Access to ATMPs in the Visegrád Four nations

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Objectives

The objective of this research was to evaluate and compare the level of access to advanced technology medicinal products (ATMPs) in the Visegrád Four (V4) nations – the Czech Republic, Hungary, Poland and Slovakia. Primarily, this involved identifying which ATMPs were officially subject to reimbursement. Additionally, the research involved an assessment and comparison of the pricing and reimbursement (P&R) regulations in place in the respective countries and their potential impact on the accessibility of ATMPs.

Methods

A search of the web pages of the relevant public bodies and institutions in the V4 countries was carried out, identifying the officially reimbursed ATMPs. A review and comparison of some relevant aspects of P&R regulations in the respective countries, including relevant information from GlobalData's Price Intelligence (POLI), was conducted. A search for other relevant information relating to the availability of ATMPs within the public healthcare system, including the number of medical centers certified to administer chimeric antigen receptor (CAR) T-cell therapy, was carried out.

Results

Of the 23 ATMPs approved for marketing in the EU as of June 2026, there are nine ATMPs listed as reimbursed in the V4 countries, the majority of which (six) are CAR T-cell therapies. The Czech Republic has the largest number of ATMPs listed for reimbursement, with nine, accounting for 39% of centrally-approved ATMPs. There are seven ATMPs reimbursed in Poland (30%), three in Slovakia (13%) and one in Hungary (4%).

In the Czech Republic, none of the reimbursed ATMPs are reimbursed under the standard outpatient reimbursement system. Eight (excluding Holoclar) are included in the institutional (hospital) care list (SCUP), and Holoclar is included in the list of individual prepared medicinal products (IPLP). In the other V4 countries, reimbursement is subject to the same procedures as the outpatient sector. The decentralization of the decision-making process in the Czech Republic appears to have helped to boost access to ATMPs. None have undergone a standard HTA evaluations and reimbursement procedures by the SÚKL, and the largest health insurer (VZP) has used its own system, involving medical expert societies, to standardize proceedings. In the longer term, however, this is not sustainable. The new EU joint HTA system will also have an impact in the deliberations of how this is managed in future. The number of medical centers certified to administer CAR T-cell therapies is the highest, proportionally, in the Czech Republic, with 9.2 per 10 million inhabitants, followed by Poland (4), Slovakia (3.7) and Hungary (2.1).

Generally, although none of the ATMPs were reimbursed in the Czech Republic under any of the alternative reimbursement pathways, the relative advancement of the country's P&R system indicates a more innovation-friendly regulatory framework. By contrast, in Hungary, where access to CAR-T therapies is limited to exceptional reimbursement, the development of the P&R system has effectively stalled over the past decade.

In Poland, the introduction of the high-level pharmaceutical technology innovation (TLI) reimbursement pathway in 2020 helped push forward the reimbursement of ATMPs, with both Zolgensma and Tecartus initially gaining reimbursement in this way. While the prices paid for ATMPs in any of the V4 markets are confidential, subject to cost/risk-sharing agreements and MEAs, it is apparent that the willingness-to-pay (WTP) thresholds are less rigid in the Czech Republic and Poland than in Slovakia, which also has strong oversight of the affordability of new therapies built into its legislation. This was apparent in the case of Zolgensma, which was approved for reimbursement in January 2024, only to be removed in April 2026 following a successful legal challenge from the two smaller private health insurance providers, who cited a lack of sufficient public funds.

