Valoctocogen roxaparvovec (severe haemophilia A)
Restriction of the authority to supply care

Resolution of: 2 February 2023 valid until: unlimited
Entry into force on: 2 February 2023
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Restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V

For the active ingredient valoctocogen roxaparvovec in the treatment of:

"Adults with severe haemophilia A (congenital factor VIII deficiency) without a history of factor VIII inhibitors and without detectable antibodies to adeno-associated virus serotype 5 (AAV5)"

the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V is limited to those care providers who participate in the required routine practice data collection.

Care providers within the meaning of this resolution are physicians participating in SHI-accredited medical care, medical care centres and facilities according to Section 95 SGB V as well as hospitals approved for care provision according to Section 108 SGB V.

Participation in the required routine practice data collection is ensured by the proper (proven in writing) participation of the (approved) healthcare provider in the data collection for the required routine practice data collection on the basis of the confirmed study protocol of the pharmaceutical company.

Courtesy translation – only the German version is legally binding.