Effective Date: 08/02/2018
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
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:
For the debridement of 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

A. FOR ALL INDICATIONS:
1. Documentation of wound description, including size, location, and tissue content (e.g., percent necrotic vs. granulation tissue)
   AND
2. Documentation that Santyl is being used for wound debridement
   AND
3. 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:

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:

One of the following prescriber specialties is only required for requests for >30g per 30 days:

-Wound care specialist
-Infectious disease specialist
-Dermatologist

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 benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Topical

DRUG CLASS:

Topical debridement enzyme

FDA-APPROVED USES:

Treatment of severe partial- or full-thickness burns, treatment of decubitus ulcer, diabetic foot ulcer, or varicose ulcer that requires debridement

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:

Santyl (collagenase) application is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase.

Treatment of wounds without necrotic tissue. Treatment of wounds with well-established (i.e., >90%) granulation tissue. Continued treatment of infected wounds that have not responded to topical antibiotic therapy (in this case, Santyl should be discontinued until the infection resolves).

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Santyl 250 unit/g topical ointment (30g or 90g tube)

REFERENCES

1. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. 2018. Available from: http://www.clinicalpharmacology.com
2. Santyl (collagenase) [package insert]. Smith & Nephew, Inc. Fort Worth (TX): 2016.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Contraindications/Exclusions/Discontinuation	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file