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

Poland	**Standard HTA process (non-orphan drugs)**
Overview of health system and P&R/HTA process	Social insurance based health system [1] General application requirements have been determined by the Act on reimbursement of medicinal products, special purpose dietary supplements and medical devices. The marketing authorization holder must initiate the procedure by submitting an application. The MoH receives applications and HTA reports, and makes the final decision. The Agency for Health Technology Assessment and Tariff System (AOTMiT) acts as an advisory body to the MoH. The Transparency Council (TC) – an independent body working with the President of the Agency - appraises the application and makes suggestions to the President. Some but not all inpatient and prescription drugs in the outpatient sector are reimbursed by the insurance fund (NFZ). The NFZ is charged with financing of health care services provided to the insured population. It manages the process of contracting health services with public and non-public service providers. The operations of the NFZ are supervised by the Ministry of Health, while its finances are entrusted to the Ministry of Finance. Co-payments apply to outpatient prescription medicines included on a positive list (lump sum, and 30% or 50% on supplementary medicines). Within special drug programs or chemotherapy drug lists, inpatient medicines are fully covered.
Differentiation of rare disease treatments in the P&R system	None
Eligible medicines	New products with marketing authorization (for both in and out patient but only Rx category)
Process	- Application and HTA reports are sent to MoH - MoH forwards the application and reports to the Agency for Health Technology Assessment and Tariff System - The Agency verifies the documentation and prepares a verification analysis - The verification analysis is subject to public consultations (clinical experts and patient organisations are also asked for opinions as part of the process of preparation of the verification analysis) - The first step of the verification is checking whether the analyses submitted with the application

Poland	Standard HTA process (non-orphan drugs)
	fulfil the minimum requirements set by the Regulation of the Ministry of Health - Applicant can be asked for supplementary analyses if the minimum requirements are not met, and has 21 days to complete the documentation - Results of the verification analysis are appraised by the TC - TC gives its opinion (non-binding), which is taken into account by the President - President of the Agency issues a recommendation independent from the TC - Negotiations take place with the Economic Commission (a part of the process in the MoH) - The MoH makes the final decision (in line with legal requirements), taking into account the opinions of both the TC and the President
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	Clinical experts and patient organisations are asked for opinions as part of the process of the preparation of the verification analysis. When the verification analysis is prepared, it is published on the website in a Public Information Bulletin, and anyone can comment on it within 7 days.
Key domains in assessment	- Clinical effectiveness - Cost-effectiveness - Budget analysis - Other [2]
Evidentiary requirements	In the HTA process there is more leniency for RDTs: The reimbursement criteria (established by the law) are the same for all conditions, but in recommendations a lower evidence quality level than RCTs may be accepted (e.g. non-RCTs, controlled observational studies or even descriptive studies such as case series). Surrogate end points are accepted only when there is evidence on the relation between the surrogate endpoint and the clinically significant outcome. Emphasis is still placed, however, on proving long-term effectiveness/efficacy and safety. Generally, a higher level of uncertainty in the evidence is accepted, but it is rather informal. This is also the case when risk sharing agreements play a big role as a condition for reimbursement, because lack of cost-effectiveness (in economic analysis) does not mean that recommendation will be negative for financial reasons. Advice is often to improve the risk sharing proposal of the marketing authorisation holder, or suggests other mechanisms of risk sharing than those presented, to minimise the burden for public payer and reduce uncertainties.
PROMs	PROMs are taken into account when they are present in the trial. Subjective assessments are considered less reliable, but they still support the final decision,

Poland	Standard HTA process (non-orphan drugs)
	especially if they refer to health related quality of life (HRQoL) with a validated questionnaire.
Appraisal framework	Additional considerations for decisions: - Safety - Rationalization analysis (specific for Poland, does not play a big role) - Health benefits vs. risks - Therapeutic alternatives [2] - Significance of clinical condition
Reimbursement decision	After negotiations with the Economic Commission, the MoH makes the final decision on reimbursement (positive or negative) based on advice from the Agency for Health Technology Assessment and Tariff System.
Pricing process	Prices are negotiated by the Economic Commission. HTA assessment offers arguments for negotiations. When recommended for reimbursement, the following pricing schemes apply: The MoH sets the official sales price of the medicine, taking into account the following criteria: - If no RCTs are included, the official sales price of the drug must be calculated in such a way that the cost of the drug is no higher than the cost of the medical technology which has been financed to date with public funds in the same indication, with the most favourable relationship of the health effects obtained to the costs of obtaining them; - The official sales price cannot be higher than 75% of the official sales price specified in the previous decision for inclusion in the reimbursement (if the drug has already been financed for a given period or if a counterpart is already available and reimbursed) [2]
Managed entry agreements	Risk sharing schemes are widely used Proposals for MEAs are often received and assessed during the HTA process. HTA assessors provide comments on these proposals (e.g. can give advice to enhance the proposal due to uncertainty as a condition for positive reimbursement decision).
Main challenges in appraising medicines for rare diseases	- Other population than that in clinical trial
Impact of special processes	---

Poland	Standard HTA process (non-orphan drugs)
Proposed policy change	Last year an amendment to the Act on reimbursement was discussed which proposed to remove the obligation of using the cost-effectiveness threshold for orphan drugs. Currently, the threshold specified in the act is the same for all drugs: 3x GDP per capita. According to the proposed changes the MAH could present a price justification instead of an economic analysis and calculating the ICER. Unfortunately, the proceedings referring to the amendment (and also other significant changes regarding the reimbursement process in Poland) have been stopped and it is not publicly known when any final decisions will be made. Now a new legislation, dedicated to orphan drugs, is being discussed. Progress is connected with the National Plan for rare diseases. Planned term of announcement: 2019
Joint initiatives	
SOURCES	
1	https://www.nfz-lodz.pl/dlapacjentow/leczenie-za-granica/leczenie-w-polsce/279-health-care-in-poland
2	Act_on_reimbursement_of_medical_products.doc

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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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