NICE National Institute for Health and Care Excellence

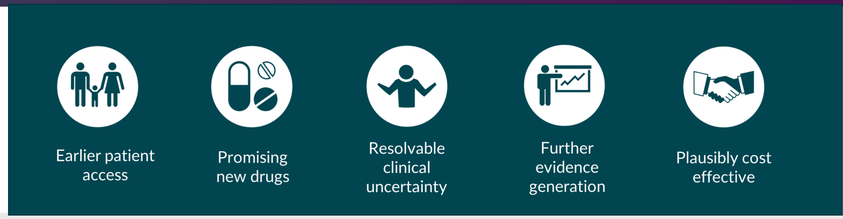
What Goes in Must Come Out: An Analysis of NICE Recommendations for Drugs Exiting Managed (Early) Access in England

Bee C, Hawksworth C, Wakefield L, Patrick H, Groves B

National Institute for Health and Care Excellence

Background

Managed access enables time-limited patient access to promising new treatments that would not otherwise be recommended for routine use within the NHS in England. Managed Access Agreements (MAAs) require additional data collection, including real-world data (RWD). The technology is then re-evaluated by NICE to assess whether, with the new evidence, it is cost-effective and can be recommended for routine use.

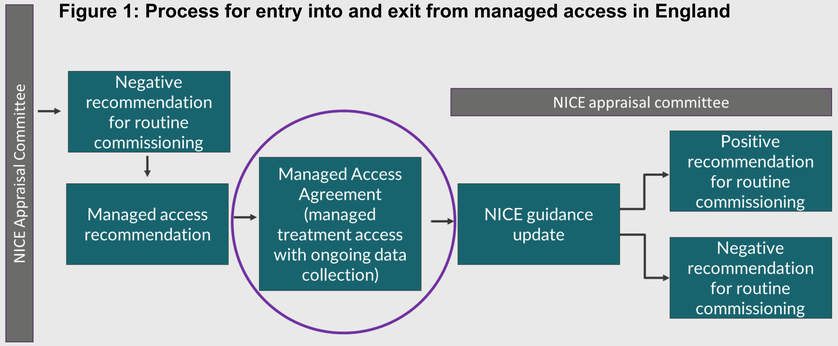


What we did and why

We reviewed National Institute for Health and Care Excellence (NICE) managed access recommendations in England over the last six years, including those recommended within the Cancer Drugs Fund (CDF[1]), which was reformed in 2016. The objective was to provide an overview of the programme to date, by highlighting the number of treatments now in routine NHS use as a result of managed access.

All MAAs in England since 2016 were reviewed to extract NICE recommendations on treatments that have exited managed access and the proportion that utilised real world data (RWD).

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

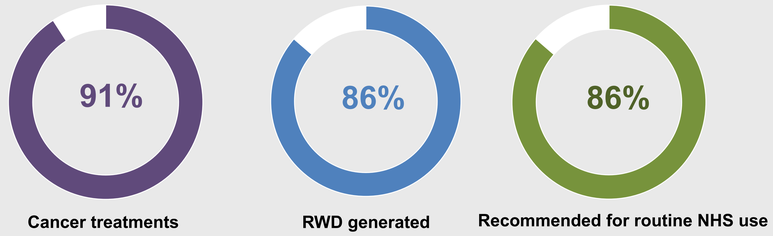


Outcomes and impact

In the six years since the first MAA was agreed, 22 technologies have been re-evaluated by NICE following a period of managed access. 20 out of 22 (91%) were treatments for cancer. 19 out of 22 (86%) involved RWD for the guidance update. Outcomes collected for NHS patients have included overall survival, treatment duration, time to next treatment and quality of life. The shortest and longest data collection periods were 2 and 60 months respectively, with a median of 18 months.

19 out of 22 (86%) of the technologies were recommended for routine use in the NHS following a period of managed access. Of the remaining three technologies, one was not recommended for routine use, one guidance update was terminated by the company, and one was withdrawn when its conditional licence was withdrawn.

Figure 2: Proportion of treatments exiting managed access by characteristic



What we learnt

- ❑ Managed access is an established mechanism in England for early patient access to promising new treatments, where significant evidential uncertainty remains.
- ❑ Managed access in England has resulted in 19 promising new treatments being recommended for routine use within the NHS in England.
- ❑ The high success rate for technologies via managed access suggests that the criteria for entry into managed access are identifying appropriate new treatments for this approach.
- ❑ Without managed access, these technologies would most likely not have been recommended for routine use within the NHS in England.
- ❑ Experience to date largely applies to cancer treatments, but applications in other disease areas are emerging and this is expected to increase in 2022 with the launch of the Innovative Medicines Fund (IMF[2]).

86% of technologies exiting a period of managed access have subsequently been approved for routine use in the NHS

References

1. NHS England (2016) Appraisal and funding of cancer drugs from July 2016.
2. NHS England (2021) The Innovative Medicines Fund: engagement on proposals.

Dr Charlotte Bee
Programme Manager – Data Projects
National Institute for Health and Care Excellence

Email:
charlotte.bee@nice.org.uk
Telephone: 44 (0)161 413 4071

nice.org.uk