

Pricing and Reimbursement of medicines in Ireland

Expenditure on State-Subsidised Medicines in Ireland Between 2018 And 2022

A special focus on expenditure on cancer and immunomodulatory medicines

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Medicines assessment & reimbursement processes in Ireland

In Ireland, the Health (Pricing and Supply of Medical Goods) Act 2013 stipulates that the healthcare payer (the **Health Service Executive; HSE**) must consider the cost-effectiveness and budget impact of new medicines prior to a reimbursement decision.

All medicines for which reimbursement is sought are considered for Health Technology Assessment (HTA). The marketing authorisation holder (MAH) of the medicine prepares and submits the HTA for independent evaluation conducted by the **National Centre for Pharmacoeconomics (NCPE)**. The NCPE provide advice to the HSE Corporate Pharmaceutical Unit (CPU), the HSE-Medicines Management Programme (MMP), the HSE National Cancer Control Programme (NCCP), the HSE Drugs Group and HSE-Leadership to inform medicines reimbursement decision-making. The NCPE assesses evidence for comparative clinical-effectiveness, cost-effectiveness, and potential budget impact of introducing the new medicine into the Irish healthcare system. This includes estimates of costs, including healthcare utilisation, and health outcomes associated with both the new medicine and existing comparator treatments.

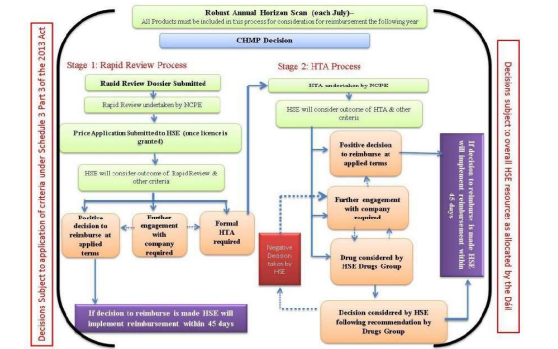


Figure 1 Diagram of the processes that the HSE will endeavour to follow in making decisions on the reimbursement of new medicines

Assessment of cancer medicines

In 2012, HTA submissions of cancer medicines comprised **19%** of all submissions to the NCPE. In 2022, cancer medicines comprised **43%** of HTA submissions to the NCPE.

A substantially higher proportion of submissions for cancer medicines are recommended for a full HTA (**69%**) compared with medicines for other non-cancer or orphan indications (**17%**). National horizon scanning, by the NCPE, indicates that 63% of medicines that MAHs intend to submit a reimbursement application in 2024 are cancer medicines.

With the aging population and the increasing survival of patients, cancer is and will become an increasingly important factor in the global burden of disease. The EU has put cancer to the fore of its health mission with its Beating Cancer Plan aiming for equal access to diagnosis and treatment for EU patients. Expectations exist from patients and clinicians to have early access to potentially beneficial medicines.

Cancer drugs that undergo a HTA appraisal by the NCPE are also discussed by the NCCP Technology Review Committee (TRC), comprising mainly of oncology and haematology clinicians. A recommendation is made by the NCCP-TRC and this is considered by the HSE Drugs Group.

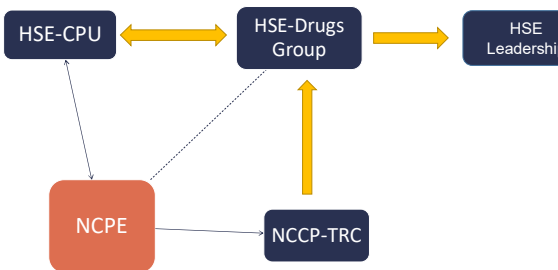


Figure 2 Stakeholders involved in the reimbursement of cancer medicines in Ireland

Reimbursement of medicines in Ireland

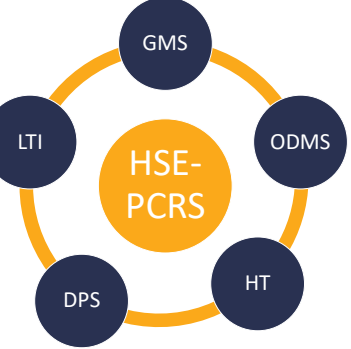


Figure 3 Some of the state subsidised medicine reimbursement schemes delivered by the HSE-Primary Care Reimbursement Service (PCRS).
GMS=General Medical Services ODMS=Oncology Drug Management System
HT=High Tech Drug Arrangement DPS=Drug Payment Scheme
LTI=Long Term Illness

In Ireland, the Health Service Executive (HSE) Primary Care Reimbursement Service (PCRS) provides reimbursement services to primary-care contractors for the provision of health services which are funded by the HSE. The PCRS holds claims data in relation to medicines provided by community pharmacies and hospitals that are reimbursed by the HSE. The PCRS database contains pharmacy claims data for medicines reimbursed through Community Drugs Schemes (including General Medical Services (GMS), Long Term Illness (LTI) and the High Tech Drug Arrangement (HT)) and hospital-based schemes (including the Oncology Drug Management System (ODMS)).

