HTA273

Managed Access Agreements in the UK: A Detailed Analysis of NICE's Utilisation and Impact on Access

Authors and affiliations

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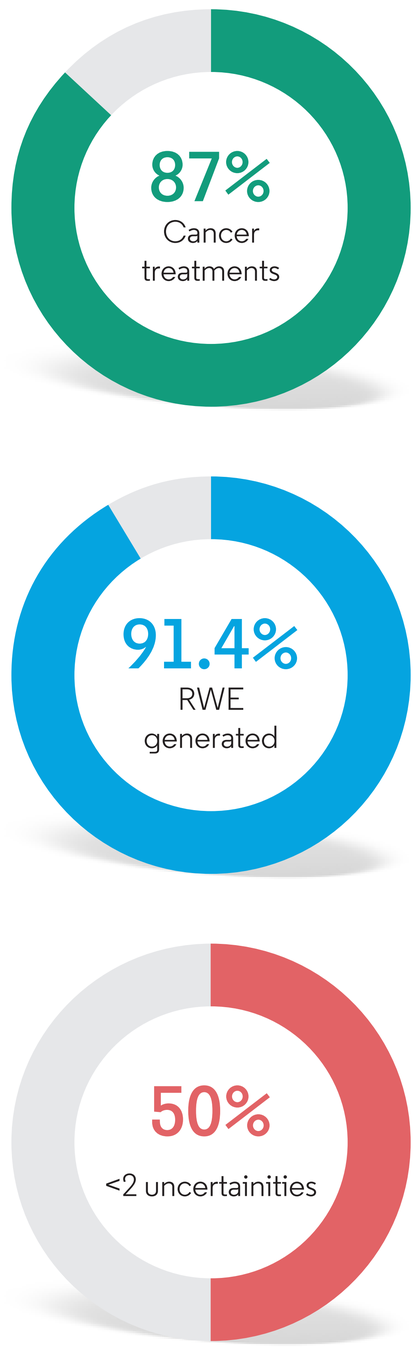
Introduction

- Standard NICE technology appraisals (TAs) have strict criteria for cost-effectiveness, sometimes resulting in a negative recommendation where long-term uncertainties exist in clinical efficacy impacting cost effectiveness
- Managed Access Agreements (MAA) allow for additional time to collect sufficient data required for decision making for new treatments where they would not otherwise be recommended for routine use within the NHS in England
- Treatments in a MAA are funded by two dedicated funds, NHS England's Cancer Drugs Fund (CDF) and NHS England's Innovative Medicines Fund (IMF)
- MAA can be proposed as part of the TA process or during the Innovative Licensing and Access Pathway (ILAP)
- As part of a MAA additional data collection is required, including but not limited to real world data (RWD)
- The treatment is then reassessed by National Institute for Health and Care Excellence (NICE) with this additional evidence included in an updated submission to assess its cost effectiveness and reviews if it can be recommended for routine use by NHS England (**Figure 1**)
- The objective of this was to understand the evolution of the programme to date, by highlighting the number of treatments now in routine NHS use as a result of managed access, and assess the attractiveness of entering into a MAA
- MAA proposals include an agreed rationale and duration for the arrangement, populations covered (in particular where they come in the care pathway), clear criteria for starting and stopping the new therapy, definition of outcomes, methods of data collection and frequency of reporting, together with a commercial proposition (price discount), financial risk management plans and an understanding of what will happen if reimbursement is eventually withdrawn.

Methodology

- We reviewed NICE managed access agreements in England between NHS England and manufacturers that are currently active ranging from late 2018 to mid-June 2023. MAA's recommended within the CDF were also included
- All included MAAs in England were reviewed to extract NICE recommendations on treatments that are currently in managed access, the types of evidence they were gathering, trends in uncertainties, endpoints, and timeframes

