PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Vyjuvek (beremagene geperpavec-svdt)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

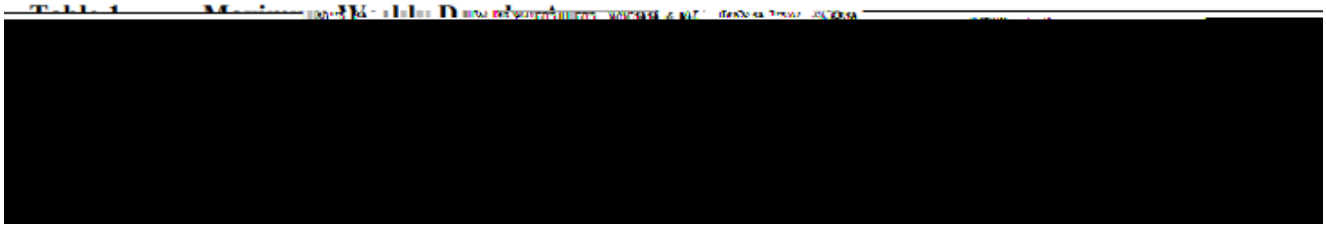
Vyjuvek, approved by the FDA in 2023, is a herpes-simplex virus type 1 (HSV-1) vector-based topical gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.
DEB is one of four types of epidermolysis bullosa (EB). It is a rare genetic disease with skin fragility and mechanically induced blistering that can lead to infections, scarring, and disfigurement. DEB is caused by mutations in *COL7A1*, the gene that codes collagen type VII (C7), the major component of anchoring fibrils in part of the skin. DEB can be autosomal dominant (DDEB) and have lower than normal functional anchoring fibrils, or less often (and more severe), recessive (RDEB) with no functional anchoring fibrils.
Vyjuvek gel addresses the underlying cause of DEB by delivering functional copies of the *COL7A1* gene to restore C7. In the GEM-3 clinical trial, complete wound healing at 3 and 6 months in DEB patients was more likely with Vyjuvek than placebo.

Vyjuvek (beremagene geperpavec-svdt) will be considered for coverage when the following criteria are met:

Dystrophic Epidermolysis Bullosa (DEB)

For **initial** authorization:

1. Member is at least 6 months of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of DEB confirmed by mutation(s) in the *COL7A1* gene; AND
4. Member has at least 1 open wound to be treated, that is clean and does not appear infected; AND
5. Member will continue standard wound care.
6. **Dosage allowed/Quantity limit:** Apply topically once a week to open wound(s).



QL: 4 vials per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.