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

Sweden	**Standard reimbursement and HTA process (outpatient)**	**Standard reimbursement and HTA process, special criteria for rare disease treatments**	**Standard reimbursement and HTA process (inpatient)**
Overview of health system and P&R/HTA process	Tax based system [1] At national level, the MoH and Social Affairs is responsible for the overall health and health care policy. At the regional level, 21 regional bodies are responsible for financing and delivering services to citizens. At the local level, municipalities are responsible for elderly care and care for the disabled (which also includes younger persons, e.g. personal assistance or home care). [1] Sometimes these services are included in an HTA assessment if they are concerned with a new treatment. The Dental and Pharmaceutical Benefits Board (TLV) conducts HTA for out- and inpatient drugs, and decides on reimbursement of outpatient drugs by 21 regional bodies. National positive list used. For inpatient drugs, regional bodies are in charge of their procurement. NT council is involved (not a government organization; regional councils cooperate by forming this council) for the recommendations. As of January 1st 2019, County Councils have been replaced by Regional bodies		
Differentiation of rare disease treatments in the P&R system	Yes, to some degree. The TLV has taken rarity of disease into account in a few cases, so far. No official definition of RDTs. Rare disease treatments considered as affecting approximately < 2 per 100,000 (still a work in progress - not strict definition; have not indicated how rare diseases have to be).		
Eligible medicines	All new outpatient drugs and indications, as well as reviews of older drugs.	In & outpatient drugs that have a good potential to being an effective treatment for very severe conditions, very rare conditions (approx. 1-2/100,000).	All new inpatient drugs and indications.

Sweden	Standard reimbursement and HTA process (outpatient)	Standard reimbursement and HTA process, special criteria for rare disease treatments	Standard reimbursement and HTA process (inpatient)
Process	- Application from company. - Questions for clarifications to the company - Investigation by TLV (contact with external experts if needed) - Memorandum to the company - Company has the possibility of having a discussion with the committee if the suggested decision in the memorandum is unfavourable for the company - Decision by the committee - Possibility to appeal to the court (decided by the company) [2]	If eligible, additional criteria would be accounted for during the assessment by TLV.	- The regional bodies may ask TLV for an assessment. - When TLV has made the assessment, a group called the Council for new therapies (NT-Council), issues a recommendation to the regions whether to use the drug or not (and for which patients) NB. Prescribers can over-rule decisions made by regions.
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	- Clinical expert opinions are collected - Patients may be invited to meetings to collect additional feedback when uncertainty exists (meetings to discuss clinical aspects with patients don't happen often, more likely to be with physicians. Patients are mostly informed in separate meetings about what is happening) - Patient representative on board, but not disease specific - Non-disease experts (patient or clinical rep) may sit in Committee (usually a same member out of 6-7 members)		- Clinical expert opinions collected - Patients may be invited to meetings to collect additional opinions
Key domains in assessment	- Cost-effectiveness (cost/QALY, societal perspective - but productivity gains/losses are not considered) - Clinical effectiveness - Severity of condition		- Same as outpatient if HTA requested

Sweden	Standard reimbursement and HTA process (outpatient)	Standard reimbursement and HTA process, special criteria for rare disease treatments	Standard reimbursement and HTA process (inpatient)
Evidentiary requirements	More leniency given to RDTs. More informal. Currently no document where it's clearly written how to do this. Lots of ongoing discussions currently. Long term effect: often they're willing to accept even if they have a short follow up in their clinical trial. Number of treated patients in the trial also has more leniency.		
PROMs	Preference for EQ5D from patients to populate the QALY		
Appraisal framework	ICER + severity (The maximum accepted ICER increases with more severe diseases), no fixed threshold.	A higher maximum ICER is accepted (if it has good potential of being a very effective treatment) *This is a work in progress, only a few decisions have actually been made so far).	NT council apply same criteria as TLV (but have a document that describes their exact criteria).
Reimbursement decision	The decision can be either of: • Reimburse without restrictions, • Reimburse with restrictions or • Don't reimburse. In addition, different kinds of CEDs (coverage with evidence developments) or MEA (market entry agreements) can be decided.		NT councils: give recommendations, but the regions make the decision (don't have to follow recommendation). Ultimately the prescriber makes the decision (a region can pressure the prescriber not to prescribe). Drug in hospital always completely free.
Pricing process	Value-based pricing (captured within the ICER)	Same as outpatient or inpatient	Procurement or price negotiation
Managed entry agreements	- Confidential discounts - Other, RSA e.g. based on treatment length		

Sweden	Standard reimbursement and HTA process (outpatient)	Standard reimbursement and HTA process, special criteria for rare disease treatments	Standard reimbursement and HTA process (inpatient)
Main challenges in appraising medicines for rare diseases	- Lack of good quality clinical data - Introducing value for money (cost justification) – some drugs with very high ICER may have a very high unmet need - Lack of long-term meaningful outcomes, e.g. extrapolation, assumptions being made		
Impact of special processes	TLV have just recently started to consider rarity, and so far have very little experience. At least in one case the new policy has allowed reimbursement of one drug that wouldn't have been reimbursed otherwise.		
Proposed policy change	They continue to develop their process and gain experience on how the new policy works		
SOURCES			
1	https://international.commonwealthfund.org/countries/sweden/		
2	Personal communication with TLV, PhD thesis E Nicod		

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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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