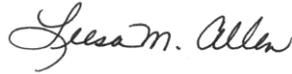


ISSUE DATE May 11, 2015	EFFECTIVE DATE June 15, 2015	NUMBER *See below
SUBJECT Prior Authorization of Santyl Ointment (collagenase) – Pharmacy Service		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers about new requirements for prior authorization of Santyl Ointment (collagenase).
2. Issue handbook pages that include instructions on how to request prior authorization of Santyl Ointment (collagenase), including the type of medical information needed to evaluate requests for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department’s Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department’s Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-13	09-15-12	27-15-11	
02-15-11	11-15-11	30-15-11	
03-15-11	14-15-11	31-15-12	
08-15-13	24-15-11	32-15-11	33-15-12

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dhs.state.pa.us/provider/healthcaremedicalassistance/index.htm>

DISCUSSION:

During the March 18, 2015 meeting, the DUR Board recommended that the Department require prior authorization of Santyl Ointment (collagenase) and proposed guidelines to determine medical necessity to ensure appropriate patient selection and drug utilization of Santyl Ointment (collagenase). The requirement for prior authorization and guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Santyl Ointment (collagenase) are included in the attached updated provider handbook pages.

PROCEDURE:

The procedures for prescribers to request prior authorization of Santyl Ointment (collagenase) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapters related to Santyl Ointment [collagenase]) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Santyl Ointment (collagenase)

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

1. Requirements for Prior Authorization of Santyl Ointment (collagenase)

A. Prescriptions That Require Prior Authorization

All prescriptions for Santyl Ointment (collagenase) must be prior authorized.

B. Emergency Supplies

The Department does not consider a delay in the receipt of Santyl Ointment (collagenase) to present an emergency and, therefore, will NOT cover emergency supplies of Santyl Ointment (collagenase) pending approval of a request for prior authorization.

C. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Santyl Ointment (collagenase), the determination of whether the requested prescription is medically necessary will take into account the following:

1. The recipient has a diagnosis of severe burn(s) or chronic dermal ulcer(s) (e.g., pressure ulcer/bedsore, venous ulcer, or diabetic ulcer) that require(s) debridement

AND

2. Santyl Ointment (collagenase) is being prescribed by, or in consultation with, a burn specialist or wound care specialist, such as a podiatrist, surgeon, or other specialized wound care practitioner, and there is documentation of an initial evaluation performed by the specialist

AND

3. The recipient is not concomitantly using any wound care products that decrease the enzymatic activity of collagenase on the same application site as Santyl Ointment (collagenase)

OR

4. The request does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer, the therapy is medically necessary to meet the medical needs of the Recipient.

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FOR RENEWALS OF PRESCRIPTIONS FOR Santyl Ointment (collagenase) – The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Santyl Ointment (collagenase), that were previously approved, will take into account the following:

1. The recipient meets all of the guidelines for initial approval of Santyl Ointment (collagenase)

AND

2. There has been documented improvement in the recipient's condition as evidenced by the characteristics of the wound or burn, such as a decrease in surface area, decrease in the amount of necrotic tissue remaining to be debrided, whether or not the wound is infected, and extent of necrotic tissue and exudate

AND

3. The wound is not covered in granulation tissue, and there is evidence of necrotic tissue or eschar remaining on the wound

AND

4. For chronic, non-healing wounds:
 - a. The recipient has been assessed for patient- and wound-specific factors that may impede healing

AND

- b. Impediments to wound healing and resolution are being actively addressed

AND

- c. There is a reasonable medical expectation that continuing treatment with Santyl Ointment will result in healing and resolution of the wound

AND

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d. Other methods of debridement have been used on the wound

OR

e. The recipient has a contraindication to other forms of debridement

AND

f. If the wound has been present for more than three months and has not responded to treatment, it has been evaluated for the presence of malignancy using biopsy

OR

5. The request for renewal does not meet the clinical guidelines listed above, but in the professional judgment of the physician reviewer, the therapy is medically necessary to meet the needs of the recipient

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Santyl Ointment (collagenase). If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

E. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for Santyl Ointment (collagenase) will be limited as follows:

1. The initial prescription will be approved for a period of up to 6 weeks of treatment
2. Renewals of prescriptions that were previously approved will be approved for a period of up to 6 weeks

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