Pharmacy Drug Policy & Procedure

Policy Name:	Synarel (nafarelin)	Policy #:	2803P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Synarel (nafarelin).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Synarel under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Endometriosis

1.1 Diagnosis of endometriosis
1.2 Documentation that member is not currently pregnant
1.3 Age 18 years or older
1.4 Ordered by or with an obstetrician-gynecologist (women's health doctor)
1.5 Failure to respond, intolerance, or contraindication to systemic contraceptive (birth control) and non-steroidal anti-inflammatory drugs (NSAIDs, such as ibuprofen, naproxen)
1.6 Documentation that member is not concurrently receiving therapy with Lupron, Zoladex, or Orilissa
1.7 Approval Time: One time approval for 6 months of therapy
- The total duration of therapy should not exceed 6 months due to decreases in bone mineral density; retreatment is not recommended by the manufacturer

2. Coverage Criteria for Central Precocious Puberty (CPP)

2.1 Onset of symptoms of puberty (breast and genital development, development of pubic hair) before 8 years of age in females or before 9 years of age in males
2.2 Blood tests show a pubertal response with a gonadotropin-releasing hormone (GnRH) agonist
- luteinizing hormone (LH) and follicle-stimulating hormone (FSH) are measured by blood test
- LH above 3.3 to 5mIU/ml suggests CPP
- LH:FSH ratio greater than 0.66 suggests CPP

2.3 Bone age is 2 SD beyond chronological age
2.4 Documented imaging tests to rule out brain tumor or steroid secreting tumors
2.5 If adrenal steroid levels are above thresholds, more tests will be used to rule out non-classical congenital adrenal hyperplasia and adrenal tumors,
- Threshold for Dehydroepiandrosterone sulfate (DHEAS): 40-135mcg/dL
- Threshold for testosterone: 35ng/dL

2.6 Approval Time
- Initial: 12 months
- Renewal: 12 months if a female and chronological age < 11 or if a male and chronological age < 12, or prescriber submits a statement of medical necessity which indicates the member requires continued therapy to prevent the onset of puberty and the request is approved by a Medical Director

CPT Codes

HCPCS Codes

References

1. Synarel (nafarelin) [prescribing information]. New York, NY: Pfizer; January 2023.
2. Saridogan E, Tomassetti C, van Hanegem N, et al. ESHRE guideline: management of women with endometriosis. Hum Reprod Open. 2022 Feb 26;2022(2):hoac009.
3. Management of Endometriosis. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician Gynecologists. Number 114. 2010 (reaffirmed 2018). Obstet & Gynecol. 2010;116(1):223-236.
4. Dysmenorrhea and endometriosis in the adolescent. ACOG Committee Opinion. No. 760. December 2018.
5. Eugster E. Treatment of Central Precocious Puberty. Journal of the Endocrine Society. 2019: 3(5): 965-972.
6. Kletter GB, Klein KO, Wong YY, et al. A pediatrician's guide to central precocious puberty. Clin Pediatr. 2015;54:414-424.
7. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009;123:e752–e762.
8. Mericq V, Cajardo H, Effers M, et al. Effects of treatment with GH alone or in combination with LHRH analog on bone mineral density in pubertal GH-deficient patients. J Clin Endocrinol Metab. 2002;87:84–89.
9. Mul D, Wit JM, Oostdijk W, et al. The effects of pubertal delay by GnRH agonist in GH-deficient children on final height. J Clin Endocrinol Metab. 2001;86(10):4655–4656.
10. Pucarelli I, Segni M, Ortore M, et al. Effects of combined gonadotropin-releasing hormone agonist and growth hormone therapy on adult height in precocious puberty: a further contribution. J Pediatr Endocrinol Metab. 2003;16:1005–1010.
11. Quintos JB, Vogiatzi MG, Harbison MD, et al. Growth hormone therapy alone or in combination with gonadotropinreleasing hormone analog therapy to improve the height deficit in children with congenital adrenal hyperplasia. J Clin Endocrinol Metab. 2001;86:1511–1517.

Created Date: 12/02/20
Effective Date: 12/02/20
Posted to Website: 01/01/22
Revision Date: 06/05/24