

Autologous anti-CD-19-transduced CD3+ cells (relapsed or refractory mantle cell lymphoma) Restriction of the authority to supply care

Resolution of: 21 July 2022 Entry into force on: 21 July 2022 Federal Gazette, BAnz AT 17 August 2022 B2 Valid until: unlimited

Restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V

For the active ingredient autologous anti-CD-19-transduced CD3+ cells in the treatment of:

"adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor"

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 SHIaccredited 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.