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
Orange = latest updates (last update in November 2020)

Norway	**Standard reimbursement and HTA process for pharmaceutical products**	**Standard reimbursement and HTA process for pharmaceutical products, special criteria for ultra-orphan drugs**
Overview of health system and P&R/HTA process	Tax based health system [1] The Norwegian Medicines Agency (NOMA) conducts HTA and makes reimbursement decisions on drugs to be provided by the National Insurance Scheme (NIS) for outpatient drugs. The Decision Forum is composed of 4 directors from each of the 4 regions. They make national decisions for inpatient drugs, which are covered by hospital budgets. The HTA by NOMA forms the basis for this decision making process. As of 01.02.2019, all RDTs will undergo the hospital route, as prescribed by hospitals or specialists. They will be financed by hospitals. [3]	
Differentiation of rare disease treatments in the P&R system	Rare diseases defined as ≤ 1/2,000 (this has been recently changed in 2019 from ≤1/10,000). For HTA, the only differentiation made is for ultra-rare diseases, which fulfil the 3 following criteria: ≤1 per 100 000 or 50 patients in Norway (whole population for the medicine); severe condition, min. 30 QALYs lost; high expected QALY gain, min. 2 QALYs incremental QALYs gained.	
Eligible medicines	All new products and indications (inpatient and outpatient)	Ultra-rare diseases, which fulfil the 3 following criteria: ≤1 per 100 000 or 50 patients in Norway (whole population for the medicine); severe condition, min. 30 QALYs lost; high expected QALY gain, min. 2 QALYs incremental QALYs gained
Process	When a new drug comes on the market, the Directory of Health suggests on pathway (in or outpatient). From 01.02.2019, all rare disease treatments will undergo the hospital route. All new products will undergo an STA by NOMA. [3]	Same process as standard process, with the main difference being less stringent requirements with regards to the relative effect documentation.

Norway	Standard reimbursement and HTA process for pharmaceutical products	Standard reimbursement and HTA process for pharmaceutical products, special criteria for ultra-orphan drugs
	Process overview: - Manufacturer prepares documentation and economic model and submits proposal - Authorities critically assess submitted documentation (dialogue with local and regional clinical experts, NOMA, Norwegian Directorate of Health) - Process is regulated by EU's Transparency Directive, which gives deadline of 180 days - The submission assessment by NOMA is conducted within 180 days, while the Decision Forum does not have an official deadline [4]	
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	NOMA involves clinical experts when evaluating the dossier, and patient organizations where possible/appropriate to help answer specific questions. Non-disease specific experts sit within the Decision Forum (one from each health region), a patient rep also sits on Decision Forum but has no formal vote.	
Key domains in assessment	- Clinical benefit - Cost-effectiveness - Budget impact - Other	
Evidentiary requirements	Less stringent requirements with regards to the relative effect documentation. Depending on the disease in question, they might accept non-randomized, surrogate outcomes, etc. This depends on the nature of the disease. E.g. For some diseases, it might not be ethical to have a placebo-arm, so they might accept a single-arm trial compared to natural history data. If the quality of data is lacking, however, they might not be able to use the trial data in the assessment. Each case has different circumstances and they have to do an overall assessment.	
PROMs	Preference for EQ-5D-3L. If EQ-5D not available, other HRQoL data from other instruments have to be mapped to EQ-5D. When relevant, caregivers can also be included.	

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Appraisal framework	Decision making criteria: - Severity - Utility - Resource use + modifiers (budget impact and certainty) Willingness to pay increases or decreases accordingly (e.g. lower WTP for higher budget impact). Budget impact/outpatient: if > NOK 100 million, NOMA cannot decide for NIS coverage. NOMA will make a recommendation to the MoH, who would need to find the funds and get approval from Parliament (time-consuming process). Outpatient: NOMA does not have a fixed threshold. Minimum is NOK 275,000/WALY (lower severity), maximum is ~NOK 825,000/QALY (would increase with decision-making criteria).	Same. Higher WTP accepted (threshold not public).
Reimbursement decision	The decision made is whether to grant public financing (unrestricted) or not (fully restricted)	
Pricing process	Outpatient: maximum price based on IRP used in CEA model and listed as official price. Price negotiations to agree on real price. Inpatient: tendering (if national tender exists, e.g. when therapeutic comparators, CEA not considered) or price negotiation based on NOMA assessment and maximum price based on IRP. Price would be negotiated, then CEA would be recalculated based on new price.	
Managed entry agreements	- Confidential discounts - Outcome-based scheme to collect additional evidence for later reassessment NB. only nusinersen has been evaluated under this scheme. Usually only flat discounts accepted (for ease of management). This might change in the future, but no more information can be provided at this point of time. All ultra-rare HTA are subject to close monitoring and data/evidence generation and possible re-evaluation.	
Impact of special processes	The definition of rare diseases has changed from 1 per 10,000 to 1 per 2,000 (change made in 2019). This change, however, has had very little impact on the assessments	

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Proposed policy change	None foreseen	
Joint initiatives	FINOSE (a Nordic cooperation, joint assessment reports for pharmaceutical products that contain both relative clinical and health economic assessments); International Horizon Scanning Initiative.	
SOURCES		
1	https://international.commonwealthfund.org/countries/norway/	
2	http://www.nordicinnovation.org/Documents/Programmes/Innovative%20Nordic%20Welfare%20Solutions/Health%20Technology%20Assessment%20(HTA)%20in%20the%20Nordic%20countries.pdf	
3	https://legemiddelverket.no/Documents/English/Price%20and%20reimbursement/Application%20for%20reimbursement/Guidelines_april_2018.pdf	
4	https://nyemetoder.no/Documents/Administrativt%20(brukes%20kun%20av%20sekretariatet!)/System%20Description%20(23012014).pdf	

Created in February 2019 by the IMPACT-HTA team with the support of the country experts. Last updated in November 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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