Scope of vignette:
- authorised products (with marketing authorisation)
- decision process about routine use (and not individual requests for reimbursement)
- submissions for P&R made by manufacturers

Green = related to/any special considerations for rare disease and ultra-rare disease treatments

Slovakia	**Standard reimbursement and HTA process for pharmaceutical products**	**Standard reimbursement and HTA process for pharmaceutical products, without economic analysis**	**Exception from standard reimbursement and HTA process for pharmaceutical products, individual requests without economic analysis**
Overview of health system and P&R/HTA process	Social insurance based health system [1] Ministry of Health makes decisions on reimbursement and pricing. A committee of experts, a pharmaco-economic committee evaluate applications. A categorization committee summarizes and assesses the evaluation by the expert and pharmaco-economic committees. Categorization committee gives a recommendation to the Minister, on which Minister bases decision.		
Differentiation of rare disease treatments in the P&R system	2 differentiations: - Prevalence below 1:50,000 inhabitants (ultra-orphan) - Orphan designation by EMA if prevalence above 1:50,000		
Eligible medicines	All new drugs, but MAH can also decide not to submit	All new drugs with OMP designation	New drugs with OMP designation that had prior discussions for RSA or lower prices, or do not submit an application. If a drug is on a positive list for an indication, named patient programme is allowed only for new indication which is not reimbursed via standard process.

Process	- An application is submitted to the Ministry of Health (MoH) via an electronic portal - It is evaluated by a committee of experts, and pharmaco-economic committee - The statement of the above two committees is summarized and assessed by a categorization committee (11 members) - The categorization committee gives a recommendation to the Minister - A decision is made by the Minister based on that recommendation Standard process takes approx. 6 – 9 months.		Several medicines for very rare diseases use individual reimbursement via patient named request by health care provider to the Health Insurance Fund (HIF). Re-evaluation timeline of the request is defined in the decision of HIF. Individual reimbursement process takes approx. 30 days.
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	Clinical experts always have to evaluate submission (sub-committees of ATC group – several groups). If application comes with CEA, it has to be evaluated by pharmacoeconomic group. No patient representatives involved in process (not standardized), but patients can write a statement to MoH and comment on legislation that has been made public.	If no pharmacoeconomic analysis, submission only evaluated by clinical experts, who give opinion to categorization committee, which gives opinion to MoH. No rare disease specific committee or specialists. Clinical experts from ATC group usually involved, which may not be the expert experienced in treating the patient group in question. Refer to Centers of Excellence for diagnosis, prevention and treatment of rare diseases to identify these experts, but not always included.	
Key domains in assessment	- Clinical-effectiveness - Cost-effectiveness - Budget impact also included, but is not a condition for reimbursement. It provides information for health insurance companies to predict budget	- Clinical-effectiveness - Cost-effectiveness only for drugs with an orphan designation from EMA and prevalence above 1:50,000 (not requested for UOMPs)	- Clinical-effectiveness

Evidentiary requirements	Need proven clinical efficacy compared to placebo and standard of care.	No lenience for orphan or ultra orphan drugs. Same conditions for all drugs to prove clinical efficacy. Information often not available for OMPs, then depends on unmet need (higher if no other treatment available). If high they can accept no data (since no active treatment to compare with). Surrogate endpoints accepted if OMPs are not from oncology.	
PROMs	No formal requirements for PROMs, but if provided would support the deliberative process. Preference for EQ5D (when cost utility analysis obligatory). Data provided should be published.		None
Appraisal framework	Assessment criteria are considered in relation to a flexible ICER threshold adjusted based on points from MCDA. Criteria used to calculate points that will adjust the threshold: - # of positive reimbursement decisions in the same indication in 4 countries (HAS, G-BA, SMC, NICE) - availability of other treatment options in Slovakia (high unmet need if no treatment, low if more than 5 drugs) - expected payment from public insurance (=sum of	For UOMPs: - No obligation to submit economic analyses. If sum of expected reimbursement for 12 months is > 1,5 million EUR, conditional reimbursement is mandatory. The condition is re-evaluated every 24 months. - OMPs with EMA designation must submit CUA and BI. A higher threshold would normally be accepted given the flexible ICER threshold adjustment criteria (see left column).	HIF has three publicly available criterion for its evaluation process, and usually it includes the following two points: - no other available alternative reimbursed via standard process or no existing treatment at all - price discount from price set based on officially set prices within EU

	payment to be requested within 12 months) - incremental utility - orphan designation Threshold is calculated as multiplication of points and average salary 2 years ago. Increase of average salary means yearly increase of threshold.		
Reimbursement decision	Y/N/conditional Positive list used All decisions are published on MoH website and made publicly available, except specific parts that are confidential. [2] Conditional reimbursement for UOMPs.		When OMPs are accepted, there are often discussions about MEAs. It is not compulsory to submit application through standard HTA process. Some MAH choose not to and undergo the patient named program (not allowed if drug indication on positive list).
Pricing process	- Application for reimbursement is conditioned by existence of officially set prices of that medicine in at least 5 different EU member States, otherwise reimbursement is set at the level of 20% of final price within pharmacy (ex factory + distributor and pharmacy margins) - Any drug applying for reimbursement can be reimbursed only if there is a EU reference price (at least one within EU28. Reference price is average of three lowest at factory prices and exchange rate is set by average of last 12 months) - If there are less than 5 prices within EU28, reimbursement is set at the level of 20% of pharmacy price - Companies usually wait until there are prices in 5 countries before submitting (same package and active drug), after which they submit (ok for MAH, as country with lower prices so MAH price later)		Same Price discount from price set based on officially set prices within EU.

Managed entry agreements	- Confidential discount - Budget cap - Outcome based scheme to collect additional evidence for later reassessment (since Jan 2018, but not really used yet) - Outcome based scheme for individual patients, only paying for certain performance (since Jan 2018 but in reality not used yet) Outcome-based MEAs are rare due to implementation challenges. Negotiations most often about price, e.g. simple discounts and budget caps.	- Confidential discount - Budget cap (these two are most comment)
Main challenges in appraising medicines for rare diseases	- Lack of real world data - Lack of criteria/transparency of OMP P&R processes e.g. CUA is obligatory but no clear guideline (e.g. how to choose a comparator) no public hearing prior to submission. Possible but only after submission to clarify or ask any questions	
Impact of special processes	Since introduction of special process (1st January 2018), several medicines for rare diseases applied for reimbursement. Positive impact: more drugs being reimbursed, processes more in line with OMP specificities. Trying to follow national program that was proven by government last year to better meet RDT needs. Main trigger was that national plan and pressure from European Commission.	
Proposed policy change	The definition of UOMP has changed since January 1st, 2019 from : "Indicated for the treatment of the disease, where the number of patient suitable for the treatment based on the registered indication is below 1:50 000" To the definition: "Indicated for the treatment of the disease, with the prevalence below 1:50 000" The reason for this change is that most of the budget was spent on oncology drugs (sub-indications) that were not orphan. Now legislation changed; has to be ultra-orphan.	
Joint initiatives	--	
SOURCES		
1	http://www.hpi.sk/en/2011/05/2-1-overview-of-the-health-system/	
2	http://kategorizacia.mzsr.sk/Lieky/Common/Requests	

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This vignette was compiled based on information provided by country experts and desk research. The information provided may be incomplete or contain inaccuracies. If you have any comments or updates, please email us at the following email addresses:

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