

Initial Prior Authorization with Quantity Limit Santyl (Collagenase)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Santyl Collagenase	collagenase	ointment

Indications

FDA-approved Indications

Collagenase Santyl Ointment is indicated for debriding chronic dermal ulcers and severely burned areas.

Coverage Criteria

Chronic Dermal Ulcers or Severely Burned Areas

Authorization may be granted when the requested drug is being prescribed for debriding chronic dermal ulcers or severely burned areas.

Continuation of Therapy

Chronic Dermal Ulcers or Severely Burned Areas

Authorization may be granted when the requested drug is being prescribed for debriding chronic dermal ulcers or severely burned areas and ALL of the following criteria are met:

- The wound has been evaluated for granulation tissue.
- Granulation tissue is NOT well established.

Quantity Limits Apply

90 grams per 25 days or 270 grams per 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 1773-C: DOA: 3 months

References

1. Collagenase Santyl [package insert]. Fort Worth, TX: Smith & Nephew, Inc.; 2016.
2. Lexicomp Online, Lexi-Drugs Online, Hudson, OH: UpToDate, Inc.; 2025; Accessed February 5, 2025.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/05/2025).
4. Lantis J, Gordon I. Clostridial Collagenase for the Management of Diabetic Foot Ulcers: Results of Four Randomized Controlled Trials. Wounds. 2017; 29(10):297-305.
5. Motley T, Caporusso J, Lange D, et al. Clinical Outcomes for Diabetic Foot Ulcers Treated with Clostridial Collagenase Ointment or with a Product Containing Silver. Advances in Wound Care. 2018; 7(10): 339-348.
6. Motley T, Lange D, Dickerson J, Slade H. Clinical outcomes associated with serial sharp debridement of diabetic foot ulcers with and without clostridial collagenase ointment. Wounds. 2014; 26(3):57-64.
7. Milne C, Ciccarelli A, Lassy M. A Comparison of Collagenase to Hydrogel Dressings in Maintenance Debridement and Wound Closure. Wounds. 2012; 24(11):317-322.

Document History

Written by: UM Development (TM)

Date Written: 03/2017

Revised: (TM) 03/2018 (no clinical changes); (RP) 03/2019 (no clinical changes), 10/2019 (Added Limit/Updated questions/Removed MDC-1 designation); (JK) 03/2020 (no clinical changes); (NZ) 03/2021 (no clinical changes); (VLS) 03/2022 (no clinical changes); (KMB) 03/2023 (added COT criteria); (TM) 03/2024 (no clinical changes); KEJ 03/2025 (no clinical changes)

Reviewed: Medical Affairs (AN) 05/2017; (CHART) 01/16/2020, 03/26/2020, 03/25/21, 03/31/2022, 03/30/2023, 03/28/2024, 03/27/2025

External Review: 06/2017, 06/2018, 06/2019, 02/2020, 06/2020, 06/2021, 06/2022, 06/2023, 06/2024, 06/2025

CRITERIA FOR APPROVAL

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|---|---|-----|----|
| 1 | Is the requested drug being prescribed for debriding chronic dermal ulcers or severely burned areas?
[If Yes, then go to 2. If No, then no further questions.] | Yes | No |
| 2 | Is this request for continuation of therapy?
[If Yes, then go to 3. If No, then go to 5.] | Yes | No |
| 3 | Has the wound been evaluated for granulation tissue?
[If Yes, then go to 4. If No, then no further questions.] | Yes | No |
| 4 | Is granulation tissue well established?
[If Yes, then no further questions. If No, then go to 5.] | Yes | No |
| 5 | Does the patient require MORE than the plan allowance of 90 grams per month?
[No further questions] | Yes | No |

RPh Note: If yes, then deny and enter a partial approval for 90 grams / 25 days or 270 grams / 75 days.

Mapping Instructions

	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for debriding chronic dermal ulcers

			<p>or severely burned areas. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Go to 3	Go to 5	
3.	Go to 4	Deny	<p>Your plan only covers this drug when your wound has been looked at. We denied your request because your doctor has not looked at your wound to see if it has granulation tissue. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Lab/test: wound evaluation]</p>
4.	Deny	Go to 5	<p>Your plan only covers this drug when you do not have granulation tissue. We denied your request because your result showed granulation tissue is well established. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review</p> <p>[Short Description: Lab/test: granulation tissue established]</p>
5.	Deny	[PA Approved for 3 months. Approve 90	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers 90 grams per month or 270 grams per 3 months. Your request for more drug has been</p>

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		grams/25 days or 270 grams/75 days]. Approve, 3 Months	denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]
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