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

Iceland	**Medicine pricing and reimbursement**	**Specialty care high-cost medicines pricing and reimbursement (since May 2014) (L marked)**

Overview of health system and P&R/HTA process	Tax based health insurance system. Everyone is insured.
	
	The Icelandic Medicine Pricing and Reimbursement Committee (IMPRC) is an independent committee: Ministry of health appoints the Chairman, one member is appointed by the Ministry of Finance, one by the State reimbursement insurance company, one by the Directorate of Health, and one by the Icelandic Medicines Agency – this Committee also has people working on it in charge of preparing the matters that committee decides on.
	
	The IMPRC makes decisions on [1]:
	- reimbursement (general and individual)
	- wholesale pricing (max price of medicines)
	- specialty care high-cost medicines (inclusion on reimbursement list according to criteria for use)
	- retail pharmacy markups
	
	State insurance then pays according to the reimbursement decision
	
	Possible reimbursement pathways:
	- **General reimbursement** (G marked)– general medicines (e.g. prescribed by a GP) sold in pharmacies (patients pay and request reimbursement), e.g. high blood pressure, depression
	- **Hospital medicines** (S marked) (if administered in hospital, free of charge to patients)
	  o Hospital products provided at home are also paid in full by the hospital
	  o No application needed for reimbursement as the hospital decides whether to use. Committee decides its max price and hospital then decides on price setting (tenders, contracts) mechanisms. These drugs are reimbursed through a special budget (budget for S marked medicines).
	- **Special care high-cost medicine** (L marked): new cancer medicines, very broad definition for this category. If committee says yes, indication (could decide to reimburse only one indication) => free of charge, reimbursed to the hospital
	  o L marked medicines undergo the same price setting process and funding as S marked processes.
	- **Named basis programme:** doctors can apply for reimbursement for medicines that are not reimbursed, and have to justify why it is appropriate – request would be made to the Committee the first time on the criteria to decide. E.g. Migraine drug – reimbursement for	

Iceland	Medicine pricing and reimbursement	Specialty care high-cost medicines pricing and reimbursement (since May 2014) (L marked)
	patients who would not respond to other treatment. State medicines agency follows with that criteria [Codes in medicine pricing catalogue] Rare disease treatments may fall in any of the above pathways Reimbursement process for all medicines and specialty high-cost medicines are detailed below.	
Differentiation of rare disease treatments in the P&R system	None	
Eligible medicines	All new medicines (general medicines)	Costly, difficult to administer, only to be used according to clinical guidelines. Should fulfil some of the following conditions: e.g. pill for cancer. Where is the knowledge to treat cancer? In-hospital – L or S marked may not be difficult to administer, but specialty would be needed for special knowledge or high cost. P&R are different paths. Can apply for price but not reimbursement. Reimbursement only by individual permit with price. If new cancer, high-cost specialty care, doctor would want to prescribe it. Patient would pay all OR named patient programme, but committee would probably say no as they would want reimbursement request for specialty care/high cost.
Process	MAH submits an application (submission is mandatory)	MAH submits an application Price and reimbursement applied for at the same time. • L marked medicines can only get reimbursement with the application of cost-effectiveness and clinical effectiveness. Both are published on their website. MAH can submit HTA done in other countries (but not required). They submit an application, the Committee makes assessment with

Iceland	Medicine pricing and reimbursement	Specialty care high-cost medicines pricing and reimbursement (since May 2014) (L marked)
		the help of the Icelandic hospitals for the clinical assessment, and the State Insurance for the cost-effectiveness assessment. • They deliver their assessments of the applications, and the Committee document the pros/cons discussed during 2-3 committee meetings. • The Committee then makes the final decision on reimbursement (price – company may have contacted hospital to agree on price – if no contract with hospitals, the price would be the max price in CEA model)
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	For G marked products, sometimes ask for opinion of doctors association. Patient groups are not usually involved. Patients can express concerns and send letters to committees regarding new treatments available, but no formal process.	Experts within the hospital who would make the clinical assessment of the medicine are involved. Patient groups are not usually involved. Patients can express concerns and send letters to committees regarding new treatments available, but no formal process.
Key domains in assessment	- Clinical effectiveness - Cost-effectiveness - Budget impact - Other [1]	
Evidentiary requirements	Committee has little resources. They look at what the other Nordic countries (DK, SW, NO) have done. Not the first country to process reimbursement applications. No strict assessment of clinical trials. Adapting resource use to Icelandic environment – new medicines for very small patient populations in Iceland, so would not be cost-effective to ask for specific requirements reflecting Iceland. They review the documentation and aim to make an assessment of full picture.	
PROMs	None	Not required, but if included accounted for.
Appraisal framework	The evaluation is based on [1]: - Safety	The evaluation is based on [1]:

Iceland	Medicine pricing and reimbursement	Specialty care high-cost medicines pricing and reimbursement (since May 2014) (L marked)
	- Clear indication and place in therapy - Price relative to efficacy and in comparison to already reimbursed drugs - Budget impact – how many patients for how long - Reimbursement in Denmark, Norway, Sweden and Finland	- Price relative to efficacy and in comparison to already reimbursed drugs - Budget impact – how many patients for how long - Clinical and economic evaluation and decision done in cooperation with the University hospital and Icelandic Health Insurance (but no cost-effectiveness threshold, assessed case by case)
Reimbursement decision	Positive list (reimburse or don't reimburse within G list)	Positive list (reimburse or don't reimburse within L list)
Pricing process	The Committee determines maximum price at wholesale and retail levels. Discounts can be given from retail price. **Original products:** Price compared to average price of corresponding original product in reference countries (Nordic countries). **Hospital products and specialty care high-cost medicines (S and L lists):** Price compared to lowest price in reference countries (Nordic countries) = maximum price in Iceland [1]. Low budget impact drugs can apply for 15% more than lowest Nordic price (~$30,000/year). Maximum prices are in catalogue in English (hospitals would not include tender/negotiated prices; G mark publish max and discounted prices for pharmacies).	
Managed entry agreements	None - No resources to monitor effectiveness	
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 Other: Main challenge is getting MAH to market their products in Iceland / through official channels (avoid exemptions)	
Impact of special processes	No known impact, treated the same as other high price medicine with potentially high budget impact	
Proposed policy change	None	

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Joint initiatives		
SOURCES		
1	Icelandic Medicine Pricing and Reimbursement Committee, June 2016	

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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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