Scope of vignette:
- authorised products (with marketing authorisation)
- decision process about routine use (and not individual requests for reimbursement)
- submissions for P&R

Green = related to/any special considerations for rare disease and ultra-rare disease treatments

Finland	**Standard HTA process (non-orphan drugs) – outpatient**	**Standard HTA process (non-orphan drugs) - inpatient**
Overview of health system and P&R/HTA process	Primarily tax based health system [1] - the model of funding is multichannel. The reimbursement for outpatient medicines is paid by the Social Insurance Institution 'Kela'. The costs of hospital-medicines are covered by counties. The Pharmaceuticals Pricing Board takes decisions on outpatient medicinal products included in the drug reimbursement system, and their wholesale prices and reimbursement categories. The secretariat of the Pharmaceuticals Pricing Board is responsible for reviewing the applications submitted by the MAH and summarizing them for the Board's decision-making. [2] Finnish Medicines Agency (Fimea) produces and compiles assessments of the therapeutic and economic value of medicines and coordinates the related collaboration. The focus of Fimea's HTA activities is on the assessment of new hospital-only medicinal products. Fimea also has licensing and supervisory authority. The Council for Choices in Health Care in Finland (COHERE Finland) issues national recommendations on the new hospital-only medicinal products (or extensions of therapeutic indications) assessed by Fimea. [3] Marketing authorisations are granted by European Commission, and the Committee for Medicinal Products for Human Use (CMPH) of the EMAissues a scientific opinion on whether the medicine may be authorised or not. [4] Fimea is the national competent authority in the EMA's regulatory network. The national HTA coordination unit (FinCCHTA) coordinates Health Technology Assessment (HTA) in Finland, and cooperates with international HTA bodies. [5]	
Differentiation of rare disease treatments in the P&R system	None	
Eligible medicines	Any (outpatient) medicinal products with marketing authorization	New hospital-only medicinal products. The following criteria are considered in the prioritisation of the topics:

Finland	Standard HTA process (non-orphan drugs) – outpatient	Standard HTA process (non-orphan drugs) - inpatient
		• Prevalence, severity and disease burden of the health problem • Economic impact of the intervention • Anticipated effects of the intervention on the treatment practices of the health problem concerned • Possibility to produce assessment data on a timely basis
Process	- The HTA process is submission based, initiated by the MAH. - An expert group (max seven members) operates in connection to the Pharmaceuticals Pricing Board. The group must include members with expertise from the fields of medicine, pharmacology and health insurance services. The expert group provides opinions, but does not make decisions. Prior to making a decision, the Pharmaceuticals Pricing Board may request the expert group for an opinion on an application. - The secretariat of the Pharmaceuticals Pricing Board is responsible for reviewing the applications submitted by the MAH and summarizing them for the Board's decision-making. When necessary, and especially when the application comprises a health economic evaluation, the Pharmaceuticals Pricing Board requests an opinion from the Social Insurance Institution. - The Pharmaceuticals Pricing Board makes decisions on the reimbursement status and wholesale price of medicinal products. The criteria for the appraisal is based on legislation. [6] - The approved reimbursement status and wholesale price are publicly available. - There is an appeal process in the case of a negative decision. - The process timeline complies with the EU Transparency directive	- Fimea follows the positive opinions issued by the CHMP of the EMA on a monthly basis and selects topics that are suitable for the assessment of hospital-only medicinal products. - The assessment of inpatient medicinal products is initiated by Fimea. At the beginning of the assessment, Fimea sends the MAH a request for information. If the MAH decides not to submit evidence, Fimea proceeds with the assessment based only on the publicly available documentation. - No committees are involved in FIMEA's HTA process. COHERE has a pharmaceutical division. - Fimea writes the assessment report, using all available materials (clinical trials, RWE, CEA, etc.) - COHERE Finland issues national recommendations on the new hospital-only medicinal products. The criteria for appraisal is based on legislation. - The assessment report is publically available and open to comments. - The HTA-report is published on Fimea's web page. The national recommendation is published on COHERE's web page. - There is no appeal process in the case of a negative decision.

