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IMF - the Innovative Medicines Fund or the Interim Medicines Fund?

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BACKGROUND/ INTRODUCTION

- NICE launched the Innovative Medicines Fund (IMF) in June 2022, ringfencing £340m with the aim of fast-tracking non-oncology drugs addressing a high unmet need. However, three years since launch, the IMFs use has been limited, with only three technologies recommended to date, all Advanced Therapy Medicinal Products (ATMPs).

Table 1 Founding principles of the Innovative Medicines Fund[1]

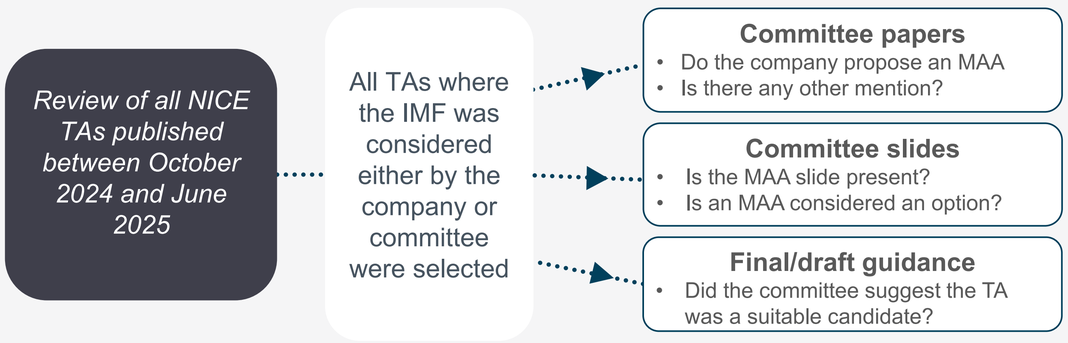
Principle 1: IMF should support equality of opportunity for non-oncology & oncology indications	**Principle 2**: IMF should prioritise the most promising medicines, with significant remaining uncertainty
Principle 3: IMF is reserved for medicines that are a) plausibly cost-effective b) priced responsibly during managed access	**Principle 4:** Managed access should be for the shortest time necessary to collect required data (< 5 years)
Principle 5: the entire eligible population, determined by NICE, should have the opportunity to access treatment	**Principle 6:** all medicines that enter the IMF will be re-evaluated by NICE for a routine decision
Principle 7: any patient treated in the IMF should have the option of continuing in the event of a NICE rejection	**Principle 8:** the IMF should never close to new entrants.

OBJECTIVE(S)

- This objective of this research was to review the National Institute for Health and Care Excellence (NICE) technology appraisals (TAs) where access through the IMF was considered to identify emerging trends in IMF use and managed access agreements (MAAs) in non-oncology indications in the UK.

METHODS

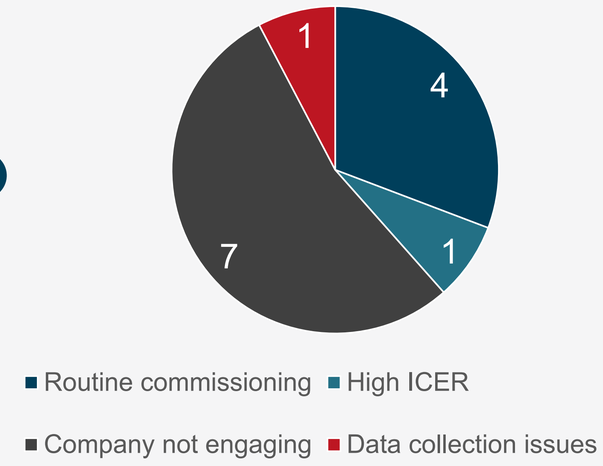
- Non-oncology technology appraisals (TAs) published between October 2024, and June 2025 were analysed.
- All TAs where the IMF (or managed access more generally) is discussed in the published documentation were included in this analysis.
- TAs currently in development were also considered, provided committee papers were available at the time of analysis.
- Those without a publication date were excluded on the basis that these TAs are not sufficiently advanced for IMF to have been deliberated, or documentation made public.
- For all included TAs, the current recommendation, entry via IMF (yes, no), and rationale where IMF was not utilised were tabulated.
- The reasons for not entering the IMF were then assigned to broad categories, to support the development of potential themes & recommendations.



