Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 11, 2021 February 1, 2022

FENSOLVI® (leuprolide acetate)

LENGTH OF AUTHORIZATION: 1 year

INITIAL REVIEW CRITERIA:

- Patient age must be between 2 - 11 years for girls and 2 - 12 years for boys
- Must have a diagnosis of Precocious Puberty (ICD-10 E22.8 - Precocious sexual development and puberty, not elsewhere classified) confirmed by ALL the following:
  - Measurement of blood concentrations of total sex steroids (estrogens/testosterone)
    - Elevated serum estrogen and testosterone measurement in girls and boys respectively help confirm the onset of puberty
  - Measurement of LH and FSH after stimulation with a GnRH analog
    - Elevated gonadotropins are expected in central precocious puberty
  - Assessment of bone vs. chronological age
    - A nondominant (typically, left) hand/wrist radiograph to estimate skeletal age. The appearance of representative epiphyseal centers on the x-ray is compared with age and gender-appropriate published standards. The most commonly used method is that of Greulich and Pyle. The bone age is typically advanced in patients with precocious puberty.
- Must be evaluated and therapy must be prescribed by a pediatric endocrinologist
- Trial and failure of either Lupron Ped Depot or intranasal Synarel
  - Failure is defined as the inability to suppress physical signs of puberty (for at least 3 months) or inability to tolerate therapy (not due to pain)

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as: 45mg of leuprolide acetate supplied in a kit for injectable suspension