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

Latvia	**Standard process (non-orphan drugs)**
Overview of health system and P&R/HTA process	Tax based health system [1] National Health Service (NHS/NVD) creates and maintains the list of reimbursable medicines, and makes reimbursement decisions. Rare Diseases Coordination Centre coordinates the doctors' consortiums to make the decision on reimbursement of the specific medicine to concrete patients. Positive list used [2] A process exists for individual patient reimbursement. The state budget sub-programme for treatment of children suffering rare diseases is separated from the reimbursement budget. Decision on funding is made by the Ministry of Health and approved by the Cabinet of Ministers. Treatment process is supervised by the Children's Clinical University Hospital.
Differentiation of rare disease treatments in the P&R system	EMA orphan designation
Eligible medicines	All new drugs [5]
Process	- Application submitted to State Agency of Medicines (SAM) to conduct medical and economic assessment - SAM conducts medical and economic assessment In assessing an application, the SAM conducts the following activities: *Medical assessment*: - Results of published clinical trials on therapeutic efficacy in comparison with another available types of medical treatment; - Compliance with the schemes developed by professional physicians' associations and international medical treatment guidelines; - Place of the drug in the treatment scheme of the particular disease; - Correspondence of the drug and strength with the treatment scheme;

Latvia	Standard process (non-orphan drugs)
	- Correspondence of the size of the packaging with the course of treatment; *Economic assessment:* - Treatment expenses; - Therapeutic efficacy and costs of the drug in comparison with another type of available treatment in accordance with the economic assessment guidelines of medicinal products approved in Annex 3 to the Regulation. [2] - Application submitted to NVD, including the SAM's conducted assessment results - NVD negotiates price with applicant, taking into account prices of the particular medicinal product or medical device in other countries - NVD makes final decision, determines reimbursement rate and sets price - Drug is added to reimbursement list [7]
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	During medical assessment the SAM evaluates the compliance of application with the schemes developed by professional physicians' associations for the treatment of specific diseases.
Key domains in assessment	- Clinical effectiveness - Cost effectiveness
Evidentiary requirements	RCT data preferred [3], but there is greater impact of the decisions of doctors' consortiums (formally, according to regulations).
PROMs	None
Appraisal framework	In addition to key domains, the following criteria are considered: - Safety - Potential impact and efficiency - Influence of technology on patients' health and quality of life - Professional ethics [6] - Therapeutic added value
Reimbursement decision	3 possible lists for reimbursement: List A: medicinal products of equal therapeutic efficacy within scope of common medicinal product name List B: medicinal products that do not comply with criteria applicable for List A List C: medicinal products that exceed 4268.62 euro per patient per year

Latvia	Standard process (non-orphan drugs)
	Additional List M: medicinal products reimbursable within the scope of the reimbursement procedures, which are used by pregnant women, women during the period following childbirth up to 70 days and children up to the age of 24 months, but which are not included on the list of reimbursable medicinal products. [2] 3 reimbursement categories: - Category I: 100% reimbursement, or amount of reference price of relevant group - Category II: 75% reimbursement, or 75% of reference price of relevant group - Category III: 50% reimbursement, or 50% of reference price of relevant group [2] The expenditures for the acquisition of the List M medicinal products shall be covered, applying the following reimbursement categories: - reimbursement in the amount of 50 % for a child up to the age of 24 months, if a diagnosis with another amount of reimbursement has not been determined for him or her; - reimbursement in the amount of 25 % for a pregnant woman or a woman during the period following childbirth up to 70 days, if a diagnosis with another amount of reimbursement has not been determined for her. [2] The drug is included in the contract with the NHS by a decision of a Commission established by the Rare Disease Coordination Centre, based on **the decision of the doctors' consortium** and the evaluation of medicines by the SAM in accordance with the legislation on the reimbursement of expenditures for the acquisition of medicinal products and medical devices for outpatient treatment; taking into account the state budget allocated for the treatment of rare diseases.
Pricing process	Internal reference pricing is applicable for the List A of reimbursable medicines and medical devices. External reference pricing is applicable for all reimbursable medicines: the price of reimbursable medicinal products or medical devices shall not be higher than the third lowest sales price of the manufacturer and the price of the wholesale trade of the medicinal products or medical devices in the Czech Republic, Denmark, Romania, Slovakia, Poland and Hungary and shall not exceed the sales price of the manufacturer and the price of the wholesale trade of the medicinal products or medical devices in Estonia and Lithuania. The applicant shall, each year by 1 February, submit electronically to the National Health Service the information on the current prices of medicinal products (EUR) in the abovementioned countries and indicate them also in the currency of the relevant country, if necessary [2]
Managed entry agreements	- Confidential discount - Budget cap - Outcome based scheme to collect additional evidence for later reassessment

Latvia	Standard process (non-orphan drugs)
Main challenges in appraising medicines for rare diseases (tick all that apply)	☐ Lack of good quality clinical data ☐ Lack of real world data ☐ Introducing value for money ☐ Monitoring treatment efficacy ☐ Managing budget impact ☐ Lack of criteria/transparency of OMP P&R processes ☐ Making arrangements to work for all stakeholders ☐ Lack of long-term meaningful outcomes X all above-mentioned (more or less), as well as the common insufficient funds for reimbursement
Impact of special processes	In 2017, 82 registered children suffering rare diseases were treated in amount of 1 960 203 euros by the separate state budget subprogramme (outside of the standard reimbursement procedure). [8]
Proposed policy change	In accordance with the Plan on Activities in Field of Rare Diseases [4] the main proposed changes related to the medication are defined as following: 1) multidisciplinary approach and coordination in order to improve diagnostic process and choose the most appropriate medication (medicines, medical devices, nutrition); 2) improvement of the patients' pathways; 3) implementation of the separate budget subprogramme for rare diseases (for adults – the same as the current sub-programme for children) The amount of allocated state budget remains topical for implementation of these changes
Joint initiatives	MEDEV (collaboration)
SOURCES	
1	http://www.vm.gov.lv/en/health_care/
2	https://likumi.lv/ta/en/en/id/147522-procedures-for-the-reimbursement-of-expenditures-for-the-acquisition-of-medicinal-products-and-medical-devices-intended-for-the-outpatient-medical-treatment
3	https://www.eunethta.eu/wp-content/uploads/2018/02/WP7-Activity-1-Report.pdf
4	https://likumi.lv/ta/id/294448-par-planu-reto-slimibu-joma-2017-2020-gadam
5	https://tools.ispor.org/PEguidelines/countrydet.asp?c=2&t=1 --> https://tools.ispor.org/PEguidelines/source/Baltic-PE-guideline.pdf
6	https://www.hspm.org/countries/latvia08052014/livinghit.aspx?Section=2.7%20Health%20information%20management&Type=Section
7	Lativa Funding Process Flow Chart 01-Oct-13.pdf
8	http://www.vmnvd.gov.lv/uploads/files/5be423aed5aad.pdf
9	https://likumi.lv/ta/id/301399-veselibas-aprupes-pakalpojumu-organizesanas-un-samaksas-kartiba

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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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