Prior Authorization

What to do if your plan requires this additional step

Key Information:

- When fully completed for an on-label indication, the majority of PAs are approved

- Smith & Nephew has several resources to help with the process, including Specialty @ Retail partnerships

  To get started submitting PAs through CoverMyMeds, visit www.covermymeds.com and click on "Create a Free Account"

- If a plan has a quantity limit (QL), Provider can complete a Prior Authorization to document quantity required based on wound size(s)

- If a PA is denied, Provider always has the option to appeal

  Appeals support is available through CoverMyMeds for denied Regranex PAs

Smith+Nephew

Collagenase
SANTYL◊
Ointment 250 units/gram

REGRANEX◊
(becaplermin) gel 0.01%

Smith+Nephew

Information that your office may need to include with prior authorization

Be thorough as the top reason for PA denials is due to incomplete forms

REGRANEX◊ (becaplermin) gel, 0.01%

- Diagnosis of diabetes and all other applicable diagnosis codes; request for the treatment of lower extremity diabetic neuropathic foot ulcers that extend into the SQ tissue or beyond
- Document current/prior diabetes medication(s)
- No neoplasm(s) at the site of application
- Wound has an adequate blood supply
- Good ulcer care practices (debridement, offloading and infection control) performed
- Note any previous treatments failures and treatments tried on the wound — include OTCs
- Provide clinical records for the last 3 visits, including wound size, location, and progression
- Justification of quantity prescribed if over 15gm (document wound size)

Collagenase SANTYL◊ Ointment

- Diagnosis (e.g. chronic dermal ulcer, severe burn)
- Document wound size, location, and duration
  - Include total grams required based on wound dimensions and days supply
- Previous treatments — include OTCs

REGRANEX Indications and Important Safety Information
Indications: REGRANEX (becaplermin) gel 0.01% ("REGRANEX") is a prescription only medication indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, an not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. Contraindications: REGRANEX is contraindicated in patients with known neoplasm(s) at the site(s) of application. Warnings and Precautions: Malignancies distant from the site of application have occurred in REGRANEX users in a clinical study and in postmarketing use. REGRANEX contains becaplermin, a recombinant human platelet-derived growth factor, which promotes cellular proliferation and angiogenesis. The efficacy of REGRANEX has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue or ischemic diabetic ulcers. The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans. REGRANEX is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention. Adverse Reactions: In clinical trials, erythematous rashes occurred in 2% of subjects treated with REGRANEX (and good ulcer care) or placebo (and good ulcer care). In a retrospective follow-up study, eight of 291 subjects (2.7%) from the REGRANEX group, and two of 200 subjects (1%) from the placebo group were diagnosed with cancers during the follow-up period. An increased rate of death from systemic malignancies in patients dispensed three or more tubes of REGRANEX, observed in one of three retrospective postmarketing studies. Other adverse reactions that have been reported include a burning sensation, and erythema at the site of application. The risk information provided herein is not comprehensive. To see the complete prescribing information, please see the FDA-approved product labeling, here: https://regranex.com/pdf/PI_Full_Version.pdf. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

SANTYL Indications and Important Safety Information
Collagenase SANTYL Ointment ("SANTYL") is a prescription-only medication indicated for debriding chronic dermal ulcers and severely burned areas. Contraindications: SANTYL is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase. Warning and Precautions: The optimal pH range of collagenase is 6 to 8. Higher or lower pH conditions will decrease the enzyme's activity and appropriate precautions should be taken. The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury and silver which are used in some antiseptics. As such, the wound should be properly cleansed prior to application of SANTYL. Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia. A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when SANTYL was not confined to the wound. SANTYL is not indicated for wound closure. Discontinue use of SANTYL after granulation tissue is well-established. Adverse Reactions: No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. The risk information provided herein is not comprehensive. For complete prescribing information, please refer to the accompanying PI or visit: https://santyl.com/sites/default/files/2019-12/SANTYL-PI.pdf. You are encouraged to report negative side effects of prescription drugs to FDA. Visit MedWatch or call 1-800-FDA-1088.

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