Sample Formulary Exception

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

To Whom It May Concern:

I am writing to request a formulary exception be granted for the use of VYJUVEK™ (beremagene geperpavec-svdt) 5×10^9 PFU/mL for services requested for **[Patient Name, ID#, Group #]**. **[Insert payer's name]** does not include VYJUVEK on the approved formulary list.

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.

Included in this exception letter are information on the treatment rationale, medical records, medical necessity data and medical studies confirming currently prescribed product as an effective treatment for the diagnosis associated with ICD-10-CM Q81.2.

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

Outline of Medical Studies:
[A brief overview of the studies evaluating the use of the currently prescribed product in this condition and/or patient population and the FDA approved indications and usage are available in the approved Prescribing Information.]

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 and the denials for the patient's use of the drug should be reversed. Please call my office at **[Office Phone Number]** if I can provide further information or speak with a review board to appeal the denial of coverage decision. I look forward to reaching a resolution of overturning the denied status of the currently prescribed product for this patient.

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

VYJ-2200031