Reference number(s)
1989-A, 1990-A, 2117-A

SPECIALTY GUIDELINE MANAGEMENT

leuprolide acetate injection

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Prostate cancer: Leuprolide acetate is indicated in the palliative treatment of advanced prostate cancer.
2. Central precocious puberty (CPP): Leuprolide acetate is indicated for the treatment of pediatric patients with central precocious puberty.

B. Compendial Uses
1. Use as a stimulation test to confirm the diagnosis of CPP
2. Use in combination with growth hormone for children with growth failure and advancing puberty
3. Prostate cancer
4. Inhibition of premature luteinizing hormone (LH) surges in members undergoing ovulation induction or assisted reproductive technology
5. Androgen receptor positive salivary gland tumors
6. Triggering of oocyte maturation and ovulation in assisted reproductive technology cycle

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

For central precocious puberty, submission of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay is required to initiate the prior authorization.

III. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)
1. Authorization of 12 months may be granted for treatment of CPP in a female member when all of the following criteria are met:
   a. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging, such as computed tomography (CT) scan, magnetic resonance imaging (MRI), or ultrasound.
   b. 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.
   c. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   d. The member was less than 8 years of age at the onset of secondary sexual characteristics.

2. Authorization of 12 months may be granted for treatment of CPP in a male member when all of the following criteria are met:
   a. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging, such as CT scan, MRI, or ultrasound.
   b. 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.
   c. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   d. The member was less than 9 years of age at the onset of secondary sexual characteristics.

B. Stimulation test for CPP diagnosis
Authorization of one dose may be granted for use as a stimulation test to confirm the diagnosis of CPP.

C. Advancing puberty and growth failure
Authorization of 12 months may be granted for treatment of advancing puberty and growth failure in a pediatric member when leuprolide acetate is used in combination with growth hormone.

D. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

E. Salivary gland tumors
Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors as a single agent when the tumor is androgen receptor positive.

F. Inhibition of premature luteinizing hormone (LH) surge‡
Authorization of 12 months may be granted for the inhibition of premature LH surge in a member undergoing ovulation induction or assisted reproductive technology (ART).

G. Oocyte maturation and ovulation trigger‡
Authorization of 12 months may be granted for the triggering of oocyte maturation and ovulation in members undergoing ovulation induction or assisted reproductive technology (ART).

‡ Specialty Guideline Management coverage review will be bypassed for leuprolide if it is being requested for a procedure that has been approved under a member's medical benefit plan. Such members will be exempt from the requirements in Section III. A medical authorization number and confirmation of the approved procedure(s) will be required. *NOTE: Some plans may opt-out of medical benefit alignment. Members receiving coverage under such plans must meet the requirements in Section III.*

IV. CONTINUATION OF THERAPY

A. **Central precocious puberty**
1. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age and the member meets both of the following:
   a. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   b. The member is not experiencing treatment failure such as clinical pubertal progression, lack of growth deceleration, and/or continued excessive bone age advancement.
2. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age and the member meets both of the following:

a. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
b. The member is not experiencing treatment failure such as clinical pubertal progression, lack of growth deceleration, and/or continued excessive bone age advancement.

B. All members (including new members) requesting authorization for continuation of therapy for the specified indications below must meet all initial authorization criteria:
1. Stimulation test for CPP diagnosis
2. Advancing puberty and growth failure
3. Inhibition of premature LH surge
4. Oocyte maturation and ovulation trigger

C. Authorization of 12 months may be granted for continued treatment of salivary gland tumors in members requesting authorization who are experiencing clinical benefit to therapy and who have not experienced an unacceptable toxicity.

D. Authorization of 12 months may be granted for continued treatment of prostate cancer in members requesting authorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

V. REFERENCES

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