Regranex

**Description**

Regranex (becaplermin)

**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 labeled 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).

Regranex has a boxed warning for an increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of Regranex in a post-marketing retrospective cohort study. 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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Regranex may be considered medically necessary in patients 16 years of age and older with diabetes for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply and when the conditions indicated below are met.

Regranex is considered investigational in patients less than 16 years of age and for all other indications.

Prior-Approval Requirements

Age 16 years of age or older
Diagnoses

Patient must have ALL of the following:

1. Diabetes
2. Lower extremity neuropathic ulcers
   a. That extend into the subcutaneous tissue or beyond with adequate blood supply

AND NONE of the following:

1. Neoplasm(s) at the sites(s) of application
2. Use in pressure ulcers, venous stasis ulcers, or ischemic diabetic ulcers
3. Exposed joints, tendons, ligaments, and bone (at application site)
4. Use in wounds that close by primary intention (such as suturing or gluing)

Prior – Approval Renewal Requirements

Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 3 tubes per 20 weeks

Prior – Approval Renewal Limits

Duration 3 tubes per 20 weeks

Rationale

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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2014</td>
<td>New addition to PA</td>
</tr>
<tr>
<td>September 2015</td>
<td>Annual editorial review.</td>
</tr>
<tr>
<td>December 2016</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Policy number change from 9.14.06 to 5.90.06</td>
</tr>
<tr>
<td>September 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>March 2018</td>
<td>Addition of quantity limit of 3 tubes</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>September 2019</td>
<td>Annual review and reference update</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.