

## Collagenase Ointment (Santyl)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Wound healing is a complex process that can be complicated by the presence of nonviable or necrotic tissue in the affected area. Debridement of chronic dermal ulcers and severely burned areas, involves the removal of necrotic tissue to prevent infection and promote healing and is a crucial part of wound care. There are various methods of debridement, including surgical, autolytic, enzymatic, and mechanical, each with its advantages and limitations depending on the patient's condition and wound type.

Enzymatic debridement uses proteolytic enzymes, such as collagenase, to break down denatured proteins in wound tissue, promoting the removal of nonviable tissue. Collagenase Ointment (Santyl) is an FDA-approved enzymatic debriding agent that contains collagenase derived from the bacterium *Clostridium histolyticum*. This ointment specifically targets and breaks down collagen in necrotic tissue, making it particularly effective for wound healing. It is important to note that collagen in healthy tissue or newly formed granulation tissue remains unharmed.

Collagenase Ointment (Santyl) is primarily used for treating chronic dermal ulcers, such as pressure ulcers, venous stasis ulcers, and diabetic foot ulcers, as well as second- and third-degree burns. By enzymatically breaking down collagen in necrotic tissue, the ointment helps remove dead and devitalized tissue, promoting healthy granulation tissue formation and supporting wound healing. It is typically applied once daily directly onto the necrotic tissue and covered with a non-adherent dressing to maintain moisture and prevent contamination. More frequent application is recommended if a dressing becomes soiled or soaked with wound or other fluids.

Patients with known hypersensitivity to collagenase or any other component of the ointment should avoid its use, as well as those using detergents, antiseptics, or other topical medications that might inactivate the enzyme or interfere with its activity.

### Definitions

**“Collagenase”** is an enzyme that breaks down collagen, a major structural protein found in connective tissues, such as skin. Collagenase is used in some medical treatments, such as enzymatic debridement, to help remove necrotic tissue from wounds and promote healing.

**“Debridement”** is a medical procedure that involves the removal of dead, damaged, or infected tissue from a wound to promote healing and prevent infection.

**“Granulation”** refers to the formation of new connective tissue and blood vessels during the wound healing process. Granulation tissue is a soft, pink, or red, and moist tissue that fills in the wound bed, providing a foundation for the re-growth of skin (epithelialization).

**“Necrotic tissue”** refers to dead, devitalized, or damaged tissue that is often found in wounds or as a result of injury or disease. The presence of necrotic tissue can slow the wound healing process and increase the risk of infection. Debridement is often used to remove necrotic tissue and promote healing.

### Medical Necessity Criteria for Initial Authorization

The Plan considers Collagenase Ointment (Santyl) medically necessary when **BOTH** of the following criteria are met:

1. The member has a confirmed diagnosis of chronic dermal ulcers (e.g., pressure ulcers, venous stasis ulcers, or diabetic foot ulcers) **OR** severely burned areas; **AND**
2. The requested product meets **ONE** of the following:
  - a. It is prescribed for use within the Plan's Quantity Limit of 90 grams per 30 days; **or**

- b. If the requested dosing<sup>#</sup> instructions exceed the Plan's Quantity Limit and Collagenase Ointment (Santyl) is prescribed by or in consultation with a wound care specialist, infectious disease specialist, or dermatologist.

*#It is highly recommended that healthcare providers refer to the manufacturer's dosing calculator (<https://santyl.com/hcp/dosing>) for accurate and patient-specific dosing of Collagenase Ointment (Santyl) to ensure the most appropriate treatment plan. The dosing calculator takes into account various factors, such as wound size and depth, to provide tailored recommendations for each patient.*

**If the above prior authorization criteria is met, Collagenase Ointment (Santyl) will be approved for 3 months.**

#### **Medical Necessity Criteria for Reauthorization**

Reauthorization for a three-month period will be approved if **BOTH** of the following are met:

1. The member continues to meet the relevant initial criteria; **AND**
2. Recent medical records (within the past three months) provide documented evidence of **BOTH** of the following:
  - a. Wound improvement with the use of collagenase; **and**
  - b. Need for further debridement (e.g., due to persistent necrotic tissue without well-developed granulation tissue).

#### **Experimental or Investigational / Not Medically Necessary**

Collagenase Ointment (Santyl) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Non-wound-related applications (e.g., using Collagenase Ointment for purposes other than wound debridement, such as cosmetic or other skin treatments).
- Treating acute or superficial wounds.
- Treating undiagnosed skin conditions.

## Applicable Billing Codes (HCPCS/CPT Codes)

<b>Service(s) name</b>	
<b>CPT/HCPCS Codes considered medically necessary if criteria are met:</b>	
<i>Code</i>	<i>Description</i>
97602	Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (eg, wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session
J3590	Unclassified biologics
<b>ICD-10 codes considered medically necessary if criteria are met:</b>	
<i>Please note that this list is not exhaustive, and the specific code used will depend on the type and location of the ulcer or burn injuries, as well as any associated complications (i.e., other codes may still be applicable depending on the clinical context).</i>	
<i>Code</i>	<i>Description</i>
L89.0 - L89.9	Pressure ulcer, with specific codes for the anatomical site and severity
I83.0	Varicose veins of lower extremities with ulcer
I83.2	Varicose veins of lower extremities with both ulcer and inflammation
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
L97.0 - L97.9	Non-pressure chronic ulcer of lower limb, with specific codes for the anatomical site and severity
L98.4	Non-pressure chronic ulcer of skin, not elsewhere classified
T20-T32	Codes for burns and corrosions, with specific codes for the anatomical site, severity, and extent of the burns

## References

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## Clinical Guideline Revision / History Information

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