PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/07/2024

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 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

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 tried BOTH of the following (i and ii):
     - **i.** Podofilox gel or solution; AND
     - **ii.** Imiquimod cream.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Veregen is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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.