

JURISDICTION SPECIFIC MEDICARE PART B

VANTAS (histrelin acetate)

POLICY

I. COVERED USES

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

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Prostate cancer

B. Central precocious puberty

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
- B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.
- C. Documentation supporting ongoing follow-up visits at least every 3 to 4 months

III. CRITERIA FOR APPROVAL

A. Prostate Cancer

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

B. Central Precocious Puberty

Authorization of 12 months may be granted for treatment of central precocious puberty in children with a disability who are covered under Medicare.

IV. DOSAGE AND ADMINISTRATION

Reference number(s)
3940-A

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 27, 2021.
2. Billing and Coding: LHRH Analogs (A52453) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 27, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 27, 2021.
4. Vantas [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; February 2019.