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Apr 23, 2026 · Approved Cellular and Gene Therapy Products Below is a list of licensed products from the Office of Therapeutic Products (OTP).  
Nov 24, 2025 · Yes, several gene therapies are now FDA-approved for hemophilia A and B. Learn about the approved treatments like Roctavian, Hemgenix, and Beqvez, how they work, and who is eligible. “Gene therapy for hemophilia has been on the horizon for more than 2 decades,” Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research, said in a statement about the ...  
Oct 31, 2025 · Gene therapies are approved by the U.S. Food and Drug Administration (FDA) for both hemophilia A and hemophilia B, and investigational gene therapies are in development. Dec 11, 2025 · A complete, up-to-date list of every FDA-approved gene therapy and cell therapy — from Kymriah (2017) to the latest 2025 approvals. Includes pricing, indications, and approval dates. Apr 26, 2024 · Pfizer has gained its first FDA approval for a gene therapy, scoring with Beqvez for hemophilia B and will charge \$3.5M for the one-time therapy. Today the FDA approved Roctavian (valoctocogene roxaparvovec), the first gene therapy for adults with severe hemophilia A. This is the second gene therapy approval for a form of hemophilia—a common ...  
Dec 10, 2024 · Improvements in AAV technology, protein expression, and immunogenicity may make AAV-mediated gene therapies more efficient, longer lasting, and safer for people with hemophilia A ...  
Nov 13, 2024 · Hemgenix ® is a gene therapy that was approved by the FDA on November 22, 2022, for the treatment of hemophilia B (factor IX deficiency) in adults. Hemgenix ® is made of a virus modified ...  
A complete list of all FDA-approved therapies to treat bleeding disorders. Explore FDA-approved therapies for bleeding disorders, including hemophilia A, hemophilia B, and more. Stay informed ...

## First FDA-Approved Gene Therapy for Hemophilia - JAMA Network Gene therapy for hemophilia - American Society of Hematology

[Gene therapy for hemophilia - Hemophilia News Today](#)  
[FDA-Approved Bleeding Disorder Therapies in the US | NBDF](#)  
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## Every FDA-Approved Gene Therapy: The Complete List (2026) FDA Approves First Gene Therapy to Treat Severe Hemophilia A [Is there a FDA approved gene therapy for hemophilia? Approved ...](#)

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