

PRIOR AUTHORIZATION CRITERIA

BRAND NAME: REGRANEX (all topical)
(generic) (becaplermin)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Regranex gel 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.

The efficacy of Regranex gel 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 (Stage I or II, IAET staging classification) or ischemic diabetic ulcers.

The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans.

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

COVERAGE CRITERIA

Regranex will be covered with prior authorization when the following criteria are met:

- Regranex is being prescribed as treatment of lower extremity diabetic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply
AND
- The patient does not have a neoplasm(s) at site of application
AND
- The patient will have good ulcer care practices including initial sharp debridement, pressure relief and infection control performed

REFERENCES

1. Regranex [package insert]. Raritan, NJ: Ortho-McNeil Janssen Pharmaceuticals, Inc.; September 2012.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 2015.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 2015.