Original Effective Date: 10/01/2012
Current Effective Date: 08/23/2023
Last P&T Approval/Version: 07/26/2023
Next Review Due By: 07/2024
Policy Number: C4958-A

Synarel (nafarelin acetate, nasal solution)

PRODUCTS AFFECTED

Synarel (nafarelin acetate, nasal solution)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Central precocious puberty, Endometriosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. CENTRAL PRECOCIOUS PUBERTY (CPP):
1. Diagnosis of central precocious puberty and member is currently less than 13 years old AND
2. Onset of secondary sexual characteristics with one of the following: Females </= 8 years of age OR Males < / = 9 years of age

AND

3. Confirmation of diagnosis as defined by ONE of the following: (a) Pubertal basal level of luteinizing hormone (based on laboratory reference ranges) OR (b) Pubertal luteinizing hormone in response to a GnRH stimulation test OR (c) Bone age advanced one year beyond chronological age [DOCUMENTATION REQUIRED]

B. ENDOMETRIOSIS:

1. Documentation of a diagnosis of endometriosis
   AND
2. Documentation cause of pain is due to endometriosis
   AND
3. Documentation member has tried/failed or has an absolute contraindication to ALL the following:
   (i) ONE formulary NSAID (i.e., Ibuprofen, naproxen)
   AND
   (ii) ONE of the following hormonal agents: a formulary preferred oral estrogen-progestin contraceptive, medroxyprogesterone or norethindrone acetate
   AND
4. At the time of request, member is not pregnant
   AND
5. Lifetime duration does not exceed 6 months total

CONTINUATION OF THERAPY:

A. CENTRAL PRECOCIOUS PUBERTY (CPP):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Documented disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, and improvement in final height prediction
   AND
3. Member is not currently older than age 12 OR Prescriber has provided contributing factors that may include bone age and height age, predicted height, and discontinuation plan or date.
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., convulsions, development or worsening of psychiatric symptoms, etc.)
   AND
5. Requested dose does not exceed 1800 micrograms/day

B. ENDOMETRIOSIS: NA

DURATION OF APPROVAL:

CPP: Initial authorization: 12 months, Continuation of Therapy: 12 months
ENDOMTERIOSIS: Initial authorization: 6 months, total duration of therapy should not exceed 6 months due to decreases in bone mineral density; retreatment is not recommended by the manufacturer.

PRESCRIBER REQUIREMENTS:

CPP: Prescribed by or in consultation with a pediatric endocrinologist
ENDOMETRIOSIS: Prescribed by or in consultation with a gynecologist
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

CPP: Refer to required medical information

Endometriosis: 18 years of age and older

QUANTITY:
Central precocious puberty (CPP): 1800 mcg/day
Endometriosis: 800 mcg/day

PLACE OF ADMINISTRATION:
The recommendation is that intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intranasal

DRUG CLASS:
LHRH/GNRH agonist analog pituitary suppressants

FDA-APPROVED USES:
Treatment of CPP (gonadotropin-dependent precocious puberty) in children of both sexes; Management of endometriosis, including pain relief and reduction of endometriotic lesions.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Synarel (nafarelin) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Synarel (nafarelin) include: Hypersensitivity to GnRH, GnRH-agonist analogs, or any of the excipients in Synarel, undiagnosed abnormal vaginal bleeding, use in pregnancy or in women who may become pregnant while receiving the drug, and use in women who are breast-feeding.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Synarel SOLN 2MG/ML (8ml bottle)

REFERENCES

1. Synarel Prescribing Information. New York, NY: G.D. Searle, LLC. Division of Pfizer, Inc.; January 2023.
2. Committee on Practice Bulletins - Gynecology. Management of endometriosis. July 2010 (reaffirmed 2016); 116(1): 223-236.
3. Kaplowitz P, Bloch C. Evaluation and referral of children with signs of early puberty. Pediatrics.2016; 137(1): e20153732

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Contraindications/Exclusions/Discontinuation References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file