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

Denmark	**Standard reimbursement process (inpatient)**	**Named patient programme**
Overview of health system and P&R/HTA process	Tax based system [1] As of 2017, new Medicinraadet - Danish Medicines Council (DMC) to evaluate cost-effectiveness of new pharmaceuticals. [2, 4] The DMC provides guidance for regional decision-making and the administration of tenders within Amgros, which is the regional purchasing organisation. [4] RDTs may undergo the hospital route or the named patient programme. Patients receive specialised care through hospitals, and continue prescription through the hospital. Costs are managed by hospital budgets. [2] Amgros makes the final decision on reimbursement.	Named patient programme: those drugs not approved by the Regional Medicine Council or not yet evaluated will undergo a named-patient basis programme. The appraisal is local and the costs are reimbursed at the regional level. Different regions may choose differently While RDTs may go through the hospital route *or* the named patient programme, very RDTs are more likely to go through the named patient programme.
Differentiation of rare disease treatments in the P&R system	None	
Eligible medicines	New medicines and new indications (inpatient) [3]	Initiated by the treating doctor
Process	- The MAH is to submit the application to DMC before EC EMA approval is received - 2-5 weeks later, DMC issues a report on the added clinical value, after which there is a hearing - during the hearing the applicant can input on the added clinical value - In parallel, Amgros conducts an assessment of economic evaluations (until week 10 following EMA approval) - Week 10-12, negotiation with Amgros (for added clinical benefit categories 1-4): aims to reach a reasonable relationship between the added benefit and added costs. - After which a decision is made - Decision is communicated to regions	The treating doctor will write an application to the hospital board of directors, which includes a description of the patient, the indication and the orphan drug they wish to use. The application will include a presentation of the current evidence (literature) for the treatment. Specialists at the Department of Clinical Pharmacology will evaluate the existing evidence, and give a recommendation to the hospital board of directors. The hospital board will discuss the case and consider the price of the drug. The hospital board can say yes or no to the treatment or they can

Denmark	Standard reimbursement process (inpatient)	Named patient programme
	- Amgros publishes the assessment of the economic evaluation [3] - Amgros negotiates prices and purchases products on behalf of the regions for the hospitals	submit the application to the regional management if in doubt, who will then decide if to provide the treatment or not
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	The DMC consults disease-specific clinical experts in their assessments Patients participate in all parts of the assessment (e.g. clinical discussions) Patient representative from an umbrella organisation sits on the Appraisal Committee/Council	
Key domains in assessment	- Clinical benefit assessment (DMC uses the PICO approach) - Cost analysis (total incremental costs to society per patient compared to SoC) (Amgros conducts economic assessment) - Budget impact analysis (Amgros conducts economic assessment)[3]	
Evidentiary requirements	Quality of the evidence addressed through the PICO approach. [5] No formal or informal lenience in evidence requirements for RDTs; RCTs and comparative data are preferred.	Informally, there may be leniency in evidence requirements; if the evidence is clear and strong, less may be accepted. If a specific patient in this programme diverts in any way from the included patients in the studies available, the case will be rejected.
PROMs	PROMs are not formally required or accepted, but depending on the case, an evaluation of treatment may be requested, which may include quality of life measures.	
Appraisal framework	- Added clinical benefit ranked in 7 categories (7th category recently implemented for products that wouldn't have a documentable added benefit, e.g. RDTs). Severity is not accounted for. - Decision is based on the ratio between clinical benefit and price , not cost/QALY.	
Reimbursement decision		
Pricing process	- Tender: if existing tenders exist (or therapeutic comparators) - Price negotiation: Amgros negotiates prices (for added benefit categories 1-4) and purchases pharma products on behalf of the 5 regions [3]	
Managed entry agreements		

Denmark	Standard reimbursement process (inpatient)	Named patient programme
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 ☐ Making arrangements to work for all stakeholders ☐ X Lack of long-term meaningful outcomes ☐ Other, please specify	
Impact of special processes		
Proposed policy change	Process currently changing - QALYs will be implemented in the assessment by the DMC.	
Joint initiatives		
SOURCES		
1	https://international.commonwealthfund.org/countries/denmark/	
2	Presentation by Sune Lindgaard at WODC, Barcelona Nov 2018	
3	http://www.amgros.dk/en/health-economics/new-medicines-and-new-indications/	
4	http://www.nordicinnovation.org/Documents/Programmes/Innovative%20Nordic%20Welfare%20Solutions/Health%20Technology%20Assessment%20(HTA)%20in%20the%20Nordic%20countries.pdf	
5	https://medicinraadet.dk/media/5139/process-and-methods-guide-join-regional-assessment-of-the-clinical-added-value-of-new-medicines-and-indications-002.pdf	

Created in September 2019 by the IMPACT-HTA team with the support of the country experts. Last updated in January 2020.

Acknowledgments: We would like to thank the country experts for their time and valuable contribution in providing the information used to create and validate this vignette. This research is funded under the EC's Horizon 2020 Programme within IMPACT-HTA. Results reflect the authors' views. The EC is not liable for any use of the information communicated.

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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