

Indiana Medicaid Therapeutics Committee **Therapeutic Class Review Summary**

Therapeutic Class:

Wound Care Products

Overview:

The goals of wound care are to prevent infection and promote tissue growth. Necrotic tissue, which often occurs in stage III and stage IV wounds, delays healing, promotes infection, and must be removed for proper tissue growth. The methods of necrotic tissue removal include surgical, sharp, mechanical, and enzymatic debridement. Enzymatic debridement involves application of enzymatic products to dissolve necrotic tissue. The process of enzymatic debridement is slow, and it should be considered for patients who are not candidates for surgical debridement.

The only available enzymatic agent is collagenase which digests collagen in necrotic tissue, facilitating granulation. The available product is Santyl. This product is designed to remove necrotic tissue and is indicated for debriding chronic dermal ulcers and severely burned areas.

Papain containing products were available for many years, and were used to remove necrotic tissue. On September 23, 2008, the FDA announced that it has ordered companies to stop marketing unapproved drug products that contain papain in a topical dosage form. Under this notice, firms marketing any unapproved topical papain products must stop manufacturing these products by November 24, 2008. Companies or others engaged in shipping these products must stop shipping them by January 21, 2009. After these dates, all topical products containing papain must have FDA approval to be manufactured or shipped interstate. Topical drug products containing papain have historically been marketed without approval; there are no approved topical drug products containing papain. FDA is taking this action because adverse events with use of topical papain drug products reported to the agency raise serious safety concerns regarding these products. These drugs can produce harmful or near fatal effects including hypersensitivity resulting in anaphylactic reactions. Hypersensitivity manifestations have also resulted in cardiovascular symptoms such as hypotension and tachycardia. Furthermore, the effectiveness of these products is not supported by scientifically sound studies in the medical literature. These products are no longer available.

A relatively new wound care agent, becaplermin (Regranex), was developed to promote tissue growth. Becaplermin has biological activity similar to that of endogenous platelet-derived growth factor. It is indicated for the treatment of lower extremity neuropathic diabetic ulcers. However, its effects diminish when used in areas without adequate blood supply. Although becaplermin has been used in the management of pressure ulcers, it is not an FDA approved indication. Recently, an increased rate of mortality secondary to malignancy was observed in patients treated with three or more tubes of Regranex Gel in a postmarketing retrospective cohort study. As a result, Regranex should only be used when the benefits can be expected to outweigh the risks, and should be used cautiously in patients with known malignancy.

GENERIC NAME	BRAND NAME	MANUFACTURER	GENERIC
Collagenase	Collagenase Santyl®, Santyl®	Healthpoint Ltd	N
Becaplermin, rh-PDGF	Regranex®	Ortho-McNeil	N

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Becaplermin promotes tissue growth, which is different from enzymatic debridement agents. Becaplermin should be reserved for the treatment of diabetic ulcer of lower extremities and with adequate blood supply.