Santyl (collagenase)
Policy Number: C15159C

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
8/2/2018	7/26/2018	7/26/2019
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J3490	RxPA	Q3

PRODUCTS AFFECTED:
Santyl (collagenase)

DRUG CLASS:
Topical debridement enzyme

ROUTE OF ADMINISTRATION:
Topical

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Santyl 250 unit/g topical ointment (30g or 90g tube)

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:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: For the debridement of chronic dermal ulcers and severely burned areas

REQUIRED MEDICAL INFORMATION:

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)

DURATION OF APPROVAL:
Initial authorization: 2 months**,** Continuation of Therapy: for up to 2 months

QUANTITY: 30g (1 tube) every 30 days
(or use Santyl dosing calculator for requests for larger quantities:https://www.santyl.com/hcp/dosing)

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

GENDER:
Male and female

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)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
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:

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.

APPENDIX:

REFRENCES:
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.