PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/13/2021

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 (2015) 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 (Zyclara, generics) or 5% cream (Aldara, generics), podofilox 0.5% solution or gel (Condylox, generics for solution available), or sinecatechins 15% ointment (Veregen). The CDC recommended provider-applied regimens include: cryotherapy with liquid nitrogen or cryoprobe, trichloroacetic acid or bichloroacetic acid 80-90%, or surgical removal by tangential scissor excision, tangential shave excision, curettage, or electrosurgery. Alternatives listed are podophyllin resin, intralesional interferon, photodynamic therapy, and topical cidofovir.

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 Indications

1. **Genital or Perianal Warts, External.** Approve for 4 months if the patient meets the following criteria (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 one other treatment for the management of external genital or perianal warts.
     Note: Examples of treatment for the management of external genital or perianal warts include imiquimod cream, podofilox gel or solution, cryotherapy, trichloroacetic or bichloroacetic acid, surgical removal, podophyllin resin, intralesional interferon, photodynamic therapy, and topical cidofovir.

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® [prescribing information]. Melville, NY: Fougera Pharmaceuticals; February 2020.
2. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015. *MMWR*. 2015;64(No. RR-3):1-140.