

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 indication is listed below:

Prostate cancer

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 in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

- A. Relevant medical history
- B. Physical examination
- C. Results of pertinent diagnostic tests (including prostate-specific antigen and testosterone levels)
- D. Any relevant procedures
- E. Documentation supporting ongoing follow-up visits at least every 3 to 4 months

III. CRITERIA FOR APPROVAL

Prostate Cancer

Authorization of 12 months may be granted for treatment of advanced prostate cancer when all of the following criteria are met:

- A. Orchiectomy and/or estrogen administration are either not indicated or unacceptable to the patient.
- B. The provider will measure serum concentrations of prostate-specific antigen (PSA) and testosterone periodically through the year.
- C. The member will be seen by the provider in follow-up at least every 3 to 4 months.

Reference number(s)
4014-A

IV. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

1. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L34822) Version R6. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 1, 2021.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776) Version R1. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 1, 2021.
3. Vantas [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; December 2020.