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

SUPPLEMENTAL SPECIALTY PA

SYNAREL (nafarelin acetate)

POLICY

I. 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.

A. FDA-Approved Indications
1. Central precocious puberty
   Synarel is indicated for treatment of central precocious puberty (CPP) (gonadotropin-dependent precocious puberty) in children of both sexes.
2. Endometriosis
   Synarel is indicated for 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.

B. Compendial Uses
1. Uterine leiomyomata (fibroids)
2. Hirsutism
3. Preservation of ovarian function in patients with cancer
4. Prevention of recurrent menstrual related attacks in acute porphyria
5. Inhibition of premature luteinizing hormone (LH) surges in women undergoing assisted reproductive technology
6. Triggering of follicle maturation and ovulation in assisted reproductive technology cycle

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

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)
1. Authorization of 12 months may be granted for treatment of CPP in a female member when all of the following criteria are met:
   i. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging, such as computed tomography (CT scan), magnetic resonance imaging (MRI), or ultrasound.
   ii. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.

iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
iv. The member was less than 8 years of age at the onset of secondary sexual characteristics.

2. Authorization of 12 months may be granted for treatment of CPP in a male member when all of the following criteria are met:
   i. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging, such as CT scan, MRI, or ultrasound.
   ii. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third-generation LH assay.
   iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   iv. The member was less than 9 years of age at the onset of secondary sexual characteristics.

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

C. Uterine leiomyomata (fibroids)
Authorization of up to 3 months may be granted for initial treatment of uterine leiomyomata (fibroids) when either of the following criteria is met:
1. Member has anemia due to uterine leiomyomata, or
2. The requested medication will be used prior to surgery for uterine leiomyomata.

D. Hirsutism
Authorization of a total of 6 months may be granted to members for the treatment of hirsutism.

E. Preservation of ovarian function in patients with cancer
Authorization of 3 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

F. Prevention of recurrent menstrual related attacks in acute porphyria
Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria when the requested medication is prescribed by or in consultation with a physician experienced in the management of porphyrias.

G. Inhibition of premature luteinizing hormone (LH) surge‡
Authorization of 12 months may be granted for the inhibition of premature LH surge in a member undergoing ovulation induction or assisted reproductive technology (ART).

H. Oocyte maturation and ovulation trigger‡
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 Section III. 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 Section III.*

IV. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

1. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age and the member meets both of the following:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure such as clinical pubertal progression, lack of growth deceleration, and continued excessive bone age advancement.
2. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age and the member meets both of the following:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure such as clinical pubertal progression, lack of growth deceleration, and continued excessive bone age advancement.

B. Uterine leiomyomata (fibroids)

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

1. Member has anemia due to uterine leiomyomata, or
2. The requested medication will be used prior to surgery for uterine leiomyomata.

C. All other indications

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

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