Finland	Standard HTA process (non-orphan drugs) – outpatient	Standard HTA process (non-orphan drugs) - inpatient
		Overview of timelines: • **Initiation of assessment**: CHMP positive opinion. The assessment is initiated in such a manner that its outcomes are available as soon as possible after the marketing authorisation has been granted. • **Request for information:** the Company will be allowed four weeks for submitting its responses to Fimea's request for information. In case CEA material is submitted, eight weeks will be allowed. • **Assessment phase:** no official timelines. Usually takes 1 - 2 months from the company's evidence submission. • **Checking for confidential information:** The Company will be allowed two weeks to note on the draft any previously unpublished information the Company considers confidential, or declare that the draft does not contain any confidential information. • **National recommendation:** after Fimea's HTA-report is published.[6]
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	The applicant may attach expert opinions to the application. Patient organisations have the opportunity to submit statements. When necessary, the Pharmaceuticals Pricing Board may request expert opinions on applications.	A clinical expert(s) is involved in the assessment, primarily in defining the scope of the assessment and commenting the draft report. Comprehensive Cancer Center Finland (FICAN) is the contact point for identifying clinical experts for oncology products. Finnish Coordinating Center for Health Technology Assessment (FinCCHTA) or relevant clinical expert are contacted if the assessment topics need to be prioritised.
Key domains in assessment	-Therapeutic value (please see appraisal framework below) - Reasonable wholesale price (please see Pricing process below)	-Clinical effectiveness and safety - Cost effectiveness -budget impact - Other (ethical, organisational, social or legal) [4]

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Evidentiary requirements	Assessed case-by-case. There is no leniency in evidence requirements for RDTS is defined in the legislation.	Assessed case-by-case. There is no leniency in evidence requirements for RDTS defined in Fimea's HTA documentation or legislation guiding the work of COHERE.
PROMs	It's stated in the application instructions for health economic evaluation, that the outcomes should primarily be measured using QALYs. The measurement HQoL is preferably done using generic QoL-instrument. No additional PROM requirements have been stated.	No PROM requirements defined in Fimea's HTA documentation or legislation guiding the work of COHERE.
Appraisal framework	In addition to the key domains, the following are included in the appraisal: Reimbursement status: • Application, evidence and documents by MAH • Other publicly available evidence, appraisals and recommendations • Statements/consultations: Social Insurance Institute (Health economic assessment), Expert Group, Patient Organizations, Societies of medical specialties • Description of technology • Health problem and current use of technology • Target patient population and sub-groups • Patient exposure in clinical trials and routine clinical practice The assessment, appraisal, price negotiations and decision are made within the same process in the Health Insurance Act, section 6. [7]	The appraisal of evidence is done by COHERE. Their work is guided by Health Care Act.
Reimbursement decision	The possible decisions are: - Basic reimbursement status, or - Special reimbursement status Both can be restricted to a certain population within the approved indication. Conditional	COHERE issues recommendations. The recommendations may include clinical criteria or other conditions.

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	reimbursement (MEA) can be a part of the decision. [7]	
Pricing process	Reasonable wholesale price is based on: • Relative benefits and costs, cost-effectiveness • Sales estimates, market forecasts, number of patients • Prices in EEA countries The criteria for reasonable wholesale price are mentioned in the Health Insurance Act chapter 6, section 7. [7]	The procurement and price negotiations are the responsibility of hospitals or hospital districts.
Managed entry agreements	Outpatient: As a part of conditional reimbursement. No restrictions on the type of agreement MAH can propose have been issued. All of the agreements, however, have been financial. Inpatient: there is limited information on the use of MEAs in Finnish hospitals. Simple discounts are common and other types of financial agreements are also in use. So far there is little experience with outcome based agreements.	
Main challenges in appraising medicines for rare diseases (tick all that apply)	x Lack of good quality clinical data x Lack of real world data x Introducing value for money x Monitoring treatment efficacy x Managing budget impact x Lack of criteria/transparency of OMP P&R processes x Making arrangements to work for all stakeholders x Lack of long-term meaningful outcomes	
Impact of special processes	N/A	
Proposed policy change	None	
Joint initiatives	Nordic collaboration: A memorandum of understanding has been signed by the Director Generals of Fimea, NoMA and TLV, to formally start collaboration between the three authorities. [4] EUnetHTA	
SOURCES		
1	http://www.euro.who.int/__data/assets/pdf_file/0011/355979/Health-Profile-Finland-Eng.pdf?ua=1	

Finland	Standard HTA process (non-orphan drugs) – outpatient	Standard HTA process (non-orphan drugs) - inpatient
2	http://www.hila.fi/en/	
3	https://www.fimea.fi/web/en/development/therapeutic_and_economic_value_of_medicines	
4	https://www.fimea.fi/web/en/development/therapeutic_and_economic_value_of_medicines/assessment-of-hospital-only-medicinal-products	
5	https://www.ppshp.fi/Tutkimus-ja-opetus/FinCCHTA/Sivut/In_other_languages.aspx	
6	http://www.hila.fi/en/operations-and-organisation/legislation	
7	http://www.hila.fi/c/document_library/get_file?folderId=238847&name=DLFE-10815.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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