High Tech Drug Arrangement (HT)

The HT is a community-based reimbursement scheme, introduced in 1996, to facilitate the supply of certain high-cost medicines. The HT is one of the drivers of pharmaceutical expenditure in the last decade with an increase in spending of €415million between 2012 and 2020. Cancer medicines expenditure on the HT increased year-on-year at a rate of 15% between 2012 and 2020.

Oncology Drug Management System (ODMS)

The NCCP introduced the Oncology Drug Management System in July of 2012 to oversee and manage the funding of specified hospital-administered systemic anti-cancer drug treatments to public hospitals. The system allows for the introduction of a 'money follows the patient' funding model.

Analysis of expenditure across community schemes 2018-2022

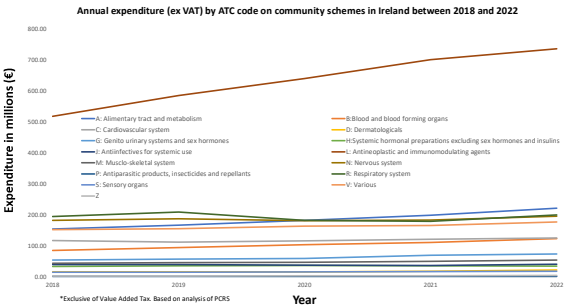


Figure 4 Annual expenditure, excluding Value Added Tax (VAT), by ATC code on community schemes between 2018 and 2022, based on analyses conducted by the NCPE in May 2023.

Total expenditure on PCRS community schemes, exclusive of Value Added Tax (VAT), rose from **€1.61 billion** in 2018 to **€2.02 billion** in 2022. This increase in expenditure is largely driven by an increase in spending on medicines with an Anatomical Therapeutic Classification (ATC) code L. Expenditure on anti-neoplastic and immunomodulating agents (ATC class L) rose from €518 million, excluding VAT, in 2018 to €737 million excluding VAT in 2022. Spending on 'L' drugs comprised **32.23%** of the community scheme budget in 2018, increasing to **36.34%** in 2022.

High Tech Drug Arrangement (HT)

Tumour necrosis factor alpha (TNF- α) inhibitors are the therapeutic class with the highest expenditure on the HT. **Adalimumab** is the individual drug with the highest expenditure. However, spending on **adalimumab** and **etanercept** on the HT decreased substantially from 2019 due to implementation of the best-value biologic (BVB) initiative by the HSE-MMP. The BVB initiative involved publication of guidance on the product the HSE-MMP consider to be the BVB for each medicine. In addition, a gain-share incentive scheme was launched which offered the relevant clinical service €500 for each patient initiated on, or switched to a BVB medicine. Spending on **adalimumab** has been increasing annually since 2020, which may be explained by increasing patient volume.

A generic version of **lenalidomide** was reimbursed in December 2021. However, this does not explain the sharp decrease in expenditure between 2021 and 2022 as the price of Revlimid® remained stable. A decrease in consumption volume may be the reason.

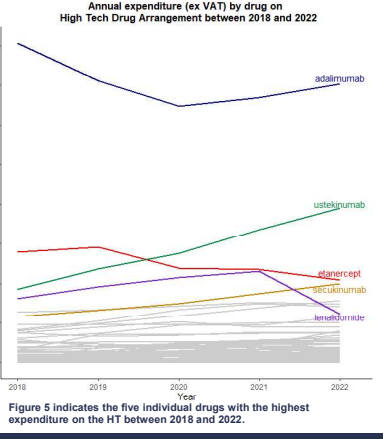


Figure 5 indicates the five individual drugs with the highest expenditure on the HT between 2018 and 2022.

Analysis of expenditure on ODMS 2018-2022

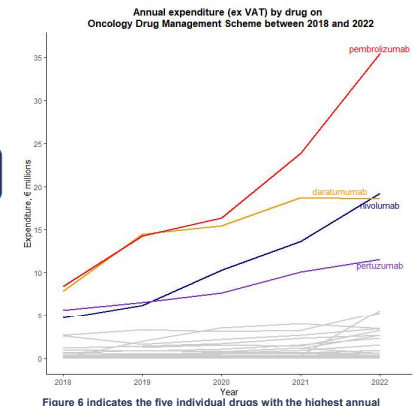


Figure 6 indicates the five individual drugs with the highest annual expenditure on the ODMS between 2018 and 2022.

Expenditure on hospital oncology medicines (through the HSE-ODMS) tripled between 2018 and 2022, the largest percentage increase for a PCRS scheme, to €151 million in 2022. This is largely driven by increased utilisation of PD-1 inhibitors, namely **pembrolizumab** and **nivolumab**. Spending on **pembrolizumab** has increased year-on-year at a rate in excess of 40%. This is due to an increasing number of license extensions being granted for pembrolizumab, resulting in increased utilisation.

Limitations & Future Plans

- Confidential discounts may be negotiated by the HSE as part of reimbursement agreements; therefore, actual expenditure is likely to be less than figures reported here.
- Drug budget sustainability is a priority. A Medicines Sustainability Task Force has been established.
- Promoting increased use of generic/biosimilar products.
- PD-1 inhibitors: indefinite versus fixed treatment duration?