RESULTS

- Between October 2024 to June 2025, 14 TAs were identified where access via the IMF was considered.
- Of these, one technology (Casgevy® or exagamglogene autotemcel for sickle cell disease) was recommended via the IMF.
- Of the 13 TAs which did not proceeding with the IMF, there were several reasons including:
  - The company chose not to engage with the IMF (7 of 14)
  - There was no plausible potential to be cost-effective (1 of 14)
  - There were data collection issues (1 of 14)
  - A recommendation via routine commissioning meant there was no need for IMF (4 of 14).

Figure 1: Reasons for the IMF not being utilised



- Notable, nearly all of the companies not engaging, (6 of 7) used the IMF for interim funding in the first 90 days after a positive recommendation before proceeding to funding through routine commissioning.

Table 1: Analysis of NICE Technology Appraisals where Managed Access (via IMF) was considered

Technology	Therapy area	Company	TA #	Recommended?	IMF entry?	Rationale If No
Efgartigimod	Generalised myasthenia gravis	Argenx	TA1069	N	N	Company not engaging
Leniolisib	APDS	Pharming Group	HST33	Y	Interim funding	Company not engaging
Ruxolitinib	Acute GVHD	Incyte	TA1054	Y	Interim funding	Company not engaging
Olipudase alfa	ASMD	Sanofi	HST32	N	N	High ICER
Fenfluramine	Lennox-Gastaut syndrome	UCB	TA1050	Y	Interim funding	Company not engaging
Exagamglogene autotemcel	SCD	Vertex	TA1044	Y	Y	NA
Vamorolone	DMD	Santhera	TA1031	Y	N	Routine commissioning
Ublituximab	Relapsing MS	TG Therapeutics	TA1025	Y	Interim funding	Company not engaging
Elafibranor	Primary biliary cholangitis	Ipsen	TA1016	Y	Interim funding	Company not engaging
Pegzilarginase	Arginase-1 deficiency	Immedica	GID-HST10054	TBC	N	Routine commissioning
Fosdenopterin	MoCD	Sentynl Therapeutics	GID-HST10055	TBC	N	Routine commissioning
Sparsentan	Primary IgA nephropathy	Travere Therapeutics	GID-TA11359	Y	N	Routine commissioning
Marstacimab	Severe Haemophilia A or B	Pfizer	GID-TA11397	Y	Interim funding	Company not engaging
Spesolimab	Generalised pustular psoriasis flares	Boehringer Ingelheim	GID-TA10871	Y	N	Data collection issues

Abbreviations: APDS, Activated phosphoinositide 3-kinase delta syndrome; ASMD, Acid sphingomyelinase deficiency; DMD, Duchene Muscular Dystrophy; GVHD, Graft Versus Host disease; IgA, Immunoglobulin A; MoCD, Molybdenum cofactor deficiency type A; MS, Multiple Sclerosis; SCD, Sickle Cell Disease; TBC, to be confirmed

DISCUSSION

- During the analysis period, the only technology which was funded through the IMF was Vertex's Casgevy® for sickle cell disease; a one-time gene therapy.
- The most common reason for not pursuing the IMF for long-term funding was the company's lack of engagement.
- However, 6 TAs (43%) noted use of the IMF for interim funding in the first 90 days after a positive recommendation before proceeding through routine commissioning funding.
- This highlights how the IMF is being used for short-term access support rather than the long-term funding it was intended for.

CONCLUSIONS

- During this analysis period the top two reasons the IMF was not used were funding proceeding via routine commissioning and the company not engaging.
- Three years since launch, the IMF has only been utilised three times as a fund to support managed access, with several examples of its use for interim funding.
- One possible explanation for this is that manufacturers are concerned about the IMF's requirement to provide drug free of charge should a price agreement not be reached following conclusion of the managed access period.
- This may explain why use is thus far limited to single-use technologies.

REFERENCES

1. National Institute for Health and Care Excellence, The Innovative Medicines Fund Principles, 2022. Available from: https://www.england.nhs.uk/wp-content/uploads/2022/06/B1686-the-innovate-medicines-fund-principles-june-2022.pdf

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