

# The Bulgarian pathway to Beremagene geperpavec access and reimbursement

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## INTRODUCTION

- Epidermolysis bullosa (EB) is a rare, debilitating genetic disorder for which few disease-modifying therapies exist
- Beremagene geperpavec (Vyjuvek) is a non-integrating, replication-deficient HSV-1 vector that delivers functional COL7A1 to restore type VII collagen in dystrophic EB wounds
- In April 2025, Vyjuvek became the first EMA-approved topical gene therapy for dystrophic EB, marking a paradigm shift in disease management
- However, the therapy's high cost and regulatory novelty present major challenges for reimbursement and access across Europe
- Bulgaria was among the first countries to secure access to Vyjuvek, providing a unique early example of policy responsiveness in rare disease care

## METHODS

- In Bulgaria, access to innovative therapies for rare diseases is possible through established legal mechanisms for exceptional reimbursement
- Applications are submitted by treating physicians via hospital commissions and validated by the hospital director
- Treatment costs are initially covered by the hospital and subsequently reimbursed by the National Health Insurance Fund (NHIF)
- Protocols are renewed every three months
- This pathway was first applied to severe EB in 2023, when Birch triterpenes (Filsuvez) became available for patients under 18 years of age (Fund for Treatment of Children, NHIF)
- Later, Vyjuvek followed the same reimbursement framework

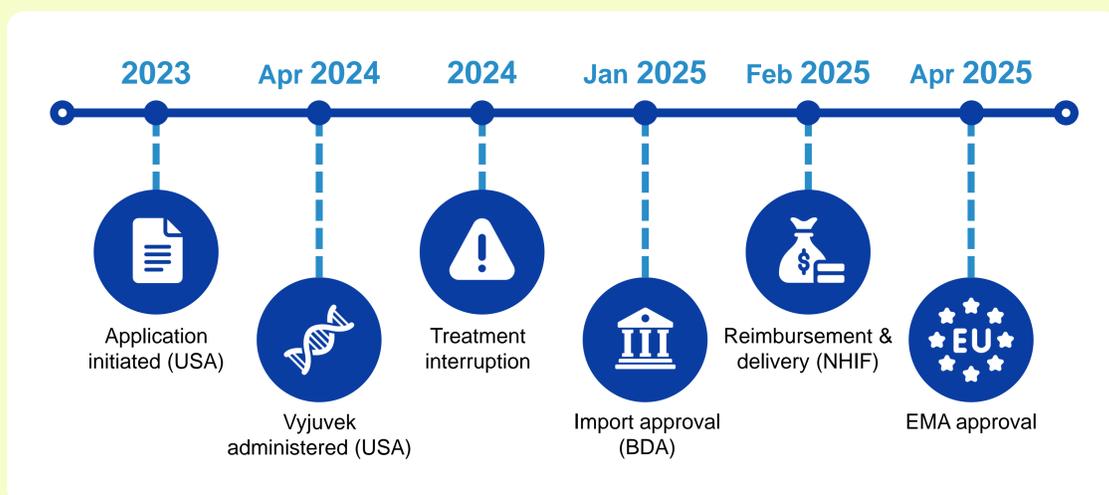
## CONCLUSION

- Filsuvez opened the door for therapy access in EB, while Vyjuvek marked the first gene therapy adopted through this mechanism
- Vyjuvek tested the limits of financial sustainability but demonstrated the effectiveness of patient-driven advocacy within existing legal frameworks
- Bulgaria's case illustrates a replicable model for international EB communities seeking to persuade governments to reimburse novel therapies

## RESULTS

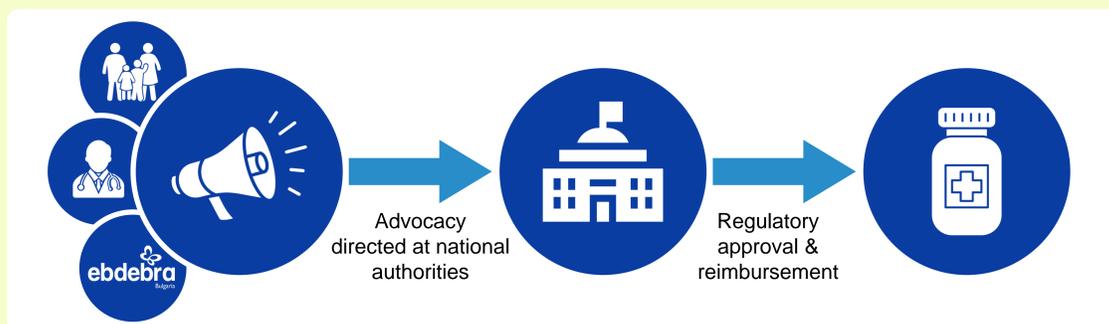
Timeline: (Figure 1)

- A 3-year-old Bulgarian boy with severe recessive dystrophic EB carrying two nonsense COL7A1 variants (c.2005C>T, p.Arg669Ter; c.6994C>T, p.Arg2332Ter) received Vyjuvek in the United States in April 2024 following an application initiated in mid-2023
- Rapid disease worsening occurred after treatment interruption upon return to Bulgaria, prompting urgent actions
- Under the mechanisms of Ordinance №10/2011 allowing exceptional use of non-authorized medicinal products, the Bulgarian Drug Agency (BDA) approved the import of Vyjuvek in January 2025
- Immediate reimbursement by the National Health Insurance Fund enabled national delivery of the first doses in February 2025, several months prior to EMA approval
- This made Bulgaria one of the first countries in Europe to provide funded access to the gene therapy, demonstrating effective use of existing legislation to integrate breakthrough treatments ahead of formal European authorization



**Figure 1.** Timeline for early access to Vyjuvek in Bulgaria

- The introduction of Filsuvez in 2023 catalyzed the establishment of EB DEBRA Bulgaria, creating a platform for international collaboration, national advocacy, and structured support for EB families
- This process strengthened dialogue between clinicians, patients, and health authorities, laying the groundwork for the subsequent, more complex integration of Vyjuvek (Figure 2)



**Figure 2.** The role of advocacy in governmental decision-making and therapy access

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