132785

Timely reimbursement: the impact of early and accelerated access programmes in non-squamous non-small cell lung cancer

Sarah Webb and James Mercure

OPEN Health HEOR & Access Market Access, London, UK

INTRODUCTION

Early and accelerated access programmes

- Early and accelerated access programmes (EAPs) aim to accelerate access to new, innovative treatments for patients, either by making treatments available to patients ahead of marketing authorisation (MA) or by speeding up regulatory and reimbursement pathways.
- In England, there are several EAPs made available by the Medicines and Healthcare Products Regulatory Agency (MHRA), including:
  - Early Access to Medicines Scheme (EAMS)[1] – aims to give patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need
  - Project Orbis (PO)[2,3] – aims to deliver faster patient access to innovative cancer treatments via the concurrent submission and review of oncology products among regulatory authorities in the United States, United Kingdom (UK), Australia, Canada, Singapore, Switzerland, Brazil and Israel. The UK's MHRA joined the Project Orbis collaborative review scheme in January 2021
  - Innovative Licensing and Access Pathway (ILAP)[4] – aims to accelerate regulatory and reimbursement pathways to improve patient access to innovative medicines. The pathway was established in March 2021 and is delivered in partnership by the MHRA, All Wales Therapeutic and Toxicology Centre, National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium

Evolving treatment landscape for NS NSCLC

- The treatment landscape for non-squamous (NS) non-small cell lung cancer (NSCLC) is very complex, with a broad range of available treatment options, the eligibility for which can be defined by the presence of genetic mutations, line of therapy and patient fitness.
- Since 2018, the treatment landscape in England has rapidly evolved, with 23 new treatment options recommended by NICE.
- Given ongoing therapy developments in the area of NS NSCLC, it may be important to understand whether making use of EAPs accelerates time to NICE recommendation, providing patients with timely access to effective treatment options.

OBJECTIVES

- The aim of this research was to determine whether an EAMS-positive scientific opinion, approval through Project Orbis or the awarding of an Innovation Passport reduced the NICE review timelines compared with treatments that did not enter an EAP.

METHODS

- Treatments reimbursed in England by NICE for patients with NS NSCLC between 1 January 2018 and 31 May 2023 were identified through a web search of published NICE technology appraisals.
- A web search was performed to determine whether the treatment and indication under consideration:
  - Had a current or expired positive scientific opinion from EAMS[5]
  - Had been assessed as part of PO[6]
  - Had been awarded an Innovation Passport via the ILAP
- The time interval from MA to NICE reimbursement was calculated for each treatment option, considering the indication specified in each NICE appraisal.
  - For therapies originally approved by the European Medicines Agency, the original MA date was considered, rather than the date the MHRA adopted MA.
- The intervals between MA and NICE reimbursement were compared for treatments that entered an EAP vs those that did not enter an EAP.

RESULTS

Participation in EAPs

- Overall, 10 of the 24 recommended treatments made use of EAPs (Figure 1), including:
  - 5 products with a positive scientific opinion from EAMS[4,5]
  - 6 products assessed as part of PO[2]
  - 4 products were awarded an Innovation Passport (3 of which were also assessed by PO and 1 of which also had a positive opinion from EAMS and was assessed by PO).

Impact of EAPs on NICE timelines

- Overall, the time from MA to NICE technology appraisal guidance (TAG) varied from 69 to 958 days for NS NSCLC treatments (Figure 2).
- The average length of time from MA to reimbursement was 296 days for drugs that entered into an EAP compared with 355 days for those not using an EAP.
- Two treatments, atezolizumab monotherapy and entrectinib, were both recommended in less than 100 days despite not entering any of the EAPs.
- Nivolumab and pembrolizumab, which received EAMS positive scientific opinions, both took over 500 days from MA to NICE.

