Characterising Medicines Reimbursed under Managed Access Protocols in Ireland (2015–2025)

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BACKGROUND

Ireland's well-established reimbursement process for new medicines involves two key stages: a Rapid Review and, when necessary, a full Health Technology Assessment (HTA) conducted by the National Centre for Pharmacoeconomics (NCPE)[1]. These assessments evaluate the clinical effectiveness, cost-effectiveness, and budget impact of new medicines compared with existing therapies. Following the NCPE evaluation, recommendations are submitted to the Health Service Executive (HSE) Drugs Group, which is responsible for national pricing and reimbursement decisions. The Drugs Group considers the NCPE's findings, clinical need, financial sustainability, and broader policy priorities before making a final recommendation.

In some cases, medicines are approved for funding under a Managed Access Protocol (MAP)[2]. MAPs are a form of conditional or restricted reimbursement that are typically used when:

1. The estimated budget impact is very high.
2. There are concerns about off-label or inappropriate use.
3. There is uncertainty in the clinical or cost-effectiveness evidence, such as limited trial data or immature survival outcomes.

Under a MAP, which are managed by the Medicines Management Programme, specific eligibility criteria, are defined. This ensures that medicines can be provided to suitable patients while additional evidence is gathered to inform future reimbursement decisions. However, the inclusion of a MAP can also extend overall reimbursement timelines, adding further complexity to the reimbursement process.

It is important to understand MAPs in terms of their frequency, design, and implications for both the health service and the pharmaceutical industry. Understanding the evolving role of MAPs between 2015 and 2025 can help inform company planning, evidence generation, and engagement approaches within Ireland's reimbursement landscape.

OBJECTIVE

The objective of this study is to characterise medicines subject to a MAP in Ireland.

METHODS

We compiled a dataset of all new medicines that were evaluated by the NCPE from 2015 to June 2025, including indication, oncology/orphan status, reimbursement scheme and reimbursement recommendation from the NCPE website[3]. Data from the HSE Drugs Group meetings were added to the database, including date of first HSE and last Drugs Group meeting, number of meetings required and date of reimbursement recommendation[4]. Reimbursement status and date was also added to the database from multiple sources including the NCPE[3], the National Cancer Control Programme (NCCP)[5], and the Primary Care Reimbursement Service (PCRS) websites[6]. Finally, details of the MAPs from the MMP website were added to the database[2]. Descriptive statistics were then applied to the data.

RESULTS

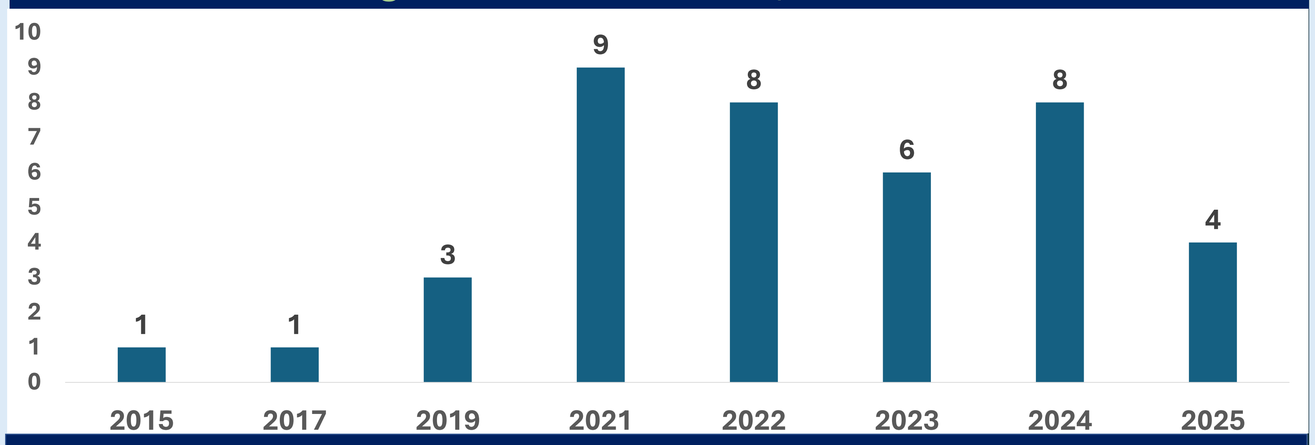
The number of medicines reimbursed under MAPs in Ireland has increased substantially over the past decade (see Figure 1). Early implementation was limited, with only one MAP recorded in 2015 and 2017, and three in 2019. A marked rise was observed from 2021 onwards, peaking at nine MAPs in 2021. From 2015 to June 2025, 40 new medicines or indications have been reimbursed with a MAP.

