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

Ireland	**Standard process (non-orphan drugs)**
Overview of health system and P&R/HTA process	Tax based health system [1] National level: The Health Service Executive (HSE) is responsible for decisions regarding the reimbursement of new drug technologies. The Corporate Pharmaceutical Unit (CPU) of the HSE commissions the National Centre for Pharmacoeconomics (NCPE) to appraise new medicines following receipt of an application for reimbursement. [2]
Differentiation of rare disease treatments in the P&R system	None
Eligible medicines	- New active substances (including orphan designation from EMA) - New indications for currently reimbursed drugs - Drugs that are already reimbursed by the HSE, and are associated with high expenditure or uncertain clinical benefit. [3]

Process	NCPE uses a two-step process to make recommendations and minimise time to market access: 1. Following the receipt of a positive opinion from the CHMP, all medicines go through a preliminary Rapid Review (4 weeks). 2. Products with a high cost relative to potential comparators and/or net impact on the drugs budget, or where there is uncertainty regarding comparative clinical efficacy and/or value for money, will be subjected to a formal health technology assessment (HTA)(90 days). 3. After formal HTA, a full appraisal report with NCPE conclusions and recommendations is sent to the HSE Corporate Pharmaceutical Unit (HSE-CPU) to support evidence-based decision-making on reimbursement. For oncology drugs, the report is also sent to the National Cancer Control Programme (NCCP). A technical (public) summary and a plain language summary are published on the NCPE website. 4. Decisions on drug reimbursement are then made by the HSE, based on set criteria, described in Schedule 3, Part 3 of the Health (Pricing and Supply of Medical Goods) Act 2013. [3, 4] Process details: - NCPE compiles an independent assessment report for the HSE. - The NCPE report outlines the background to the decision problem, documents the evidence submitted to the NCPE by the applicant, and presents the outcomes of the NCPE's assessment of the submission and available evidence. - The NCPE report highlights the strengths and weaknesses of applicant submissions in addressing the decision problem, and highlights any relevant gaps or uncertainties in the evidence base. [5]
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	A Rare Diseases Technology Review Committee (RDTRC) has been established in Ireland since late 2018. The role of the Committee is to enable clinicians and other stakeholders (e.g. patients) to have input in the assessment process in the post HTA phase, and to review proposals in relation to MEAs. The committee provides input on recommendations and /or guidelines to the decision maker (Health Services Executive (HSE)). This process is intended for orphan drugs, excluding orphan oncology drugs, and could be viewed as an add-on to the existing appraisal process. It operates after the NCPE has conducted the HTA, and in response to specific requests made by the HSE.
Key domains in assessment	The outcome of the NCPE appraisal process addresses 3 out of 9 criteria, which are specified in the Health (Pricing and Supply of Medical Goods) Act 2013 [3]: - Comparative effectiveness (efficacy, effectiveness and added therapeutic benefit) - Cost-effectiveness, and - Budget impact
Evidentiary requirements	There is no leniency in evidentiary requirements for RDTs

PROMs	The use of generic preference based methods such as the EQ-5D-3L is recommended to measure utilities [6]
Appraisal framework	Besides the NCPE's 3 criteria, the HSE also considers an additional 6 criteria: - Health needs of the public - Proposed costs, benefits and risks of the item or listed item relative to therapeutically similar items, and the level of certainty in relation to the evidence of those costs, benefits and risks - Availability and suitability of the drug for supply and reimbursement under the current schemes - Clinical need for the drug - Availability of the appropriate level of clinical supervision to ensure patient safety - Resources available to the HSE [4]
Reimbursement decision	There are four possible recommendations: **1. The NCPE recommends that [Medicine] be considered for reimbursement*** A HTA of the medicine has been conducted. The NCPE recommends that the HSE consider providing the medicine. The NCPE believes the medicine may work as well or better than other ways of managing the indicated condition, and believe the medicine is value for money. The HSE considers a number of factors along with the NCPE recommendation when deciding whether to provide the medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013. **2. The NCPE recommends that the medicine be considered for reimbursement if cost-effectiveness can be improved relative to existing treatments*** The NCPE has completed a full HTA for the medicine. The NCPE recommends that the HSE consider providing the medicine if the HSE can agree a suitable price reduction with the pharmaceutical company. The NCPE believes the medicine may work as well or better than other ways of managing the indicated condition. However, the price of the medicine is too high compared with other ways to manage the condition, and the NCPE believes that the medicine is not value for money. The HSE considers a number of factors along with the NCPE recommendation when deciding whether to provide this medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013. **3. The NCPE recommends that the medicine not be considered for reimbursement unless cost effectiveness can be improved relative to existing treatments*** The NCPE has completed a full HTA for the medicine. The NCPE recommends that the HSE consider **not** providing the medicine unless the HSE can agree a suitable price reduction with the pharmaceutical company. This is because the NCPE believes the medicine may work as well or better than other ways of managing the indicated condition. However, the price of the medicine too high compared with other ways to manage the condition, and the NCPE believes that the medicine is very poor value for money. **Or**

	the NCPE believes it is not clear that the medicine works as well or better than other ways of managing the indicated condition. The price of the medicine is too high compared with other ways to manage the condition, and the NCPE believes that the medicine is very poor value for money. The HSE considers a number of factors along with the NCPE recommendation when deciding whether to provide this medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013. **4. The NCPE recommends that the medicine not be considered for reimbursement*** The NCPE has completed a full HTA for the medicine. The NCPE recommends that the HSE consider **not** providing this medicine. This is because the NCPE did not receive enough information to clearly assess how well the medicine works compared with other ways of managing the indicated condition **or** whether the medicine is value for money. The HSE considers a number of factors along with the NCPE recommendation when deciding whether to provide this medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013. ***This recommendation should be considered while also having regard to the criteria specified in the Health (Pricing and Supply of Medical Goods) Act 2013**
Pricing process	The three main reimbursement schemes in Ireland for calculating drug costs are: 1. Community Drug Schemes (CDS): Numerous reimbursement schemes are administered by the PCRS. Most common community drug schemes include the General Medical Services Scheme (GMS), Drugs Payment Scheme (DPS) and Long-Term Illness (LTI) scheme, but excluding the High Tech Drug Arrangements. 2. High Tech Drug Arrangements (HT) 3. Hospital Drugs [8] Ireland uses a system of external reference pricing whereby the price sought by an applicant should be the average of that sought in 14 other nominated EU states (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK). [3]
Managed entry agreements	MEAs, where they exist, are most often (but not limited to) the following: - Price discounts - Budget Caps - Outcome based

Main challenges in appraising medicines for rare diseases	- 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
Impact of special processes	--
Proposed policy change	Most recent was the establishment of the Rare Diseases Technology Review Committee (RDTRC) in late 2018.
Joint initiatives	Beneluxa, EUnetHTA
SOURCES	
1	https://health.gov.ie/wp-content/uploads/2014/04/UHI-Explained-.pdf
2	http://www.ncpe.ie/submission-process/process-flochart/
3	https://www.hse.ie/eng/about/who/cpu/iphaagreement2016.pdf
4	http://www.ncpe.ie/submission-process/
5	http://www.ncpe.ie/submission-process/hta-guidelines/critical-appraisal-criteria/
6	http://www.ncpe.ie/submission-process/submission-templates/format-of-full-submissions/ ("Applicant template")
7	http://www.ncpe.ie/submission-process/public-consultation-2/
8	http://www.ncpe.ie/wp-content/uploads/2018/09/Guidelines-for-Inclusion-of-Drug-Costs-in-Pharmacoeconomic-Evaluations-v2.0.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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