



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Sinecatechins

Brand Name: Veregen™®

Medication Class: topical botanicals

FDA Approved Uses: External genital or perianal warts (Condylomata acuminata) in immunocompetent patients of 18 years and older.

Available Dosage Forms: 15% ointment in 15 g and 30g aluminum tubes.

Usual Dose: Apply about 0.5 cm strand of ointment topically to each external genital and perianal warts three times daily.

Duration of Therapy: Until complete clearance of all warts but no longer than 16 weeks.

Approximate monthly cost (based on AWP 2008): \$227-250/ 15 g tube

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Patient is immunocompetent
- Patient is 18 years of age or older
- Clinically documented external genital or perianal warts
- Patient has tried and failed maximum allowed duration or intolerant to current available products imiquimod, podofilox gel or solution.

Criteria for Continuation of Therapy:

- Incomplete clearance or developing of new warts
- Duration of therapy is less than 16 weeks

Cautions:

- Use of Veregen on open wounds should be avoided
- Sexual contact should be avoided while ointment is on the skin
- Avoid application into vagina or anus
- May weaken condom or vaginal diaphragms, avoid these combinations

Monitoring:

- Routine gynecological exam (females)

Contraindications:

- Patient has a history of hypersensitivity to any component of the product.



Not Approved if:

- Patient does not meet the above listed criteria
- The product is being used to treat conditions other than FDA indicated uses.
- Patient has any contraindications.

Special Considerations:

- This product has not been studied for the treatment of urethral, intra-vaginal, cervical, rectal, or intra-anal human papilloma virus disease and should not be used for the treatment of these conditions.
- This product contains green tea extract as its major active ingredient.
- There were only two phase 3, randomized, double-blind clinical trials that compared this product against placebo but not against currently available products.

Drug name	Package size	Cost/package
Sinecatechins ointment 15 % Veregen®/ Doak	15 g tube	\$250.65
Podofilox gel 0.5 % Condylox®/ Oclassen	3.5 g tube	\$184.99
Podophyllum liquid 2.5 % Podocon-25®/ Paddock	15 ml bottle	\$66.70
Podophyllum liquid 25 % pododerm®/ Physician total Care	15 ml bottle	\$76.22
Imiquimod cream Aldara®/ 3M Pharma	12 single use/ box	\$206.10

P&T Approval: _____ Date: _____