PRIOR AUTHORIZATION POLICY

POLICY: Veregen Prior Authorization Policy
- Veregen® (sinecatechins ointment – Fougera)

REVIEW DATE: 02/11/2026

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. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

POLICY STATEMENT

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.

Veregen® (sinecatechins ointment – Fougera) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Genital or Perianal Warts, External.** Approve for 4 months if the patient meets ALL of 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 tried BOTH of the following (i and ii):
      i. Podofilox gel or solution; AND
      ii. Imiquimod cream.

CONDITIONS NOT COVERED

Veregen® (sinecatechins ointment – Fougera) is(are) considered not medically necessary for ANY other use(s); 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.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	No criteria changes.	02/07/2024
Annual Revision	No criteria changes.	02/12/2025
Annual Revision	No criteria changes.	02/11/2026

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