Clinical Policy: Histrelin Acetate (Vantas, Supprelin LA)
Reference Number: ERX.SPMN.96
Effective Date: 07/16
Last Review Date: 06/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that histrelin acetate (Vantas® and Supprelin LA®) are medically necessary for members meeting the following criteria:

I. Initial Approval Criteria
   A. Prostate Cancer (must meet all):
      1. Age ≥ 18 years;
      2. Diagnosis of advanced prostate cancer (stage T3 through T4 or high risk through nodal/metastatic disease);
      3. Treatment intent is palliative;
      4. Prescription is for Vantas;
      5. Prescribed dose does not exceed 50 mg administered as one 12-month implant;
      6. Member has a contraindication to or has failed a trial of leuprolide acetate generic injection, Lupron Depot, or Zoladex.

   Approval Duration: 12 months

   B. Central Precocious Puberty (CPP) (must meet all):
      1. Females, age ≥ 2 and ≤ 11 years, or males, age ≥ 2 and ≤ 12 years;
      2. Diagnosis of CPP confirmed by a through c:
         a. Elevated basal LH level and/or elevated leuprolide stimulated LH level > 5 IU/l;
         b. Assessment shows significantly advanced bone age versus chronological age;
         c. Age at onset of secondary sex characteristics is < 8 years if female, or < 9 years if male;
      3. The following conditions have been ruled out:
         a. Intracranial tumor with diagnostic brain imaging;
         b. Steroid secreting tumors with pelvic/testicular/adrenal ultrasound;
         c. Chorionic gonadotropin secreting tumor via measurement of human chorionic gonadotropin levels;
         d. Congenital adrenal hyperplasia via measurement of adrenal steroids;
      4. Prescription is for Supprelin LA;
      5. Prescribed dose does not exceed one implant every 12 months containing 50 mg histrelin acetate.
Approval Duration: 12 months

C. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy

II. Continued Approval (must meet all as applicable)
A. Prostate Cancer:
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria.

   Approval Duration: 12 months

B. Central Precocious Puberty (CPP):
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
   2. Females, age ≥ 2 and ≤11 years, or males, age ≥ 2 and ≤12 years;
   3. Therapeutic effect is evidenced by decreased growth velocity, menses cessation if female, and arrested pubertal progression.

   Approval Duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Histrelin acetate is a GnRH agonist that acts as a potent inhibitor of gonadotropin secretion when given continuously in therapeutic doses.

FDA Approved Indications:
- Vantas is a GnRH agonist/subcutaneous implant indicated for the palliative treatment of advanced prostate cancer.
- Supprelin LA is a GnRH agonist/subcutaneous implant indicated for the treatment of children with CPP.

Appendices

Appendix A: Abbreviation Key
CPP: central precocious puberty
GnRH: gonadotropin-releasing hormone
LH: luteinizing hormone

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>05/16</td>
<td>06/16</td>
</tr>
</tbody>
</table>
References

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2016 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.