]

Authorization of a total of 6 months may be granted to members for treatment of endometriosis.

Uterine Leiomyomata (Fibroids)[13,14]

Authorization of up to 3 months may be granted for initial treatment of uterine leiomyomata (fibroids) when either of the following criteria is met:

- Member has anemia due to uterine leiomyomata.
- The requested medication will be used prior to surgery for uterine leiomyomata.

Hirsutism[13,15,16]

Authorization of a total of 6 months may be granted to members for the treatment of hirsutism who have had an inadequate response, intolerable adverse event, or a contraindication to at least a six-month trial of an oral contraceptive with an antiandrogen (e.g., spironolactone).

Preservation of Ovarian Function in Patients with Cancer[9,10]

Authorization of 6 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria[11,12]

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria.

Inhibition of Premature Luteinizing Hormone (LH) Surges‡[17-21]

Authorization of 12 months may be granted for the inhibition of premature LH surges in members undergoing ovulation induction or assisted reproductive technology (ART).

Oocyte Maturation and Ovulation Trigger‡[17-21]

Authorization of 12 months may be granted for members undergoing ovulation induction or assisted reproductive technology (ART).

‡ Supplemental Specialty PA coverage review will be bypassed for Synarel if it is being requested for a procedure that has been approved under a member's medical benefit plan. Such members will be exempt from the requirements in the coverage criteria. A medical authorization number and confirmation of the approved procedure(s) will be required. NOTE: Some plans may opt-out of medical benefit alignment. Members receiving coverage under such plans must meet the requirements in the coverage criteria.

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Continuation of Therapy

Central Precocious Puberty (CPP)[2,4,7]

Authorization of up to 12 months may be granted for continued treatment of CPP when the member meets both of the following criteria:

- The member is either a female less than 12 years of age or a male less than 13 years of age.
- The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

Uterine Leiomyomata (Fibroids)[13,14]

Authorization of up to 3 months (for a lifetime maximum of 6 months total) may be granted when either of the following criteria is met:

- Member has anemia due to uterine leiomyomata.
- The requested medication will be used prior to surgery for uterine leiomyomata.

All Other Indications

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

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