Drug Coverage Policy

Effective Date.....5/1/2025
Coverage Policy Number.....IP0393
Policy Title.....Veregen

Veregen

- Veregen® (sinecatechins ointment – Fougera)

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Veregen, a botanical drug product, is indicated for the topical treatment of **external genital and perianal warts** (*Condylomata acuminata*) in immunocompetent patients ≥ 18 years of age.[1]

Limitations of Use: The safety and efficacy of Veregen have not been established in immunosuppressed patients, in treatment of external genital and perianal warts beyond 16 weeks, or for multiple treatment courses.

Guidelines
The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases Treatment Guidelines (2021) detail the patient-applied and provider-applied treatment options for the management of external angogenital warts (i.e., penis, groin, scrotum, vulva, perineum, external anus, or perianus).[2] The CDC guidelines note that treatment should be guided by wart size, number of lesions, location of the wart(s), the preference of the patient, cost of treatment, convenience, adverse effects, and the experience of the healthcare provider with the various provider-applied options. There is no definitive evidence available which has demonstrated the superiority of one product over others for all patients and all warts. Most patients will require a course of therapy vs. a single treatment. Most warts will typically respond to therapy in 3 months, but if response does not occur, then treatment options should be reassessed and modified if needed. The CDC recommended patient-applied regimens include: imiquimod 3.75% or 5% cream, podofilox 0.5% solution or gel, or Veregen.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for prescription benefit coverage of Veregen. All approvals are provided for the duration noted below.

Veregen is considered medically necessary when the following criteria are met:

1. **Genital or Perianal Warts, External.** Approve for 4 months if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is immunocompetent, according to the prescriber; AND
   - **C)** Patient has failure, contraindication or intolerance to BOTH of the following (i and ii):
     - **i.** Podofilox gel or solution; AND
     - **ii.** Imiquimod cream.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Veregen for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Veregen® ointment [prescribing information]. Melville, NY: Fougera; November 2022.
2. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2021. *MMWR.* 2021;70(4):1-192.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** coverage policy title from Sinecatechins to Veregen.	6/1/2024
Annual Revision	**No criteria changes**	5/1/2025

The policy effective date is in force until updated or retired.