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 OMPs/UOMPs

Hungary	**Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products**
Overview of health system and P&R/HTA process	Tax based health system. [1] The Ministry of Human Capacities (MAHs) is ultimately responsible for the necessary legal actions after a review, including pricing. The MAHs submits a reimbursement application dossier to the National Health Insurance Fund (NHIF). The NHIF invites the National Institute of Pharmacy and Nutrition (NIPN) to provide a review of the submission. The Health Technology Assessment (HTA) committee makes a final conclusion about a submission. Hungary uses a positive reimbursement list in the outpatient sector. Medicines Agency is responsible for marketing authorization. [2]
Differentiation of rare disease treatments in the P&R system	None
Eligible medicines	Drugs for which the manufacturer submits a dossier for reimbursement
Process	The MAHs submits a reimbursement application dossier to the National Health Insurance Fund (NHIF), which invites the National Institute of Pharmacy and Nutrition (NIPN) to provide a review of the submission and its appendices alongside the domains of health technology assessment. Assessment: Based on assessment criteria included in the dossier (see below), the NIPN formulates critical conclusions of the submitted drug. Appraisal: These conclusions are brought in front of a Health Technology Assessment Committee (chaired by the National Health Insurance Fund, but consisting of NHIF, NIPN and medical experts) which develops and agrees on a final conclusion on the professional aspects of the submission (i.e. unmet need, relative effectiveness, cost-effectiveness, budget impact, conditions to be met for reimbursement, etc.).
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	The Health Technology Assessment (HTA) Committee (chaired by the NHIF, but consisting of NHIF, NIPN and medical experts) develops and agrees on a final conclusion on the professional aspects of a submission.

Hungary	Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products
Key domains in assessment	- Efficacy/safety of the submitted pharmaceutical and its comparators - Cost-effectiveness - Budget impact
Evidentiary requirements	If the manufacturer used the highest possible quality of evidence available, the may be more leniency for the evidence requirements for RDTs. It is checked whether there is any better available evidence. If substantial uncertainty is identified that may manifest in financial risks, those might be reflected in MEAs developed by the payer.
PROMs	None
Appraisal framework	In addition to the key domains, the following criteria are included in the assessment : - Unmet need (may benefit RDTs) - Relative effectiveness
Reimbursement decision	There is a comparison made between national and international therapeutic practices related to the use of the submitted pharmaceutical. If the conclusion of the HTA committee is negative, the reimbursement process ends. If positive, the conclusion on reimbursement status is used to develop a recommendation for the Ministry of Human Capacities, which takes the necessary legal actions (such as modification of a decree or law, whichever necessary). Once the MoHC makes a decision, the appropriate governmental decrees are modified, the technology goes on to the positive list, and a decision is made on the reimbursement rate. - Reimbursement rates: 100%, 90%, 80%, 70%, 55%, 50%, 25%. - Patients are usually required to make co-payments. - Reimbursement rates mainly depend on the therapeutic value of the medicine, the severity and duration of the disease and the price. - In general, a higher reimbursement rate is granted if the disease is considered more severe or longer lasting or the medicine is more effective. Two major reimbursement categories: 1. Indication linked: only for a subset of confirmed indications. Reimbursement rates in this category are 50%, 70%, 90% (for less severe chronic conditions) or 100% (for more severe, life-threatening diseases). For medicines that are 100% reimbursed in this category, a fixed co-payment (prescription fee) of 300 Hungarian forints (approximately €1) per package must be paid by the patient.

Hungary	Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products
	2. Normative reimbursement: medicines that can be prescribed by all physicians authorized to prescribe. It may be used for all authorized indications of a medicine included in the positive list. Depending on the therapeutic value of the medicine, and the severity of the disease, the reimbursement rates for this category are 25%, 55% and 80%. The reimbursement rate for substances of the pharmacopoeia and magistral products (prepared in the pharmacies) is 50%, resulting in a 50% co-payment. [2] *Rare diseases are currently reimbursed under a so-called "unique reimbursement" scheme, where MAHs are not required to submit any particular documentation related to HTA unless the therapy affects less than a given number of patients. RDTs are usually reimbursed at 100% due to the high price of treatments.
Pricing process	Internal reference pricing for off-patent medicines (generics and biosimilar medicines) - patient pays the difference between reference price and actual pharmacy retail price if the chosen product is priced above the reference price. There are no co-payments for medicines applied in the inpatient sector - these are fully covered through the hospital financing system. [2]
Managed entry agreements	- Reimbursement volume agreements - Confidential list of MEAs published - None in inpatient sector - products go through procurement, but the contract is designed in a way that it has risk-sharing elements [2]
Main challenges in appraising medicines for rare diseases (tick all that apply)	☐ Lack of good quality clinical data ☐ Lack of real world data ☐ Introducing value for money ☐ Monitoring treatment efficacy ☐ Managing budget impact ☐ Lack of criteria/transparency of OMP P&R processes ☐ Making arrangements to work for all stakeholders ☐ Lack of long-term meaningful outcomes
Impact of special processes	Not relevant
Proposed policy change	There is a continuous and fruitful discussion between stakeholders on the reimbursement / HTA process, although creating a stand-alone process for the reimbursement of therapies for rare diseases does not seem feasible.
Joint initiatives	
SOURCES	
1	https://www.hspm.org/countries/hungary25062012/livinghit.aspx?Section=2.1%20Overview%20of%20the%20health%20system&Type=Section

Hungary	Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products
2	http://www.euro.who.int/__data/assets/pdf_file/0011/376625/pharmaceutical-reimbursement-eng.pdf?ua=1

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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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