Pharmacy Medical Policy
Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions

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Policy Number: 186
BCBSA Reference Number: 2.01.16

Related Policies
- Orthopedic Applications of Platelet-Rich Plasma, #737
- Negative Pressure Wound Therapy in the Outpatient Setting, #543
- Electrostimulation and Electromagnetic Therapy for Treating Wounds, #655
- Noncontact Ultrasound Treatment for Wounds, #657
- Bio-Engineered Skin and Soft Tissue Substitutes, #663

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td>Formulary Status</td>
</tr>
<tr>
<td>Regranex®</td>
<td>PA Required</td>
</tr>
</tbody>
</table>

We cover Regranex® (becaplermin) 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 when all of the following criteria are met:
• The Member has a/some confirmed Neuropathic diabetic ulcer(s)

And
• The member has a full-thickness ulcer(s) (Stage III or IV), extending through the dermis into subcutaneous tissues

And
• The member adequate tissue oxygenation, as measured by a transcutaneous partial pressure of oxygen of 30 mm Hg (millimeters of mercury) or greater on the foot dorsum or at the margin of the ulcer

And
• the member participates in a wound-management program, which includes sharp debridement, pressure relief (non-weight bearing), and infection control

OR
• The member has a/some confirmed Pressure ulcer(s)

And
• The member has a full-thickness ulcer(s) (Stage III or IV), extending through dermis into subcutaneous

And
• The ulcer(s) is/are in an anatomic location that can be off-loaded or completely relieved for the duration of treatment

And
• The member’s albumin level is greater than 2.5 g/dL

And
• The member’s total lymphocyte count is greater than 1,000

And
• The member has normal values of vitamins A and C

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We do not cover the medications listed above for other conditions not listed above.

Individual Consideration
All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed Care Authorization Information
• Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization.
  Pharmacy Operations: (800)366-7778
• Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
• Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com
**PPO and Indemnity Authorization Information**

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization.
  
  Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at [https://provider.express-path.com](https://provider.express-path.com)

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>10/2016</td>
<td>Moved to Pharmacy Medical Policy Format – Criteria remained the same.</td>
</tr>
<tr>
<td>9/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>6/2013</td>
<td>PRP is covered for Medicare Advantage members enrolled in a clinical trial. Retroactive to August 2, 2012.</td>
</tr>
<tr>
<td>11/2009</td>
<td>National policy review. Revisions to coverage statement made</td>
</tr>
</tbody>
</table>

**References**


To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below: