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

Slovenia	Standard pricing and reimbursement process
Overview of health system and P&R process	Social insurance based health system (1). Publicly funded medicines go through the standard P&R process. Pricing is separate from the reimbursement process. The competent authority for the pricing process is the Agency for Medicinal Products and Medical Devices (JAZMP), while reimbursement decisions, including price negotiations, are under the responsibility of the Health Insurance Institute of Slovenia (HIIS). Price is determined through external reference pricing (ERP). A company can apply for a higher price than the ERP reference price by undergoing an assessment of comparative effectiveness, budget impact, unmet need…. (2) In order to obtain reimbursement, a company has to prepare a file (that includes cost-effectiveness analysis, clinical benefit, budget impact analysis etc.) that is assessed by an independent commission coordinated by the HIIS. Based on their recommendations, HIIS can enter the negotiations with the company. Once price and other conditions are agreed, including MEAs, the medicine is put onto a positive list and reimbursed. (3) There are no special procedures for rare disease treatments. In the reimbursement process, however, there are criteria that allow to take into account rarity (e.g. ethical considerations, including rarity of disease).
Differentiation of rare disease treatments in the P&R system	None
Eligible medicines	All new medicines that seeks reimbursement.
Process	Reimbursement procedure: - company prepares submission with all relevant clinical studies, appropriate clinical guidelines, list of EU countries where drug is reimbursed, cost-effectiveness and budget impact study for Slovenia - company submission to HIIS once marketing authorisation granted and maximum allowable price determined (through external reference pricing conducted by JAZMP) - HIIS requests to National Committee for Reimbursement of Medicines for opinion in terms of the importance and (ir)replaceability of the medicinal product in the health care system, the

Slovenia	Standard pricing and reimbursement process
	type and size of clinical benefit, the costs of medicine and its impact on budget, and ethical considerations; and gives the opinion about reimbursement. - The opinion of the Committee is published online and it is publicly available. - In case of a positive or conditional positive opinion, the HIIS may enter negotiations with the pharmaceutical company about the price and other conditions of sales (e.g. potential MEA)
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	Clinicians from all major therapeutic areas are involved in The National Committee for Reimbursement of Medicines. In addition, the Committee or the HIIS can request opinions and information from different bodies and institutions.
Key domains in assessment	- Clinical effectiveness - Cost-effectiveness - Budget impact
Evidentiary requirements	There are no special evidentiary requirements for rare disease treatments; however, there is flexibility in the interpretation of the quality of evidence submitted
PROMs	PROMs are not requested in the submission, but would be considered if provided
Appraisal framework	The domains are defined by the Rules on the classification of medicines on the list (Official Gazette of RS, no. 35/13) (4) - the importance of drug from a public health perspective, - the priorities of the program of health care, - the therapeutic value of the drug, - relative therapeutic value of the drug - pharmacoeconomic data - ethical aspects* - data and estimates from the reference sources Ethical aspects are defined as a criterion that takes into account the severity and rarity of disease. Drugs to treat rare (e.g. orphan drugs) and very rare diseases would be recognised as such. There is no formal rule about it weight, but in practice, if considered it has an important influence on decision.
Reimbursement decision	Reimbursement decision made by HIIS can be (1) positive or positive with conditions (e.g. MEA), which would be included on a positive national formulary, or (2) negative, which would not be included on the formulary.
Pricing process	External reference pricing is used to determine the maximum allowed price (which is updated

Slovenia	Standard pricing and reimbursement process
	twice a year for every medicine (the packaging size level) that is reimbursed). The actual price can be lower, based on negotiations. Internal reference pricing is done on two levels – first on the level of mutually interchangeable medicinal products; and second on the therapeutic groups of medicines.
Managed entry agreements	It is possible. There can be financial based or performance based agreements, but financial based on population level is most common (discount, cap, price-volume, etc).
Main challenges in appraising medicines for rare diseases (tick all that apply)	X Lack of good quality clinical data Lack of real world data X Introducing value for money Monitoring treatment efficacy Managing budget impact X Lack of long-term meaningful outcomes X Lack of criteria/transparency of OMP P&R processes Making arrangements to work for all stakeholders
Impact of special processes	There is no special procedure for orphans or medicines for rare diseases, however, in the assessment and negotiation process the rarity of disease is taken into account.
Proposed policy change	To date, there is no official HTA body. Elements of an HTA process are being considered in certain cases (e.g. assessment for reimbursement; process of exceptional high price). To improve systematic support to decisions, a more official HTA process with appointed HTA body may be required.
Joint initiatives	
SOURCES	
1	http://www.zzzs.si/zzzs/internet/zzzseng.nsf/o/DB29291A87496668C1256E8900489918
2	https://www.jazmp.si/en/human-medicines/pricing-of-medicinal-products/
3	http://www.zzzs.si/zzzs/internet/zzzseng.nsf/o/7A6B2DB165A3A313C1256E89004927A4
4	https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/2013-01-1323?sop=2013-01-1323

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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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