

2024 coding and Medicare payment for application of Collagenase SANTYL[®] Ointment (250 units/g) in hospital-based outpatient wound care departments that bill under the Medicare Hospital Outpatient Prospective Payment System (HOPPS) CPT[®] code

SANTYL Ointment is the only FDA-approved biologic debridement agent indicated for debriding BOTH chronic dermal ulcers and severely burned areas. When debriding a wound via enzymatic debridement, there is one relevant CPT code:

97602 Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session

NOTE: Under Medicare, this code is only separately payable to hospital-based outpatient wound care departments that bill under the Medicare Hospital Outpatient Prospective Payment System (HOPPS).

NOTE: This code is only payable when it is the only method of debridement performed for a specific wound during a hospital-based outpatient wound care department visit.

HCPCS code

For tracking purposes, SANTYL Ointment, may be reported under HCPCS code:

J3590 *unclassified biologics*

Under Medicare payment rules, no separate payment will be made for SANTYL Ointment.

Revenue code

Following is the revenue code typically used to report the 97602 service:

051x Clinic

The most commonly accepted revenue code for J3590 is expected to be:

0636 Drugs/biologicals requiring detailed coding

Many Medicare contractors require providers to include the name of the product on the claim form.

Medicare payment

Below is an overview of the 2024 Medicare nationally unadjusted average payment rate for CPT[®] code 97602. The Medicare payment rate for the CPT code is effective January 1, 2024 through December 31, 2024

Important Safety Information: Contraindications: SANTYL is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase. Please see additional Important Safety Information on next page.

NOTE: Under Medicare, 97602 is only separately payable to hospital-based outpatient wound care departments that bill under the Medicare hospital outpatient prospective payment system (HOPPS) called the ambulatory payment classification (APC) system.

NOTE: 97602 is only payable when it is the only method of debridement performed for a specific wound during a hospital-based outpatient wound care department visit.

Medicare payment rate* for application of Collagenase SANTYL^o Ointment, when covered by the Medicare Administrative Contractor

Setting	Coding System	Code	Total Medicare Allowable ¹	Medicare Payment ¹	Patient Copayment ¹
APC paid facility	CPT	97602 ²	\$190.94	\$152.75	\$38.19

*Payments are nationally unadjusted average amounts, and do not account for differences in payment due to geographic variation.

1 These rates do not account for the impact of the sequester

2 Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator “S”, “T”, or “V”. In other circumstances, payment is made through a separate APC payment.

Information on reimbursement in the U.S. is provided as a courtesy. Due to the rapidly changing nature of the law and Medicare payment policy, and our reliance on information provided by outside sources, the information provided herein does not constitute a guarantee or warranty by Smith & Nephew Advanced Wound Management that reimbursement will be received or that the codes identified herein are or will remain applicable. This information is provided “AS IS” and without any other warranty or guarantee, expressed or implied, as to completeness or accuracy, or otherwise. This information has been compiled based on data gathered from many primary and secondary sources, including the American Medical Association, and certain Medicare contractors. Physicians and other providers must confirm or clarify coverage and coding from their respective payers, as each payer may have differing formal or informal coding and coverage policies or decisions. Physicians and providers are responsible for accurate documentation of patient conditions and for reporting procedures and products in accordance with particular payer requirements.

Important Safety Information

Indications: Collagenase SANTYL Ointment (“SANTYL”) is indicated for debriding chronic dermal ulcers and severely burned areas. Contraindications: SANTYL is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase. Warning and Precautions: The optimal pH range of collagenase is 6 to 8. Higher or lower pH conditions will decrease the enzyme’s activity and appropriate precautions should be taken. The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury and silver which are used in some antiseptics. As such, the wound should be properly cleansed prior to application of SANTYL. Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia. A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when SANTYL was not confined to the wound. SANTYL is not indicated for wound closure. Discontinue use of SANTYL after granulation tissue is well-established. Adverse Reactions: No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. The risk information provided herein is not comprehensive. To see the complete Prescribing Information, please see the FDA-approved product labeling, here: <https://santyl.com/sites/default/files/2019-12/SANTYL-PI.pdf>. You are encouraged to report negative side effects of prescription drugs to FDA. Visit MedWatch or call 1-800-FDA-1088.

