Drug Name: Leuprolide Acetate Injection

Totally Revised Date: 7-2018

Drug Name:	Leuprolide Acetate Injection
Prescriber Restrictions:	n/a
Inclusion Criteria:	**FDA-Approved Indications** • Prostate cancer: Leuprolide acetate is indicated in the palliative treatment of advanced prostate cancer. • Central precocious puberty (CPP): Leuprolide acetate is indicated in the treatment of children with central precocious puberty. **Compendial Uses** • Use as a stimulation test to confirm the diagnosis of CPP • Use in combination with growth hormone for children with growth failure and advancing puberty • Prostate cancer • Inhibition of premature luteinizing hormone (LH) surges in women undergoing assisted reproductive technology **All other indications are considered experimental/investigational and are not a covered benefit.**
Required Medical Information:	Approve if Meet the Following **Central precocious puberty (CPP)** o Authorization up to age 12 may be granted for the treatment of CPP in a female member when all of the following criteria are met: • 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 • The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age • The member was less than 8 years of age at the onset of secondary sexual characteristics o Authorization up to age 13 may be granted for the treatment of CPP in a male member when all of the following criteria are met: • 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 • The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age • The member was less than 9 years of age at the onset of secondary sexual characteristics OR **Stimulation test for CPP diagnosis** • Use as a stimulation test to confirm the diagnosis of CPP. OR

	Advancing puberty and growth failure • For the treatment of advancing puberty and growth failure in a pediatric member when leuprolide acetate is used in combination with growth hormone. OR **Prostate cancer** • Treatment of prostate cancer. • Coverage will not be provided for members with prostate cancer if leuprolide acetate is used as neoadjuvant androgen deprivation therapy (ADT) for radical prostatectomy. OR **Inhibition of premature luteinizing hormone (LH) surge** • For the inhibition of LH surge in a member with infertility.
Note(s):	Coverage review will be bypassed for drug(s) being requested for a procedure that has been approved under a member's medical benefit plan.
Coverage duration:	**Central precocious puberty (CPP):** Female Member: up to age 12, Male Member: up to age 13 **Stimulation test for CPP diagnosis:** One Dose **Advancing puberty and growth failure:** 12 months **Prostate cancer:** 12 months **Inhibition of premature luteinizing hormone (LH) surge:** 12 months