A retrospective analysis of reimbursement timelines in Ireland: What does a 10-year analysis show?

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01. Introduction

Globally, healthcare systems are under increasing pressure to provide timely access to innovative medicines amidst rising drug costs and persistent budget constraints. In Ireland, the National Centre for Pharmacoeconomics (NCPE) plays a central role in evaluating new medicines for reimbursement. These evaluations are conducted through Rapid Reviews (RR) and, when necessary, full Health Technology Assessments (HTAs). Following these assessments, the Health Service Executive (HSE-CPU) engages with the applicant company before issuing a final reimbursement decision.

In Ireland, a Managed Access Protocol (MAP) is a structured reimbursement agreement that allows patients access to certain high-cost or uncertain medicines under defined clinical criteria, while further data on effectiveness and value are gathered.

Reimbursement delays can significantly impact patient access to life-changing treatments. By understanding the factors that influence time to reimbursement decision (TTRD), including the MAPs, this research provides valuable insights for policymakers, healthcare providers, and pharmaceutical stakeholders. The findings may support more transparent, efficient, & equitable decision-making processes.

This research aims to:

1. Analyse trends in reimbursement decisions made by the Irish authorities over a ten-year period:
   a. Examine the volume of submissions processed and categorise according to whether reimbursement was granted following a RR or a full HTA.
   b. Assess patterns in Irish TTRD's for new medicines over the past decade, identifying key trends in the assessment and reimbursement process.
2. Investigate how condition-specific MAPs, which allow for controlled access to high cost or uncertain-value medicines, affect the likelihood and speed of reimbursement decisions.
3. Discuss the findings in the research and identify potential bottlenecks in the Irish reimbursement process.

02. Irish Reimbursement Process

The key elements of the Irish reimbursement process, including the NCPE assessment and post-NCPE phase, are outlined in Figure 1.

Figure 1: Overview of reimbursement pathway in Ireland

Step 1 - NCPE

Rapid Review Submission

- An initial and concise assessment of the new medicine, including clinical efficacy, place in therapy, comparators and budget impact.
- Official NCPE assessment timeline is **4 weeks.**

4 weeks

Rapid Review Outcome

- The NCPE can issue one of five possible recommendations.
- These are; recommended for reimbursement with/without price discussions, not recommended for reimbursement, or recommended for a full HTA.

Step 2 - NCPE

HTA Submission

- A formal HTA is usually recommended for products with a high cost, high budget impact or uncertainty in the comparative clinical efficacy.
- This process begins with a pre-submission meeting between the applicant and the NCPE, where a discussion is had regarding the main assumptions and inputs for the HTA dossier.
- The NCPE state they aim to complete HTA assessments within **90 days** using a stop-clock approach.

90 days (stop-clock)

HTA Outcome

- The NCPE can issue one of four possible HTA recommendations:
  - Reimbursement recommended
  - Reimbursement recommended if cost effectiveness is improved
  - Reimbursement not recommended unless cost effectiveness is improved
  - Reimbursement not recommended
- If cost effectiveness needs to be improved, applicants will subsequently proceed to price discussions with the HSE-CPU.

HSE-CPU

Price Discussions and Approval

- During a price discussion meeting, the HSE-CPU will review the commercial offering proposed by the company and advise on payer expectations.
- If a product is shown to have a low budget impact and minimal associated uncertainty, it is possible for the HSE-CPU to subsequently approve reimbursement at their monthly products committee meetings.
- Where uncertainty exists, consideration of a MAP may be introduced as part of commercial discussions.
- For all other products, the offering is typically brought to the HSE Drugs Group, who will review it alongside all available information for the submission.

Reimbursement

- Following approval by the HSE Senior Leadership Team, a new drug may be added to the relevant reimbursement list within 45 days.

03. Methods

A centralised Microsoft Excel® database is updated at AXIS, detailing assessments reported on the NCPE website. This analysis includes assessments over the past ten years (June '16-June '25). The HSE website was also reviewed to identify MAPs. Currently, MAPs are in place for atopic dermatitis (AD) and migraine - the only MAPs established for specific disease areas rather than individual drugs. A sub-analysis was therefore conducted focusing on these two therapeutic areas to explore trends in NCPE recommendations to proceed to full HTA following RR and to examine potential links between MAP availability and reimbursement pathways. The specific data points extracted from each source are detailed in Table 1.

Table 1: Overview of sources and extracted data

	NCPE website	HSE website
Extracted data points	Date of RR submission Date of RR outcome Date of NCPE pre-submission meeting Date of HTA submission Date of issue of NCPE preliminary questions Date of HTA outcome Date of confirmed reimbursement	MAP for AD MAP for migraine

Analysis Plan

The data collected from various sources were consolidated in Microsoft Excel®. Since the NCPE publicly discloses only the month of reimbursement, it was conservatively assumed that reimbursement occurs on the first day of each respective month for the purpose of timeline calculations.

For each appraisal, the following timelines were calculated:

- The time from RR submission to RR outcome.
- The time from HTA submission to HTA outcome.
- The time from RR submission to reimbursement decision (i.e., TTRD).

Further analyses was conducted on medicines which entered the MAP (AD & migraine):

- The time from RR submission to reimbursement decision (i.e., TTRD).
- Difference in TTRD for first medicines in MAP and subsequent medicines in MAP.

