Original Effective Date: 08/02/2018
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Last P&T Approval/Version: 04/30/2025
Next Review Due By: 04/2026
Policy Number: C15159-C

Santyl (collagenase)

PRODUCTS AFFECTED

Santyl (collagenase)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic dermal ulcers and severely burned areas

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:
1. Documented diagnosis of chronic dermal ulcers or severely burned areas
   AND
2. Documentation of wound description, including size, location, and tissue content (e.g., percent

necrotic vs. granulation tissue)
AND

3. Documentation that Santyl is being used for wound debridement
AND
4. Documentation that other general wound care measures are being taken, as appropriate (e.g., the wound should be cleansed of debris and digested material prior to application of Santyl; whenever infection is present, an appropriate topical antibiotic powder should be used prior to the application of Santyl)

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:
1. Documentation of wound improvement
AND
2. Documentation that wound debridement is still incomplete (e.g., continued presence of necrotic tissue without well-established granulation tissue)

DURATION OF APPROVAL:

Initial authorization: 2 months, Continuation of Therapy: for up to 2 months

PRESCRIBER REQUIREMENTS:

For requests for >30g per 30 days ONLY: Prescribed by or in consultation with a Wound care specialist, Infectious disease specialist, or Dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

No restrictions

QUANTITY:

30g (1 tube) every 30 days
(or use Santyl dosing calculator for requests for larger quantities: https://www.santyl.com/hcp/dosing)
*There is no well-established maximum dose for the approved indication according to the prescribing information

PLACE OF ADMINISTRATION:

The recommendation is that topical medications in this policy will be for pharmacy or medical benefit coverage and patient self-administered or topical product administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Topical

DRUG CLASS:

Enzymes – Topical

FDA-APPROVED USES:

Indicated for debriding chronic dermal ulcers and severely burned areas

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Clostridial collagenase, derived from fermentation by Clostridium histolyticum, digests collagen in necrotic tissue while sparing healthy and new granulation tissue. Moist necrotic tissue provides a medium for infection, initiates an inflammatory response, and slows wound healing. Because collagen provides the framework to hold necrotic cells to the tissue bed, collagen removal by collagenase facilitates granulation tissue formation, which is necessary for proper epithelialization. Optimal wound management is very patient-specific. Santyl ointment is generally used as part of a comprehensive wound care plan that also includes removal of necrotic tissue by mechanical debridement, antibiotic administration for clinically infected wounds, application of wound dressings, and maintenance of a moist environment to help promote wound healing.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Santyl (collagenase) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Santyl (collagenase) include: patients who have shown local or systemic hypersensitivity to collagenase.

OTHER SPECIAL CONSIDERATIONS:
Whenever infection is present, it is desirable to use an appropriate topical antibiotic powder. Should the infection not respond, therapy with Collagenase Santyl Ointment should be discontinued until remission of the infection. Use of Collagenase Santyl Ointment should be terminated when debridement of necrotic tissue is complete and granulation tissue is well established**.**

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Santyl OINT 250UNIT/GM 30g or 90g tube

REFERENCES

1. Santyl (collagenase) ointment [prescribing information]. Fort Worth, TX: Smith & Nephew, Inc.; December 2019.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information	Q2 2025
REVISION- Notable revisions: Place of Administration Contraindications/Exclusions/ Discontinuation Other Special Considerations References	Q2 2024
REVISION- Notable revisions: Prescriber Requirements Drug Class FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q2 2023
REVISION- Notable revisions: Contraindications/Exclusions/Discontinuation	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file