

Policy Name:	Regranex (becaplermin)	Policy #:	583P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage for Regranex (becaplermin).

Statement of the Policy

Health Alliance Medical Plans will approve the coverage of Regranex (becaplermin) when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Failure of prolonged treatment of lower-extremity diabetic neuropathic ulcers with conventional therapy, such as:
 - Dressings
 - Soaks
 - Irrigations
 - Debridement (chemical and/or mechanical)
 - Modifications of shoes (if diabetic foot ulcers)
 - Debrisan®
 - Sorbsan®
 - Duoderm®
 - Granulex®, etc.
- 1.2 An authorization is needed for each occurrence/re-occurrence of a diabetic ulcer.

2. Additional Information

- 2.1 Authorization for becaplermin is necessary due to its limited efficacy in clinical trials. Based upon the Steed, et al (1995) efficacy study in lower extremity diabetic ulcers, complete healing rates were 15% after 8 weeks, and 25% after 10 weeks. Becaplermin is only for use in patients with chronic and non-healing lower-extremity diabetic ulcers, only as adjunct to surgical debridement.

3. Approval Period

- 3.1 6 months

CPT Codes

HCPCS Codes

References

1. Martí-Carvajal AJ, Gluud C, Nicola S, et al. Growth factors for treating diabetic foot ulcers. *Cochrane Database Syst Rev* 2015; :CD008548.
2. Regranex (becaplermin) [prescribing information]. Fort Worth, TX: Smith & Nephew, Inc; August 2019.
3. Schaper NC, Netten JV, Apelqvist J, et al. Prevention and management of foot problems in diabetes: a Summary Guidance for Daily Practice 2015, based on the IWGDF Guidance Documents. *Diabetes Metab Res Rev*. 2016 Jan;32 Suppl 1:7-15.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.