Figure 1. Participation in EAPs for products approved by NICE in NS NSCLC since 2018

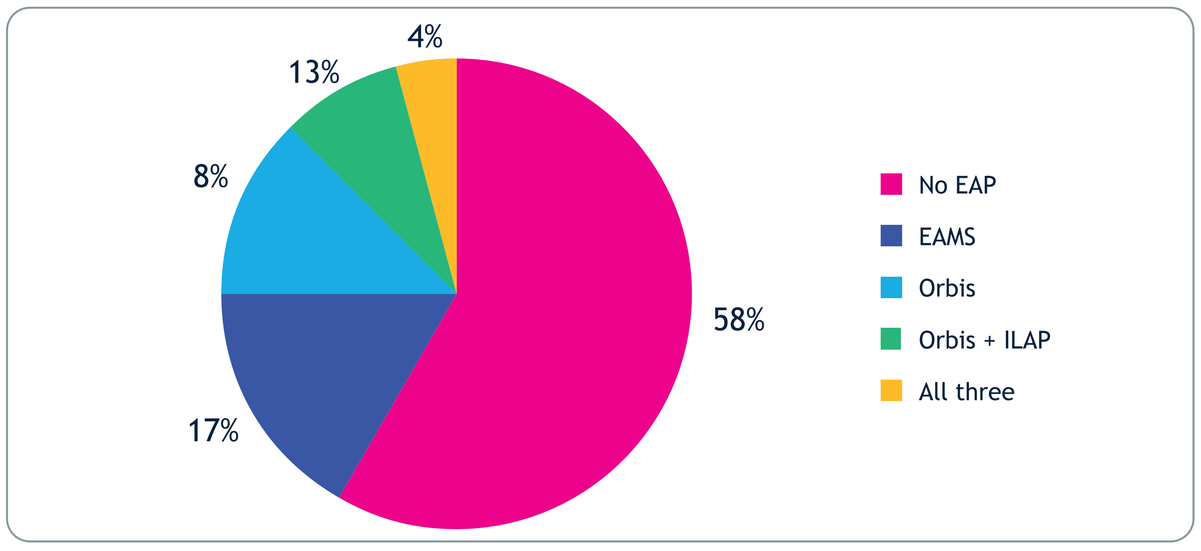
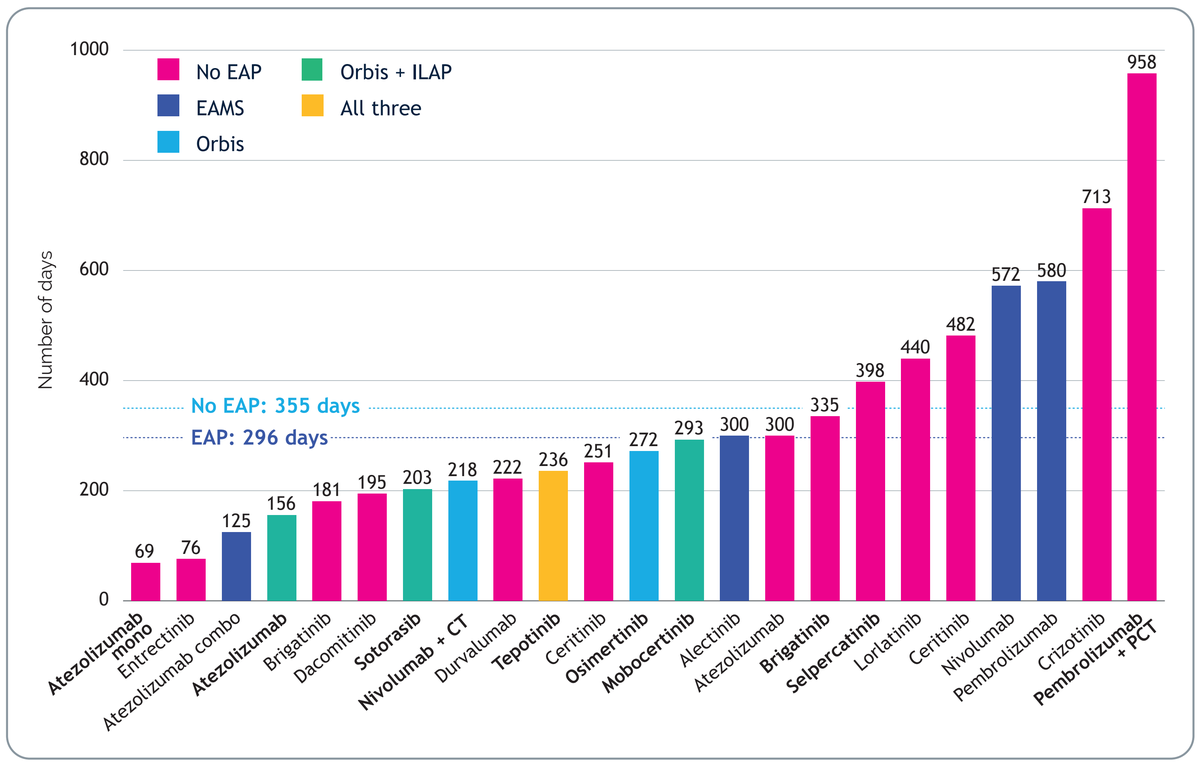


