Santyl

**Description**

Santyl (collagenase)

**Background**

Santyl (collagenase) 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 (1).

**Regulatory Status**

Santyl ointment is indicated for debriding chronic dermal ulcers and severely burned areas (1).

**Related policies**

Regranex

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Santyl ointment may be considered **medically necessary** in patients who have chronic dermal ulcers or have severely burned areas that require debridement if the conditions indicated below are met.

Santyl ointment is considered **investigational** for all other indications.
Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Chronic dermal ulcer
2. Severely burned areas

**AND ALL** of the following:
   a. Documented presence of necrotic tissue, sinus tracts, exudation or infection of soft and hard tissues
   b. Prescriber agrees to terminate treatment when debridement of necrotic tissue is complete and granulation tissue is well established

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Chronic dermal ulcer
2. Severely burned areas

**AND ALL** of the following:
   a. Improvement in wound
   b. Prescriber agrees to terminate treatment when debridement of necrotic tissue is complete and granulation tissue is well established

**Policy Guidelines**

Pre - PA Allowance

None

Prior - Approval Limits
Subject: Collagenase Santyl Ointment  

Quantity: 360 grams per 90 days  
Duration: 3 months  

Prior – Approval **Renewal Limits**  
Quantity: 360 grams per 90 days  
Duration: 3 months  

**Rationale**  

**Summary**  
Santyl 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. Santyl ointment is indicated for debriding chronic dermal ulcers and severely burned areas. Use of Santyl ointment should be terminated when debridement is complete and granulation tissue is well established (1).  

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Santyl ointment while maintaining optimal therapeutic outcomes.  

**References**  

**Policy History**  

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2017</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2017</td>
<td>Update of the tried and failed agents</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>March 2019</td>
<td>Removed requirement of inadequate treatment response, intolerance, or contraindication to iodosorb or OTC wound debridement gel or dressing</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

**Keywords**
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.