



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Histrelin

Brand Name: Supprelin LA®, Vantas™

Medication Class: Gonadotropin Releasing Hormone Agonist

FDA Approved Uses:

- Vantas™ for palliative treatment of advanced prostate cancer in men
- Supprelin LA® for the treatment of children with central precocious puberty

Available Dosage Forms:

- Vantas™ implantation kit 50 mg (release 50-60 mcg/day over 12 months)
- Supprelin® LA implantation kit 50 mg (release~ 65 mcg/day over 12 months)

Usual Dose: 50 mg implant surgically inserted every 12 months

Duration of Therapy:

- (Vantas™) Indefinitely
- (Supprelin® LA) Until the onset of puberty (Girls ~ age 11; boys ~ age 12)

Approximate monthly cost (based on ASP+6% as of 4/1/ 2008):

- Vantas™ has an ASP+6% of **\$1,508** for one implant (1 year)
- Supprelin® has an ASP+6% of **\$14,656** for one implant (1 year)

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

For Vantas™

- for men only diagnosed with advanced prostate cancer
- not for children under 18 years of age

For Supprelin®

- children age ≥ 2 years old clinically diagnosed with central precocious puberty.

Diagnosis should be confirmed by the following:

- measurement of blood concentrations of total sex steroids (estrogens/testosterone)
- measurement of LH and FSH after stimulation with a GnRH analog
- assessment of bone age vs. chronological age

Baseline evaluation should also include height and weight; diagnostic imaging of the brain, pelvic/testicular/adrenal ultrasound, HCG levels, and adrenal steroids to rule out tumors secreting any of the hormones.

- tried and failed Lupron Depot (Failure defined as the inability to suppress physical signs of puberty)



Criteria for Continuation of Therapy:

- Vantas™ -- testosterone continues below castration level
- Supprelin LA® -- height and weight slow down to a more normal linear pattern, and secondary sex characteristics do not progress

Cautions:

- Loss of bone mineral density
- Transient increase in serum estradiol level (female) or testosterone levels (female and male)
- Pituitary apoplexy
- Spinal cord compression
- Urinary tract obstruction
- Worsening of symptoms
- Not for children under 2 years old

Monitoring:

For Vantas

- Serum concentrations of PSA and testosterone
- Bone mineral density

For Supprelin

- LH, FSH, estradiol or testosterone (1 month then every 6 months)
- Height, bone age (every 6 to 12 months)
- Tanner staging

Contraindications:

- Vantas™ -- Females or children under 18 years of age
- Supprelin® -- Postpuberty women or pregnant women, or children under 2 years old
- Hypersensitivity to histrelin acetate, GnRH, GnRH-agonist analogs, or any component of the formulation

Not Approved if:

- Patient does not meet the above listed criteria
- Being used to treat conditions other than FDA indicated uses.
- Patient has any contraindications

Special Considerations:

- Lack of response should be prompt suspicion that the implant has been expelled.
- Results of diagnostic testing of pituitary gonadotropic and gonadal functions may be affected during and after therapy

P&T Approval: _____ Date: _____