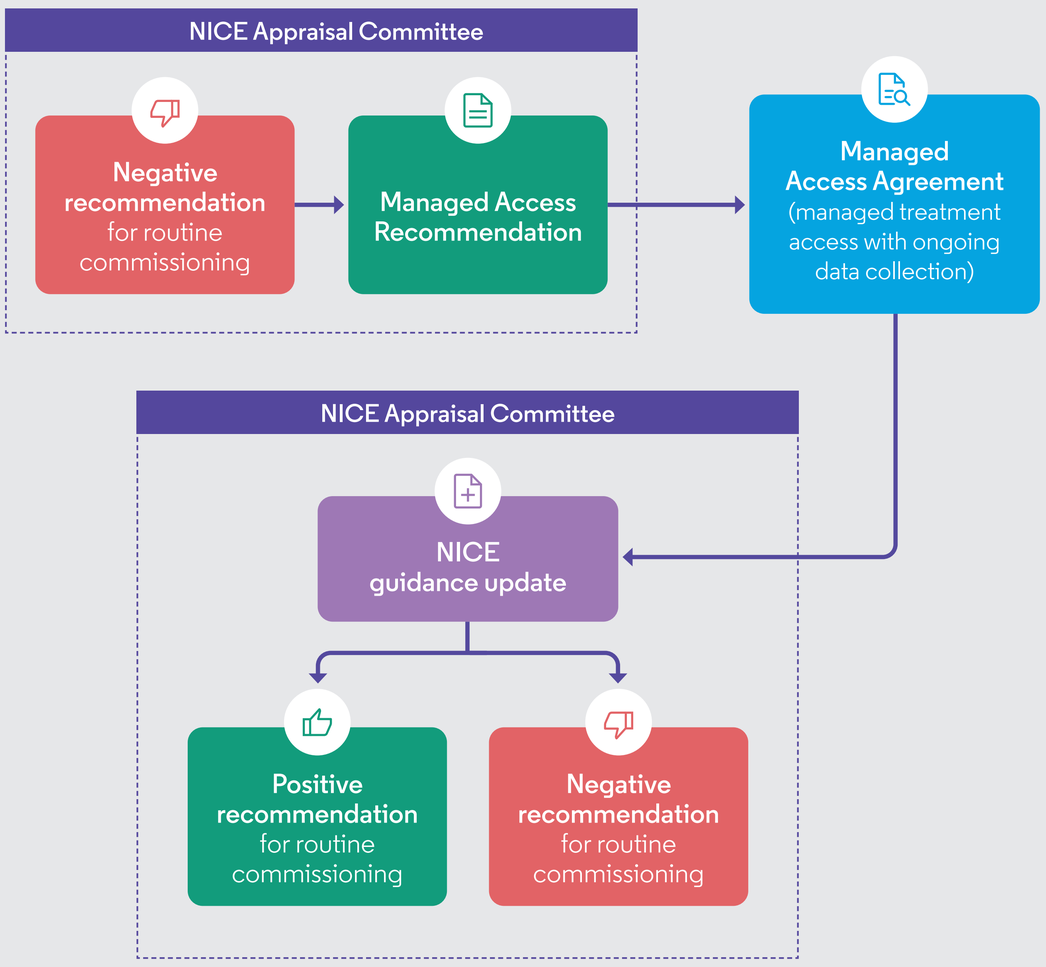
Figure 2. Proportion of treatments exiting managed access by characteristic



Results

- Thirty active MAA were identified (as of 22/06/2023), 72% were issued with a data collection time frame of more than two years and stayed in a MAA for 3 years
- Oncology products led the charge on MAA's at 87%, and the majority, 83% entered into the MAA for immaturity of data such as OS and PFS
- Uncertainties around the economic model or values used in the economic model featured highly as the uncertainties listed for needing to be entered into a MAA, with uncertainties around overall survival estimates featured in 20% of the MAAs
- In terms of the number of uncertainties 50% had 3 uncertainties listed, while 23% had 4 uncertainties listed (**Figure 2**)
- A few of the additional uncertainties featured around generalisability of data to UK clinical practise, patient numbers or time on treatment within the NHS, which would fall into long-term uncertainties
- Ongoing phase 3 randomized controlled trials (RCT) featured in 90% of the MAA's as primary data sources which were supported by secondary RWD data sources, typically a registry in 91.4% of MAAs
- As of June 2023, eight treatments had exceeded their pre-specified data collection windows on the MAA
- Of the MAAs that were currently active there was no mention of QALY gains or unmet needs as uncertainties/considerations for entering into the MAA

Figure 1. Process for entry into and exit from managed access in England



Conclusion

Analysis of MAAs suggests that the scheme is a highly attractive proposition for manufacturers. The immaturity of data in the clinical trial setting was the key uncertainty sighted in the majority of MAAs, with most of these arising from immature OS and PFS data.

MAAs could be better facilitated by understanding the prospective post-marketing data required by NICE.

Experience to data is largely from oncology treatments, so data on specific endpoints are limited OS and PFS

While there is the impression that uncertainties around clinical efficacy lead to the application of a MAA in reality it is this uncertainty adds to the economic modelling which leads to the MAA

MAA have profound value is adding an additional access route for medicines where routine commissioning does not have enough evidence to support their use. It allows the manufacturer a clear timeline to mitigate any uncertainties and a clear outcome of what will happen if the medicine does not live up to expectations

MAAs therefore provide a model that allows temporary patient access whilst additional evidence is generated for medicine that treat severe, rare or chronic diseases

References

1. NICE (2023) https://www.nice.org.uk/about/what-we-do/our-programmes/managed-access