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

Austria	**Standard process (non-orphan drugs) Outpatient (national)**	**Standard process (non-orphan drugs) Inpatient (regional)**
Overview of health system and P&R process	Social insurance based health system [1]. Health care, especially hospital care, is not only provided by the one standard national level process, but also across the 9 regions. Decisions on inpatient drug reimbursement are made by the regions. The Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz/ BMASGK) is the main policy-maker in health care at a federal level, and has overall responsibility for regulatory framework and policy making [1]. The Austrian Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG/ AGES Medizinmarktaufsicht) is subordinate to the BMASGK and is responsible for granting market authorizations of drugs and devices. Decisions on the inclusion of medicines for reimbursement in the out-patient sector are made by the Main Association of Austrian Social Security Institutions (HVB), based on recommendations of the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungs-kommission, HEK). An independent drug commission (Unabhängige Heilmittel-Kommission, UHK) within the BMASGK monitors the HBV and the HEK. The UHK acts as an appeal board for manufacturers and has the power to veto (but not overrule) any decisions taken in relation to reimbursement applications in the outpatient sector. For outpatient drugs there is a positive list: the ”Erstattungskodex (EKO)”. This includes also a negative list, which includes drugs not eligible for public reimbursement. HTA reports of medicines are only consulted on a rare basis [1, 2]. The central HTA body in Austria is the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA). [3, 4] In 2020, the Institute will be transferred to the Austrian Institute for HTA.	
Differentiation of rare disease treatments in the P&R system	There is no differentiation between non orphans and orphans, however, there is a differentiation between evidence and lack of evidence on patient-relevant endpoints - in relation to the price.	

Austria	Standard process (non-orphan drugs) Outpatient (national)	Standard process (non-orphan drugs) Inpatient (regional)
Eligible medicines	All outpatient drugs that apply for inclusion in drug list (EKO)	No systematic approach. Unsystematic: drugs with low evidence, high price, no alternatives (high publicity = pressure)
Process	Well defined process in EKO [5]	National and regional processes are in development
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	Yes	Yes: they are part of the regional drug commissions
Key domains in assessment	- Clinical effectiveness (Pharmacological analysis) - Cost-effectiveness (Health-economic considerations) - Budget impact (Economic considerations) [1, 2] (no formal thresholds)	
Evidentiary requirements	Data (clinical studies) from market authorization holder: submission-based evidence assessment Under public pressure ("Access to medicines", media coverage) lower quality evidence is accepted. Without public pressure: same level of evidence needed.	None required, but often int. HTAs (IQWIG most often) are used as basis for decisions Under public pressure ("Access to medicines", media coverage) lower quality evidence is accepted. Without public pressure: same level of evidence needed.
PROMs	If available	Not required, but in regional drug commissions PRO (patient RELEVANT, not so much reported) are taken into consideration.
Appraisal framework	- Applications are subjected to a pharmacological, medical-therapeutic and health economic evaluation [5] - Low evidence, high price (+ alternatives): no reimbursement.	- Regional expert-reference centres - No systematic framework - low evidence, high price (+ alternatives): no reimbursement.

Austria	Standard process (non-orphan drugs) Outpatient (national)	Standard process (non-orphan drugs) Inpatient (regional)
	- Low evidence, high price, no alternatives: risk-sharing agreements OR political solutions (specific funds). - Consider budget impact, severity + evidence on effectiveness	- Low evidence, high price, no alternatives: risk-sharing agreements OR political solutions (specific funds). - Consider budget impact, severity + evidence on effectiveness
Reimbursement decision	Conducted by HEK [6] Decision based on traffic light system: Green area: drugs that may be dispensed either in general or under certain conditions. Yellow area: drugs which have a significant additional therapeutic benefit for patients and which, for medical and / or health economic reasons, have not been taken into the green area of the EKO. Red area: limited period of time, drugs for which a complete application for admission to the EKO is available, pending a final decision on the application by the main association. [5]	Decisions on the inclusion of medicines in the in-patient sector (hospital) are made within the regional public hospital cooperations: Hospital drug commissions decide which drugs will be included on the drug lists. Decision processes are not public, nor are the regional drug lists.
Pricing process	Prices are negotiated with payers after reimbursement decisions between HVB and market authorization holder. Prices of non-reimbursable medicines are either calculated by the Ministry of Health advised by the PC via the method of the European Union average price, or notified by companies. These prices are maximum prices; therefore, medicines may be priced below. External reference pricing: Medicines included on the positive list have to be priced either according to the EU average price, as established by the PC, or below this price. Decisions on the reimbursement status are made by the HVB on the basis of recommendations of the HEK. The HVB decides in accordance to the Transparency Directive.	Negotiations on the regional level. All accepted inpatient drugs go through price negotiation, which occurs between regional hospitals (procurement) and market authorization holder. Prices are not public. High-cost drugs delivered or decided in hospitals: regional decisions, even if there will be national recommendations, the final decision stays with the payer/ hospitals. Standardized and transparent processes are still needed. [7]

Austria	Standard process (non-orphan drugs) Outpatient (national)	Standard process (non-orphan drugs) Inpatient (regional)
	Internal reference pricing for 'follower' medicines. Wholesalers are remunerated via a statutory regressive mark-up scheme applicable to all medicines. [2] There are also rules for setting the prices for generics.	
Managed entry agreements	None, only rebates	Increasingly conducted, but on regional agreements, not public/ not transparent
Main challenges in appraising medicines for rare diseases	X Lack of good quality clinical data X Lack of real world data X Affordability 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	None	Restrictions ("saying" no) are being implemented in some regions
Proposed policy change	With the BeNeLuxAIR agreement (supra-national negotiation for costly drugs) AND unequal access to high-priced orphan-drugs among regions (e.g. Spinraza) it became obvious that a national decision process needs to be set up. Different ideas are being discussed and piloted in 2018 and 2019. No formal decisions have been made yet.	Thresholds (3-6 months minimum in oncology is proposed) With the BeNeLuxAIR agreement (supra-national negotiation for costly drugs) AND unequal access to high-priced orphan-drugs among regions (e.g. Spinraza) it became obvious that a national decision process needs to be set up. Different ideas are being discussed and piloted in 2018 and 2019. No formal decisions have been made yet.
Joint initiatives	Supranational coop in BeNeLuxAIR	Prerequisite for supranational coop in BeNeLuxAIR is a national process in decision-making on costly drugs: this has started to be discussed and piloted
SOURCES		

Austria	Standard process (non-orphan drugs) Outpatient (national)	Standard process (non-orphan drugs) Inpatient (regional)
1	https://tools.ispor.org/htaroadmaps/Austria.asp#2	
2	Short_PPRI_PHIS_Pharma_Profile_Austria_2013_final_IS IT STILL ACTUAL	
3	Med Tech Report 2018_MTE_MTRC Research Paper Innovative Payment Schemes in Europe.pdf	
4	http://eprints.hta.lbg.ac.at/1183/1/HTA-Projektbericht_Nr.109.pdf	
5	http://www.hauptverband.at/cdscontent/?contentid=10007.693800&viewmode=content	
6	https://www.sozialversicherung.at/cdscontent/?contentid=10007.742110&viewmode=content	
7	http://eprints.hta.lbg.ac.at/1183/1/HTA-Projektbericht_Nr.109.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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