Centrally approved ATMPs listed for reimbursement in V4 countries

Name of ATMP	Manufactuer	Main indication(s)	V4 countries where product is reimbursed
Abecma (idecabtagene vicleucel)	BMS (US)	Multiple myeloma	CZ
Breyanzi (lisocabtagene maraleucel)	BMS (US)	Various types of lymphoma	CZ, PL
Carvykti (ciltacabtagene autoleucel)	J&J (US)	Multiple myeloma	CZ, PL
Holoclar (ex vivo expanded autologous human corneal epithelial cells containing stem cells)	Holostem (Italy)	Limbal stem cell deficiency after eye burns	CZ
Kymriah (tisagenlecleucel)	Novartis (Switzerland)	Acute lymphoblastic leukemia, diffuse B-cell lymphoma, follicular lymphoma	CZ, PL, SK
Luxturna (voretigene neparvovec)	Novartis (Switzerland)	Loss of vision due to inherited retinal dystrophy	PL, CZ
Tecartus (brexucabtagene autoleucel)	Gilead Sciences (US)	Mantle cell lymphoma, acute lymphoblastic leukemia	CZ, PL, SK
Yescarta (axicabtagene ciloleucel)	Gilead Sciences (US)	Various types of lymphoma	CZ, PL, SK
Zolgensma (onasemnogene abeparvovec)	Novartis (Switzerland)	Spinal muscular atrophy	CZ, PL, HU

Sources: National MoHs, drug agencies

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Comparison of relevant P&R regulations in V4 countries

Country	Accelerated or temporary reimbursement system for high-cost drugs	Separate reimbursement pathway for orphan drugs	Willingness-to-pay threshold*	Number of inpatient facilities certified for CAR T-cell therapy (per 10 million citizens)	Exceptional reimbursement	Patient involvement in HTA / decision-making on reimbursement	Centralization / decentralization of HTA / decision-making process
Czech Republic	Yes (VILP)	Yes	$55,342	10 (9.2)	No current public information on expenditure available. The largest Czech health insurance company, the VZP, approved 22,084 requests for exceptional reimbursement in 2025, which is 96% of applications.	Direct involvement of patient representatives in decision-making in orphan-drug reimbursement pathway. For other reimbursement pathways, patients' representatives can make submissions.	Decentralized, with involvement of SÚKL, MoH and seven health insurance companies.
Hungary	No	No	$25,982—$259,820**	2 (2.1)	Individual equity reimbursement accounted for around 13% of public drug spending in 2024, or approximately HUF100 billion ($305 million).	No evidence of patient involvement available.	Centralized within the NEAK and MoH.
Poland	Yes (TLI)	No	$63,160	15 (4)	Exceptional reimbursement (RDTL) accounted for 1.3% of public drug spending in 2025. It is capped at 4% of spending on medicines in drug programs and the chemotherapy list (46% of public drug spending in 2025).	The Patient Rights Ombudsman is represented in the Transparency Board, the advisory body in Poland's HTA agency, the AOTMiT, without voting rights.	Highly centralized within MoH.
Slovakia	No	No	$47,704—$238,520***	2 (3.7)	Limited to 1.9% of reimbursement spending by law in 2026 (limits to be abolished from 2027)	Patients' organizations have one representative, without voting rights, in the Categorization Committee, which makes recommendations to the Ministry of Health on reimbursement decisions.	Centralized within MoH but partially decentralized with involvement of three health insurance companies, including two private companies.

* Thresholds in Hungary and Slovakia are based on GDP per capita. Values relevant for 2025 are given, based on national statistics data for Hungary, and World Bank data for Slovakia.
**higher thresholds available for pediatric and orphan drugs
*** higher thresholds available for orphan drugs and ATMPs

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Conclusions

Access to ATMPs in the V4 countries is fairly starkly divided, with the Czech Republic and Poland showing significant progress in certain areas: the Czech Republic has among the highest number of centers delivering CAR T-cell therapy in Europe, proportionally, and has tripled the number of patients receiving this type of treatment in recent years, while in Poland, treatment of spinal muscular atrophy is at a level comparable to the most developed European countries. A change in the regulatory trajectory in Slovakia in 2024, following the 2023 election, has seen a process of retrenchment that has targeted drug spending, negatively affecting access to ATMPs. In Hungary, while ATMPs have to an extent been available through exceptional reimbursement, flawed reforms have negatively impacted their availability. All four countries face the challenge of growing demand and limited resources, while joint EU HTAs promise to reduce some of the regulatory pressures.