Most MAPs were reimbursed through the High Tech scheme (60%). Disease areas were diverse, with circulatory and nervous system disorders each accounting for 18%, followed by musculoskeletal (15%) and endocrine/metabolic conditions (10%). The majority (68%) of MAPs followed a full HTA, indicating that comprehensive assessment remains the main route to reimbursement, while Rapid Reviews (32%) were typically used for extensions to existing MAP (see Figure 2).

Medicines reimbursed under a MAP had substantially longer timelines compared with those without a MAP. The average time to reimbursement was 972 days for MAP medicines, compared to 500 days for those without a MAP. The average NCPE review time for MAP products was 386 days versus 180 days for non-MAPs, while the post-NCPE reimbursement phase averaged 579 days for MAPs compared with 304 days for non-MAPs. The longer timelines associated with MAPs reflect the complexity of reviews, development of eligibility criteria, and implementation of online application systems.

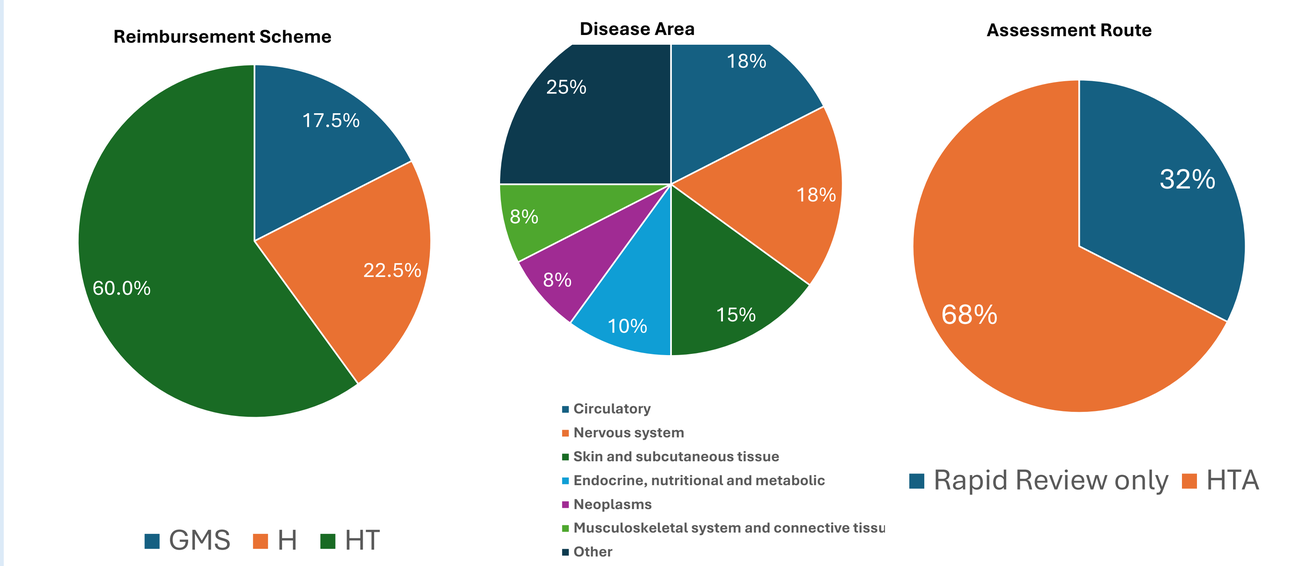
The analysis of MAP eligibility criteria shows that all protocols required an approved consultant and confirmed diagnosis, with most aligning patient age to the product indication (see Figure 4). Common additional criteria included genetic testing, use of designated centres, or exclusion conditions consistent with clinical trial parameters. Several MAPs also incorporated disease severity, treatment response, or prior therapy requirements.

