BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.90.031

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	May 12, 2017
Subject:	Santyl	**Page:**	1 of 4

Last Review Date: September 6, 2024

Santyl

Description

Santyl (collagenase)

Background
Santyl (collagenase) ointment is a sterile enzymatic debriding ointment which contains 250 collagenase units per gram of white petrolatum USP. The enzyme collagenase is derived from the fermentation by *Clostridium histolyticum.* It possesses the unique ability to digest collagen in necrotic tissue (1).

Regulatory Status
FDA-approved indication: Santyl ointment is indicated for debriding chronic dermal ulcers and severely burned areas (1).

Related policies
Regranex

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Santyl ointment may be considered **medically necessary** if the conditions indicated below are met.

Santyl ointment may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Chronic dermal ulcer
2. Severely burned areas

AND ALL of the following:

a. Documented presence of necrotic tissue, sinus tracts, exudation or infection of soft and hard tissues
b. Prescriber agrees to terminate treatment when debridement of necrotic tissue is complete and granulation tissue is well established

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Chronic dermal ulcer
2. Severely burned areas

AND ALL of the following:

a. Improvement in wound
b. Prescriber agrees to terminate treatment when debridement of necrotic tissue is complete and granulation tissue is well established

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 360 grams per 90 days

Duration 3 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Santyl ointment is a sterile enzymatic debriding ointment which contains 250 collagenase units per gram of white petrolatum USP. The enzyme collagenase is derived from the fermentation by *Clostridium histolyticum*. It possesses the unique ability to digest collagen in necrotic tissue. Santyl ointment is indicated for debriding chronic dermal ulcers and severely burned areas. Use of Santyl ointment should be terminated when debridement is complete and granulation tissue is well established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Santyl ointment while maintaining optimal therapeutic outcomes.

References

1. Collagenase Santyl [package insert]. Fort Worth, Tx. Smith & Nephew, Inc.; 2016.

Policy History

Date	Action
May 2017	Addition to PA
June 2017	Annual review
June 2017	Update of the tried and failed agents
September 2018	Annual review
March 2019	Removed requirement of inadequate treatment response, intolerance, or contraindication to iodosorb or OTC wound debridement gel or dressing
June 2019	Annual review
September 2020	Annual review
September 2021	Annual review
September 2022	Annual review
September 2023	Annual review
June 2024	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.