Sample Letter of Medical Necessity

[Insurance Company]
[Address]
[City, State, Zip]

Re: **[Patient Name]**
[Policy #]
[DOB]
[Address]
[City, State, Zip]

To Whom It May Concern:

I am writing on behalf of my patient, **[Patient Name, ID, and Group Number]** for the coverage of VYJUVEK™ (beremagene geperpavec-svdt) $5x10^9$ PFU/mL associated with ICD-10-CM Q81.2. This letter of medical necessity includes the patient's relevant past medical history, overview of prior care delivered, treatment rationale and supporting medical necessity data.

VYJUVEK was approved by the U.S. Food and Drug Administration on Friday, May 19th, 2023. VYJUVEK is a non-invasive, topical, redosable gene therapy that was systematically studied in patients with Dystrophic Epidermolysis Bullosa. VYJUVEK is the only FDA-approved medication for the treatment of DEB wounds.

Treatment Rationale:
[Provide information on patient response to past treatments, anticipated prognosis, and rationale for the currently prescribed product].

Outline of Medical Studies:
[Please see Section 14 of the attached FDA approved Prescribing Information. vyjuvek-us-pi.pdf (krystallabel.com)**]**

Medical Record Information:
[Highlight key dates and entries of the medical record how the currently prescribed product is used].

Per the included medical information, it is my professional opinion that the currently prescribed product is medically necessary in treating the patient. Please call my office at **[Office Phone Number]** if I can provide further information or speak with a review board to obtain coverage.

Sincerely,
[Physician Name and Signature]
[Phone Number]
Enclosure: [FDA approved Prescribing Information]