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

Czech Republic	**Standard process (non-orphan drugs)**	**Special process (possibility of temporary reimbursement)**
Overview of health system and P&R/HTA process	Social insurance based health system [1] SUKL (the State Institute for Drug Control) is the national regulatory and HTA agency, and is responsible both for setting the maximum ex-factory price and for decisions on reimbursement. The appeal authority against decisions made by SUKL is the Ministry of Health. [2]	
Differentiation of rare disease treatments in the P&R system	None, but discussions are ongoing while legislation update is being prepared.	
Eligible medicines	Original products (and generics, but for them the process is much simpler). [2]	Highly innovative medicinal products (HIMP) (may include OMPs)
Process	- P&R procedure runs as individual administrative proceedings with fixed terms and conditions. - The company (marketing authorization holder/MAH) has to apply (fill the form) and the decision is made within 75 days in case of application only for price or only for reimbursement (165 respectively for joint application for price and reimbursement). Steps: - 1. Application (P&R dossier) submission – procedure starts - 2. Search for price references, calculation of the maximum price (MP) and basic reimbursement (BR) - 3. Collection of motions from parties to the procedure - 4. Determination of MP/BR/reimbursement per package (BR determined based on the chosen reference product). - 5. Assessment report (AR) drafting (AR prepared by the assessment team at SUKL: assessors specialized in clinical (efficacy + safety) aspects and those specialized in pharmacoeconomics, as well as lawyers (who focus on the procedural aspects) and pricing specialist (external price referencing)) - 7. AR publication - 8. Collection of comments and objections to AR from parties to the procedure (health insurance companies, MAH), and also voluntary comments from other stakeholders (clinical expert	

Czech Republic	Standard process (non-orphan drugs)	Special process (possibility of temporary reimbursement)
	societies, patient groups). AR is also publicly available on SUKL's website. If any substantial change to the AR needs to be made based on the received comments, a second (or subsequent) report is issued) - 9. Drafting of the decision (SUKL makes the decision based on the gathered evidence by the assessment team at SUKL summarized in the (final) assessment report. - 10. Final decision publication. Parties to the procedure (MAH and health insurance companies) may appeal against SUKL´s decisions; the appeal is then decided by the Ministry of Health. There is also the possibility of judicial review afterwards. - 11. Monitoring of sent appeals from the decision - 12. Reporting to monthly published Lists of price and reimbursement of pharmaceutical products	
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	Clinical experts elaborate upon the initial AR draft. Clinical experts can comment on the AR draft.	
Key domains in assessment	- Clinical effectiveness, (clinical comparative effectiveness, clinical similarity and/or interchangeability with other MedPs) - Cost effectiveness - Budget impact [3]	
Evidentiary requirements	RTCs are preferred.	RCTs are preferred, but for OMPs, single-arm studies may be accepted in exceptional cases (however, the acceptability of lower quality of evidence is assessed on a case-by-case basis in light of other available evidence). Nevertheless, SUKL accepts all types of evidence (data from RCTs, registries, epidemiologic studies, real-world evidence, etc.).
PROMs	If available, data on quality of life are also taken into consideration.	
Appraisal framework	The only criteria which are considered are criteria relevant for clinical domains (1 – 4) and the cost and economic evaluation domain, according EUnetHTA Core Model.	If applying for temporary reimbursement, cost-effectiveness does not need to be proven; however, cost-effectiveness analysis is required to be submitted together with a proof of an acceptable budget impact estimate. This facilitates subsequent appraisal during the administrative proceeding of permanent

Czech Republic	Standard process (non-orphan drugs)	Special process (possibility of temporary reimbursement)
		reimbursement when cost-effectiveness has to be proven. In the case that an original product is requested to be considered as "highly innovative medicine" (some of these products are orphan medicines), it is also necessary to prove that it meets at least one of the criteria defined by the law (e.g. therapy of serious diseases with clinically significant benefit in terms of efficacy or safety compared to the current therapy). The definition of significant benefits is defined by the legislation. MAH must submit a written commitment outlining how the MAH will ensure continuous evaluation of treatment outcomes for future cost-effectiveness evaluation, and how the MAH manages the budget impact limitation. MAH must also commit, in the case that temporary reimbursement expires while permanent reimbursement is not granted, to cover treatment costs for already treated patients.
Reimbursement decision	Decision can be positive or negative. For positive decisions: the reimbursement price as well as reimbursement conditions are set. For negative decisions: the rationale is given and the medicine is not generally reimbursed in the Czech Republic. The only possible patient access to non-reimbursed pharmaceutical is an individual well-substantiated request to (and assessed by) a health insurance company; the request may be (or not) approved.	Temporary reimbursement may be granted for a limited period of 24 months, which may be followed by another temporary reimbursement of 12 months, that is, maximum of 36 months in total.
Pricing process	- By law, the cost for all medical procedures, including all pharmaceutical products, is covered by health reimbursement. Pharmaceutical products that are or should be used for inpatients, are fully reimbursed, without any HTA procedure/decision. HTA is mandatory only for (mainly) outpatient treatment.	

Czech Republic	Standard process (non-orphan drugs)	Special process (possibility of temporary reimbursement)
	- Prices of pharmaceuticals are set at ex-factory level or are regulated by statutory prices (these are prepared medicinal products or prepared parenteral nourishment, prepared radiopharmaceuticals and transfusion products made in the facilities of the transfusion service). - 'Basic reimbursement' is calculated based on the pricing references (ex-factory prices of products marketed in reference countries). - For highly innovative drugs it is possible to grant reimbursement only if the pharmaceutical is reimbursed in at least 2 reference basket states. [2] *May be applicable for OMPS	
Managed entry agreements	MEAs can be used. They are used by MAHs to cope with parameters required by the cost effectiveness requirement of HTA, as well as to reach an agreement with reimbursement funds about an acceptable budget impact. SUKL does not participate in concluding MEAs, but takes them into account. MEAs may also be submitted as confidential documents. MEAs are often connected with (or part of) the MAH´s obligatory commitment for highly innovative drugs. May also be applicable for OMPS	
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 x Managing budget impact ☐ Lack of criteria/transparency of OMP P&R processes x Making arrangements to work for all stakeholders ☐ Lack of long-term meaningful outcomes ☐ Other	
Impact of special processes		
Proposed policy change	The Ministry of Health is preparing an amendment to the Act No. 48, which should set up specific processes for orphan medicinal products that do not meet standard requirements. This new process will include bespoke patient involvement processes.	
Joint initiatives		
SOURCES		
1	https://ec.europa.eu/health/sites/health/files/state/docs/chp_cs_english.pdf	
2	Pricing and reimbursement - general information 2018.pdf	
3	SP-CAU-003-11version_ENG.pdf	

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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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