Pharmacy Policy Bulletin

Title:	Sinecatechins (Veregen®)
Policy #:	Rx.01.271

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for Sinecatechins (Veregen®) as provided under the member's prescription drug benefit.

Description:

Human papillomavirus (HPV) is a common cause of cutaneous and mucosal infection. Condylomata acuminata (CA; singular: condyloma acuminatum), also known as anogenital warts, are manifestations of HPV infection that occur in a subset of individuals with anogenital HPV infection. External CA typically manifest as soft papules or plaques on the external genitalia, perianal skin, perineum, or groin. For most patients, the presence of genital warts is concerning because of their cosmetic appearance, association with a sexually transmitted disease, bothersome symptoms, absence of a cure, and social stigma. Although treatment can eradicate the warts, disease recurrence is common and occurs in 20 to 30 percent of patients overall.

The mode of action of Veregen involved in the clearance of genital and perianal warts is unknown. In vitro, sinecatechins had anti-oxidative activity; the clinical significance of this finding is unknown.

Veregen is indicated for the topical treatment of external genital and perianal warts (Condylomata acuminata) in immunocompetent patients 18 years and older.

Policy:

Sinecatechins (Veregen®) is approved when all of the following are met:

1. Diagnosis of Condylomata acuminata (external genital and perianal warts); and
2. Member is immunocompetent; and
3. Member is 18 years of age or older; and
4. Inadequate response or inability to tolerate imiquimod (generic Aldara®)

Authorization duration: 4 months

Total duration of treatment is limited to 16 weeks per lifetime

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Rosen T. Condylomata acuminata (anogenital warts) in adults: Epidemiology, pathogenesis, clinical features, and diagnosis. In: Post T, ed. *UpToDate*. December 2022. www.uptate.com. Accessed April 20, 2023.

Veregen® (Sinecatechins) [prescribing information]. Melville, New York: PharmaDerm®; February 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2c1cd745-79ab-487d-b759-995794cedb92. Accessed April 20, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Veregen®	Sinecatechins

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	2.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	March 16, 2024