Louisiana Medicaid Prademagene zamikeracel (ZevaskynTM)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for prademagene zamikeracel (ZevaskynTM).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available <u>HERE</u>.

Approval Criteria

- The recipient is 6 years of age or older on the date of the request; **AND**
- The recipient has a clinical diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) as evidenced by genetic testing showing two confirmed RDEB type VII collagen mutations with recessive inheritance patterns (or confirmation that parents do not have any evidence of dominant disease); AND
- The recipient has chronic (open for ≥ 6 months) cutaneous wound(s) associated with RDEB which are adequate for treatment (e.g. stage 2 wounds $\geq 20 \text{ cm}^2$); **AND**
- The medication is prescribed by a dermatologist or wound care specialist; AND
- The following is true and **stated on the request** The recipient does not have a history of squamous cell carcinoma at the treatment site.

Duration of approval: 6 months – to allow for 1 surgical application Re-authorization is not permitted. Members must meet the initial approval criteria if request is for previously untreated or newly developed wounds.

References

ClinicalTrials.gov. Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB). https://clinicaltrials.gov/study/NCT04227106

Zevaskyn (prademagene zamikeracel) [package insert]. Cleveland, OH: Abeona Therapeutics Inc.; April 2025.

https://d1io3yog0oux5.cloudfront.net/_97c62242a52d17e584a3147d26ed2790/abeonatherapeutics/files/ZEVASKYN_Final_Label_30Apr2025.pdf

Revision / Date	Implementation Date
Policy created / July 2025	January 2026