

# Drug Policy

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| <b>Policy:</b> | <b>Veregen (sinecatechins)</b> | <b>Annual Review Date:</b><br><b>11/21/2024</b> |
|                |                                | <b>Last Revised Date:</b><br><b>11/21/2024</b>  |

### OVERVIEW

Veregen is indicated for the topical treatment of external genital and perianal warts (*Condyloma acuminata*) in immunocompetent patients 18 years of age and older. This medication is a botanical drug product for topical use. The drug substance in Veregen, sinecatechins, is a partially purified fraction of the water extract of green tea leaves from *Camellia sinensis (L.) O Kuntze* and is a mixture of catechins and other green tea components. In addition, it also contains gallic acid, caffeine, and theobromine as part of the drug substance. In two Phase 3 clinical trials, the median time to complete wart clearance with use of Veregen was 16 weeks and 10 weeks, respectively.

### POLICY STATEMENT

This policy involves the use of Veregen. Prior authorization is recommended for pharmacy benefit coverage of Veregen. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Veregen is recommended in those who meet the following criteria:

#### 1. External Genital and Perianal Warts

**Criteria.** Patient must meet the following criteria (A, B, and C):

- A. The patient is 18 years of age or older; AND
- B. The patient is immunocompetent; AND
- C. The patient has previously tried and failed to achieve clinical response with BOTH of the following medications after an adequate trial:
  - a. Generic imiquimod cream; AND
  - b. Generic podofilox solution or gel

#### Initial Approval/ Extended Approval.

- A) Initial Approval: 16 weeks
- B) Extended Approval: not recommended

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## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Veregen has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

- 1. Ophthalmic, Oral, Intravaginal, or Intra-anal Use of Veregen.** This product is approved for external use ONLY.
- 2. Treatment of Urethral, Intravaginal, Cervical, Rectal or Intra-anal Human Papilloma Virus (HPV) Disease.** Veregen has not been evaluated for the treatment of these conditions and should not be considered for therapy in these conditions.
- 3. Multiple Treatment Courses.** Safety and efficacy have not been established for Veregen in the treatment of external genital and perianal warts for multiple treatment courses.
- 4.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Sinecatechins. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated February 2020. Accessed on November 10, 2020.
2. Veregen 15% topical ointment [package insert]. Melville, NY: Fougera Pharmaceuticals, Inc. May 2018.