BlueCross BlueShield Federal Employee Program

REGRANEX (becaplermin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Regranex is a recombinant form of human platelet-derived growth factor which is applied directly to diabetic foot and leg ulcers that are not healing. The recombinant form of platelet growth factor has a biologic activity that is much like that produced naturally by the body. Growth factors cause cells to divide more rapidly. Regranex promotes the chemotactic recruitment and proliferation of cells involved in wound repair and enhancing the formation of granulation tissue (1).

Regulatory Status

FDA-approved indication: Regranex contains becaplermin, a human platelet-derived growth factor that is 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, and not a substitute for, good ulcer care practices, including initial sharp debridement, pressure relief and infection control (1).

Limitations of Use:

- 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 the subcutaneous tissue (Stage I or II, IAET staging classification) or ischemic diabetic ulcers (1).
- The effects of Regranex on exposed joints, tendons, ligaments, and bone have not been established in humans (1).

- Regranex is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention (1).

Malignancies distant from the site of application have occurred in Regranex users. Regranex should only be used when the benefits can be expected to outweigh the risks. Regranex should be used with caution in patients with known malignancy (1).

Regranex is contraindicated in patients with known neoplasm(s) at the sites(s) of application (1).

Regranex should not be used for more than 20 weeks if wound has not completely healed (1).

Safety and effectiveness of Regranex in pediatric patients below the age of 16 years have not been established (1).

Summary

Regranex promotes the chemotactic recruitment and proliferation of cells involved in wound repair and enhancing the formation of granulation tissue in lower extremity diabetic neuropathic ulcers that extended to subcutaneous tissue and beyond. Regranex should only be used when the benefits can be expected to outweigh the risks. Regranex should be used with caution in patients with known malignancy. Safety and effectiveness of Regranex in patients under the age of 16 years have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Regranex while maintaining optimal therapeutic outcomes.

References

1. Regranex [package insert]. Fort Worth, TX: Smith & Nephew, Inc.; August 2019.