04. Results

NCPE/HSE Assessments

Between June 2016 and June 2025, a total of 347 medicines or new indications which were assessed by Irish authorities were reimbursed. The average time to reimbursement decision (aTTRD) was 602.51 days. Of the medicines reimbursed:

- 53.31% (n=185) were reimbursed following RR, with an average TTRD of 336.20 days.
- 46.69% (n=162) were reimbursed following a full HTA, with a significantly longer average TTRD of 906.63 days.

Trends over the decade - RR

The NCPE assessment time for RR (Figure 2) has been consistent from 2021-2025 (31.21 days).

Although this is an improvement from the period 2017-2020, the average time to RR decision is longer than in 2016 (23.79). The average RR duration was at its highest in 2019 (50.11 days).

Figure 2: RR NCPE review time

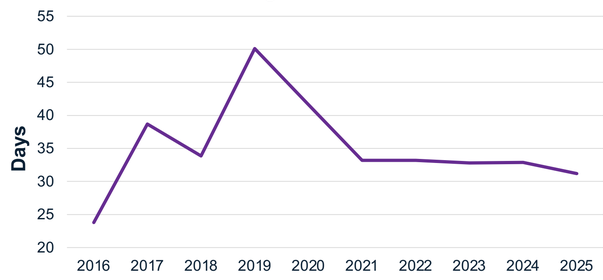
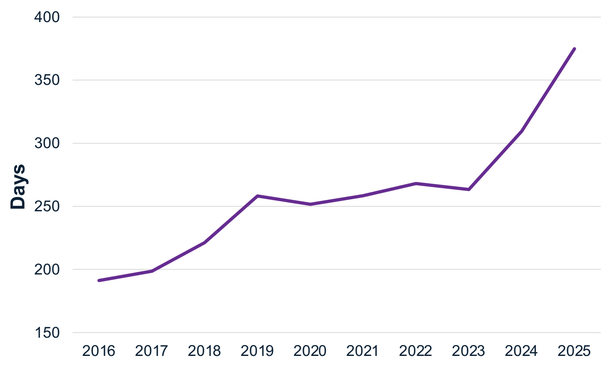


Figure 3: HTA submission to HTA outcome



Trends over the decade - Full HTA

The time from HTA submission to outcome has steadily increased (Figure 3).

In 2016, the average duration was 191.26 days, rising to 374.88 days by 2025. The biggest percentage increases in this analysis was between years 2018-2019 (16.62%) and years 2023-2024 (17.56%). Overall, there was a 96.01% increase in the total time from submission to outcome - reflecting the full TTRD including both the NCPE assessment period and the time spent at the HSE CPU.

aTTRD for MAP medicines in AD & migraine

For medicines in AD (Figure 4), the aTTRD was:

- 1235.00 days for the first intervention
- 227.67 days for subsequent interventions
  (All subsequent interventions reimbursed via Rapid Review only)

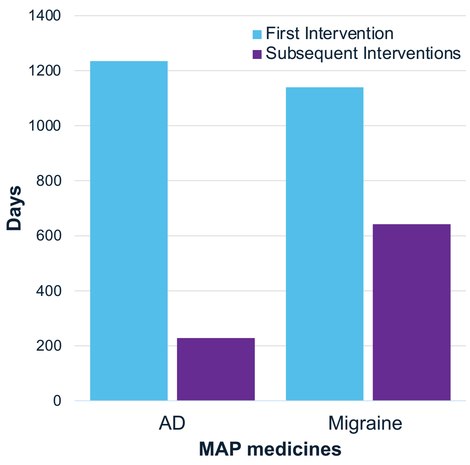
For migraine medicines, the overall aTTRD was 725.00 days, broken down as:

- 1140.00 days for the first intervention
- 642.00 days for subsequent interventions

Across both MAPs, RR assessment times were shorter for first interventions:

- AD MAP: 11.00 days (first) vs. 30.33 days (subsequent)
- Migraine MAP: 27 days (first) vs. 47.08 days (subsequent)

Figure 4: aTTR for MAP medicines



05. Conclusions

Between 2016 and 2025, the NCPE/HSE assessment process demonstrated both progress and persistent challenges in the reimbursement pathway for medicines.

Overall, the aTTRD was lengthy, at over 600 days. This highlights the ongoing complexity of bringing new therapies to patients in Ireland. However, differences between assessment routes were evident. Medicines reimbursed via RR reached patients significantly faster, with an aTTRD of 336 days, compared with over 900 days for those undergoing a full HTA.

Trends over time suggest that while RR assessment times have stabilised and become more efficient, the HTA pathway has grown increasingly challenging, doubling in duration since 2016. This divergence highlights the importance of maintaining efficiency in RR processes while addressing delays in HTA evaluations. Importantly, the HTA duration reflects both the time with the company (for response and data provision) and the time with NCPE, highlighting that delays are distributed across multiple stages of the process.

For medicines reimbursed via a MAP, analysis revealed that subsequent interventions were generally processed faster than first interventions in AD and migraine therapies. Despite this improvement, first interventions often experienced substantial delays, exceeding 1,000 days in some cases. It is important to note that this analysis is limited to two therapeutic areas, and the findings may not be generalisable across all MAPs Further research should therefore be conducted to examine timeline patterns across all MAP medicines. If a similar trend is observed more broadly, this may suggest a resource constraint within the MMP or highlight the need to review processes associated with the establishment of new MAPs in emerging therapy areas.

Delays in reimbursement can pose serious barriers to patient access to life-changing treatments. By examining the factors that influence TTRD, including the critical role of MAPs, this research offers valuable insights for policymakers, healthcare professionals, and pharmaceutical stakeholders. These findings may help foster more transparent, efficient, and equitable decision-making across Ireland's healthcare system.

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