Figure 2. Participation in EAPs for products approved by NICE in NS NSCLC since 2018



CT, chemotherapy; EAMS, Early Access to Medicines Scheme; ILAP, Innovative Licensing and Access Pathway; PCT, pemetrexed and platinum chemotherapy.

- Considering only appraisals conducted after 2021:
  - Of the 10 appraisals post 2021, 6 made use of EAPs (these are bolded in Figure 2)
  - The average length of time from MA to reimbursement was 230 days for drugs that entered into EAPs compared with 440 days for those not using EAPs
  - Although the product that had the shortest time from MA to TAG did not participate in any EAP, the next 6 products all did.

CONCLUSIONS

- Overall, participation in MHRA EAPs does not appear to reduce the length of time taken for NICE reimbursement.
- Limitations with this research include:
  - PO* and ILAP were only established in 2021, so were not available during the entire study period
    - Initial analysis of the period from 2021 to now suggests that these programmes may provide a slight advantage in accelerating time to NICE appraisal
    - It would be worthwhile repeating the analysis once these programmes are embedded to determine the impact with more clarity
  - The study period included in the analysis was impacted by the COVID-19 pandemic, which caused significant delays in MHRA and NICE processes; therefore, timelines over this period may be longer than typical pre-pandemic timelines
- The study could additionally be repeated once updated NICE protocols to streamline and improve health technology review[7] are fully implemented to determine whether participation in EAPs impacts timelines under the new processes.

*PO was established globally in 2019, but the UK was added to the programme in 2021.

REFERENCES

1. UK Government. Apply for the Early Access to Medicines Scheme. Available at: www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams (Accessed October 2023).
2. UK Government. Project Orbis. Available at: www.gov.uk/guidance/guidance-on-project-orbis (Accessed October 2023).
3. UK Government. UK medicines regulator issues its first authorisation under Project Orbis. Available at: www.gov.uk/government/news/uk-medicines-regulator-issues-its-first-authorisation-under-project-orbis (Accessed October 2023).
4. UK Government. Innovative Licensing and Access Pathway. Available at: www.gov.uk/guidance/innovative-licensing-and-access-pathway (Accessed October 2023).
5. UK Government. Early Access to Medicines Scheme (EAMS): scientific opinions. Available at: https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions (Accessed October 2023).
6. UK Government. Early Access to Medicines Scheme: expired scientific opinions. Available at: www.gov.uk/government/publications/early-access-to-medicines-scheme-expired-scientific-opinions (Accessed October 2023).
7. NICE. Health technology evaluations: interim methods and process guide for the proportionate approach to technology appraisals [PMG40]. Available at: www.nice.org.uk/process/pmg40/chapter/introduction (Accessed October 2023).

DISCLOSURES

All authors participated in the collection, analysis, and interpretation of data and contributed to writing, reviewing, and approving the final version of this poster.

Presented at ISPOR Europe 2023