Collagenase SANTYL^o

Ointment 250 units/gram

DESCRIPTION

Collagenase SANTYL^o 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.

CLINICAL PHARMACOLOGY

Since collagen accounts for 75% of the dry weight of skin tissue, the ability of collagenase to digest collagen in the physiological pH and temperature range makes it particularly effective in the removal of detritus.¹

Collagenase thus contributes towards the formation of granulation tissue and subsequent epithelization of dermal ulcers and severely burned areas.^{2,3,4,5,6} Collagen in healthy tissue or in newly formed granulation tissue is not attacked.^{2,3,4,5,6,7,8}

There is no information available on collagenase absorption through skin or its concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, degree of uptake by a particular organ or in the fetus, and passage across the blood brain barrier.

INDICATIONS AND USAGE

Collagenase SANTYL^o Ointment is indicated for debriding chronic dermal ulcers^{2,3,4,5,6,8,9,10,11,12,13,14,15,16,17,18} and severely burned areas.^{3,4,5,7,16,19,20,21}

CONTRAINDICATIONS

Collagenase SANTYL^o Ointment is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase.

PRECAUTIONS

The optimal pH range of collagenase is 6 to 8. Higher or lower pH conditions will decrease the enzyme's activity and appropriate precautions should be taken. The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury and silver which are used in some antiseptics.

When it is suspected such materials have been used, the site should be carefully cleansed by repeated washings with normal saline before Collagenase SANTYL^o Ointment is applied. Soaks containing metal ions or acidic solutions should be avoided because of the metal ion and low pH. Cleansing materials such as Dakin's solution and normal saline are compatible with Collagenase SANTYL^o Ointment.

Debliterated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia.

A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when Collagenase SANTYL^o Ointment was not confined to the wound. Therefore, the ointment should be applied carefully within the area of the wound. Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. However, one case of systemic manifestations of hypersensitivity to collagenase in a patient treated for more than one year with a combination of collagenase and cortisone has been reported.

OVERDOSAGE

No systemic or local reaction attributed to overdose has been observed in clinical investigations and clinical use. If deemed necessary the enzyme may be inactivated by washing the area with povidone iodine.

DOSAGE AND ADMINISTRATION

Collagenase SANTYL^o Ointment should be applied once daily (or more frequently if the dressing becomes soiled, as from incontinence). When clinically indicated, crosshatching thick eschar with a #10 blade allows Collagenase SANTYL^o Ointment more surface contact with necrotic debris. It is also desirable to remove, with forceps and scissors, as much loosened detritus as can be done readily. Use Collagenase SANTYL^o Ointment in the following manner:

1. Prior to application the wound should be cleansed of debris and digested material by gently rubbing with a gauze pad saturated with normal saline solution, or with the desired cleansing agent compatible with Collagenase SANTYL^o Ointment (See **PRECAUTIONS**), followed by a normal saline solution rinse.

2. Whenever infection is present, it is desirable to use an appropriate topical antibiotic powder. The antibiotic should be applied to the wound prior to the application of Collagenase SANTYL^o Ointment. Should the infection not respond, therapy with Collagenase SANTYL^o Ointment should be discontinued until remission of the infection.

3. Collagenase SANTYL^o Ointment may be applied directly to the wound or to a sterile gauze pad which is then applied to the wound and properly secured.

4. Use of Collagenase SANTYL^o Ointment should be terminated when debridement of necrotic tissue is complete and granulation tissue is well established.

HOW SUPPLIED

Collagenase SANTYL^o Ointment contains 250 units of collagenase enzyme per gram of white petrolatum USP.

Do not store above 25°C (77° F) Sterility guaranteed until tube is opened.

Collagenase SANTYL^o Ointment is available in the following sizes:

- 30 g tube NDC 50484-010-30
- 90 g tube NDC 50484-010-90

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