STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAFARELIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAFARELIN ACETATE	SYNAREL	21103		GPI-10 (3008005510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) OR histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   - The requested medication will NOT be used concurrently with another GnRH-modulating agent (e.g., elagolix, relugolix, Lupron Depot)
   - The patient has NOT received more than 6 months of treatment with Synarel per lifetime

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #96mL per 6 months.**
   If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.**
   If no, continue to #4.

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has documentation of pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Moderate to severe pain from endometriosis (condition affecting the uterus)
      3. Central precocious puberty (CPP: early sexual development in girls and boys)
   B. **If you have moderate to severe pain from endometriosis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
      3. Your diagnosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
      4. You have tried or have a contraindication (harmful for) to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
      5. You are NOT using Synarel concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as elagolix, relugolix, Lupron Depot)
      6. You have NOT received more than 6 months of treatment with Synarel per lifetime

   (Initial denial text continued on next page)

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

C. **If you are female and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 8 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NAFARELIN

GUIDELINES FOR USE (CONTINUED0

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or pain from endometriosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synarel.

REFERENCES

- Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 09/18
Client Approval: 01/23
P&T Approval: 04/22