Figure 1: Number of MAPs, 2016-2025



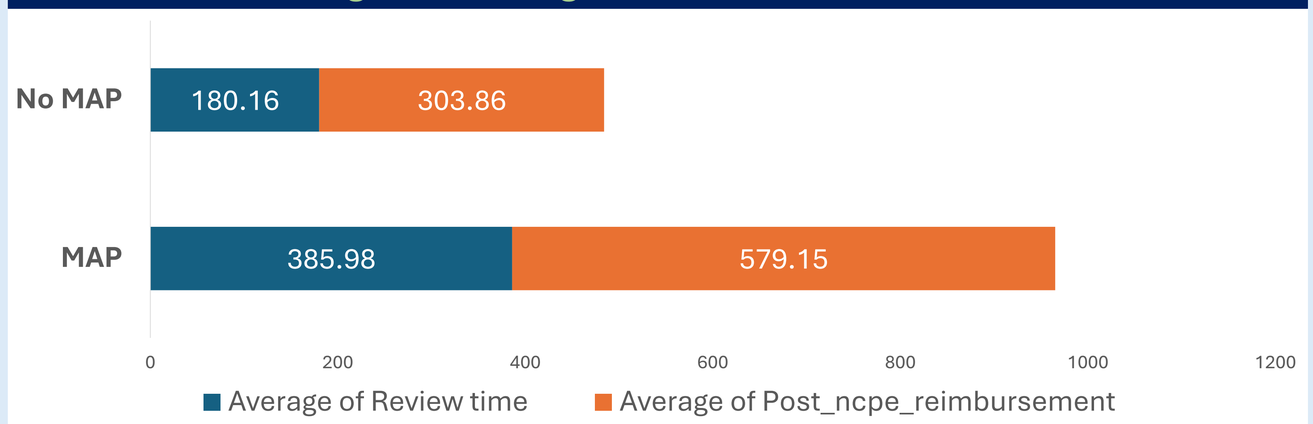
MAP: managed access protocols

Figure 2: Reimbursement Scheme, Disease Area, Assessment Route



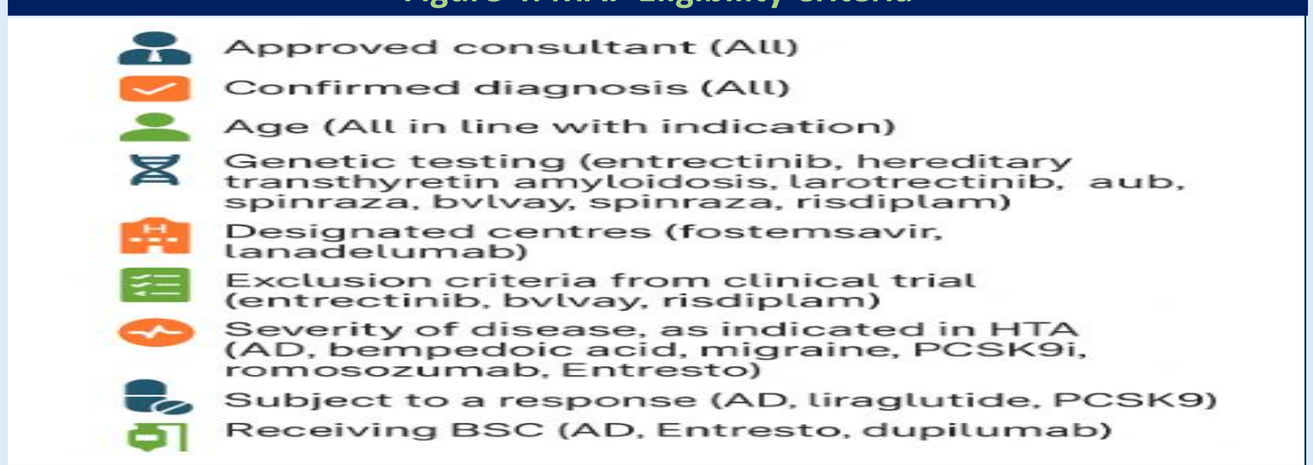
GMS: general medical services; H: hospital; HT: high tech; HTA: health technology assessments

Figure 3: Average Time to Reimbursement



MAP: managed access protocols; ncpe: national centre for pharmacoeconomics

Figure 4: MAP Eligibility Criteria



AD: atopic dermatitis; BSC: best supportive care; HTA: health technology assessments; MAP: managed access protocols; PCSK: proprotein convertase subtilisin kexin

CONCLUSION

Managed Access Protocols (MAPs) have become increasingly common in Ireland since 2021, mainly for high-cost and orphan medicines assessed through full HTA. MAPs ensure appropriate patient access through defined eligibility criteria, such as consultant approval, confirmed diagnosis, and genetic testing where required. However, they are associated with longer review and reimbursement timelines compared with standard approvals. Characterising MAPs helps clarify their impact on access and resource planning, supporting both policy development and pharmaceutical company strategies in managing uncertainty and evidentiary requirements. In addition, system streamlining and early dialogue between stakeholders may help mitigate access delays while preserving financial and clinical safeguards.

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