

Vantas® (histrelin acetate) (Subcutaneous implant)

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I. Length of Authorization

Coverage will be provided for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 50 mg implant: 1 per 12 months

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit per 12 months

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

Advanced Prostate Cancer †

- Patient is 18 years or older

† FDA Approved Indication(s)

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: QT/QTc interval prolongations, cardiovascular disease, spinal cord compression, urinary tract obstruction, severe hyperglycemia/diabetes, etc.

V. Dosage/Administration ¹

| Indication | Dose |
|-----------------|---|
| Prostate Cancer | One 50 mg implant inserted subcutaneously every 12 months |

VI. Billing Code/Availability Information

HCPCS Code:

- J9225 – Histrelin implant (Vantas), 50 mg: 1 billable unit = 50 mg

NDC:

- Vantas 50 mg implant: 67979-0500-xx

VII. References

1. Vantas [package insert]. Malvern, PA; Endo Pharmaceuticals Solutions, Inc; December 2020. Accessed March 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Histrelin acetate. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2022.
3. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A57655). Centers for Medicare & Medicaid Services, Inc. Updated on 11/21/2019 with effective date 10/03/2018. Accessed March 2022.
4. National Government Services, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A52453). Centers for Medicare & Medicaid Services, Inc. Updated on 12/22/2021 with effective date 01/01/2022. Accessed March 2022.
5. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776). Centers for Medicare & Medicaid Services, Inc. Updated on 10/08/2021 with effective date 10/21/2021. Accessed March 2022.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|--|
| C61 | Malignant neoplasm of prostate |
| Z85.46 | Personal history of malignant neoplasm of prostate |

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

| | |
|---|-------------------------------------|
| Jurisdiction(s): N | NCD/LCD Document (s): A57655 |
| https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57655&bc=gAAAAAAAAAAAA& | |
| Jurisdiction(s): H | NCD/LCD Document (s): A56776 |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56776&bc=gAAAAAAAAAAAA& | |
| Jurisdiction(s): 6, K | NCD/LCD Document (s): A52453 |
| https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A52453&bc=gAAAAAAAAAAAA%3d%3d& | |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |