Cigna National Formulary Coverage Policy

Effective Date..... 3/1/2023
Next Review Date..... 3/1/2024

Prior Authorization
Veregen® (sinecatechins ointment)

Table of Contents

Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107732

Effective 2/7/23: 79256

INSTRUCTIONS FOR USE
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. 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.

National Formulary Medical Necessity

Cigna covers Sinecatechins products (Veregen®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Veregen. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

FDA Indication(s)

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

Conditions Not Covered

Sinecatechins (Veregen®) is considered experimental, investigational or unproven for ANY other use.

Background

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]

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 genital warts.[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 health care 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% cream or 5% cream, podofilox 0.5% solution or gel, or Veregen.

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 History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	01/18/2023