

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2026 P 1087-13
Program	Prior Authorization/Notification
Medication	Regranex® (becaplermin gel)
P&T Approval Date	1/2004, 5/2006, 11/2007, 12/2008, 12/2009, 9/2010, 9/2011, 6/2012, 8/2012, 8/2013, 8/2014, 7/2015, 7/2016, 7/2017, 8/2018, 8/2019, 9/2020, 9/2021, 11/2022, 1/2024, 3/2025, 3/2026
Effective Date	6/1/2026

**1. Background:**

Regranex 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. Regranex should be 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 or venous stasis ulcers. If a member has a prescription for a diabetic medication within the last 180 days of claim’s history, the prescription for Regranex will automatically process.

**2. Coverage Criteria<sup>a</sup>:**

<p><b>A. Authorization</b></p> <p>1. <b>Regranex</b> will be approved based on <b>both</b> of the following criteria:</p> <p style="padding-left: 40px;">a. Patient has a lower extremity diabetic neuropathic ulcer</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">b. Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control and/or pressure relief)</p> <p><b>Authorization will be issued for 6 months</b></p> <p><sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
--

**3. Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Regranex [package insert]. Franklin, TN: Lynch Regenerative Medicine; June 2025.

Program	Prior Authorization/Notification - Regranex
<b>Change Control</b>	
Date	Change
8/2014	Annual review. Reference updated.
7/2015	Annual review. Revisions to formatting. Increased authorization period to six months.
7/2016	Annual review. Reference updated.
7/2017	Annual review. Reference updated.
8/2018	Annual review. No changes.
8/2019	Annual review. Reference updated.
9/2020	Annual review. References updated.
9/2021	Annual review. No changes.
11/2022	Annual review. Added state mandate footnote.
1/2024	Annual review. No changes.
3/2025	Annual review. No changes.
3/2026	Annual review. Reference updated.