



## Drug Quantity Management – Per Rx Topical Collagenase – Santyl® (collagenase santyl ointment 250 units/gram)

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### Product Identifier(s)

**Effective 1/1/23 to 2/27/23:** 108966

**Effective 2/28/23:** 61474

#### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### National Formulary Medical Necessity

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of Santyl. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

#### Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx*	Home Delivery Maximum Quantity per Rx*
Santyl® (collagenase santyl ointment, 250 units/gram)	30 gram tube	180 grams	540 grams
	90 gram tube	180 grams	540 grams

\*This is enough drug to treat approximately one 25 cm<sup>2</sup> wound when applying once daily for 30 days rounded to the nearest tube size.

## Criteria

**Cigna covers quantities as medically necessary when the following criteria are met:**

1. For individuals treating a wound area(s) greater than 25 cm<sup>2</sup> or treating more frequently than once daily, approve the requested quantity not to exceed 540 grams per dispensing at retail or 1,620 grams per dispensing at home delivery.

## Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

1. No overrides are recommended for use in compounded formulations.

## Background

### Overview

Santyl ointment is a sterile enzymatic debriding ointment indicated for **debriding chronic dermal ulcers and severely burned areas**.<sup>1</sup>

### Dosing

Santyl ointment should be applied to the affected area once daily or more frequently if the dressing becomes soiled, such as from incontinence.<sup>1</sup> In clinical trials for diabetic foot ulcers, enrolled patients treated areas ranging from 0.5 cm<sup>2</sup> to 10 cm<sup>2</sup>. According to the manufacturer dosing calculator, 150 grams of ointment will cover one 25 cm<sup>2</sup> wound for 30 days.<sup>2</sup>

### Availability

Collagenase Santyl ointment contains 250 collagenase units/gram of petrolatum and is available in 30- and 90-gram tubes.<sup>1</sup>

## References

1. Collagenase Santyl® ointment [prescribing information]. Forth Worth, TX: Smith & Nephew, Inc., May 2019.
2. Santyl Dosing Calculator. Available online at: <https://www.santyl.com/hcp/dosing>. Accessed August 23, 2022.

## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	<p>Policy was updated to include the existing quantity limits when the product is obtained via home delivery.</p> <p>Override criteria were updated to approve a quantity not to exceed 540 grams per dispensing at retail or 1,620 grams per dispensing at home delivery for patients treating a wound area(s) greater than 25 cm<sup>2</sup> or treating more frequently than once daily. Previously, 90 grams per dispensing was approved for each additional 1.5 inch by 1.5 inch wound being treated (for wounds greater than 3 inches by 3 inches). Previously, for patients treating a wound more frequently than once daily, override quantities were approved based on frequency of approval up to 270 grams per dispensing for each additional wound greater than 1.5 x 1.5 inch.</p> <p>Conditions Not Covered section was updated.</p>	09/21/2022

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