NICE Early Value Assessment: A new avenue for evidence generation and early market access in the digital therapeutics space in the United Kingdom

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INTRODUCTION

- The National Institute for Care and Health Excellence (NICE) launched the Early Value Assessment (EVA) for MedTech in 2022 to help support evaluation and uptake of digital therapeutics (DTx). Under this pathway DTx can receive conditional recommendations to support adoption contingent on future data collection.
- Over 50 DTx have been assessed since the program's inception with over 30 recommendations, potentially providing a model value framework for other countries.

METHODS

- A targeted literature review was conducted on the NICE website for EVAs for digital therapies and the resulting health technology evaluations (HTE) published until 14 June 2024.

RESULTS

- NICE review identified a diverse range of DTx covering the following conditions: anxiety, depression, weight loss, non-specific low back pain, agoraphobia, psychosis, and chronic obstructive pulmonary disease. These technologies were categorized into eight HTEs, each reviewing between three to twelve DTx.
- The evidence package assessed in each HTE included one to fourteen randomized controlled trials (RCTs). In total, 57 DTx were evaluated, leading to 71 recommendations: 52.1% were conditional, 39.4% were for research only, and 8.5% were either not recommended or excluded.

Figure 1: Recommendations by HTE

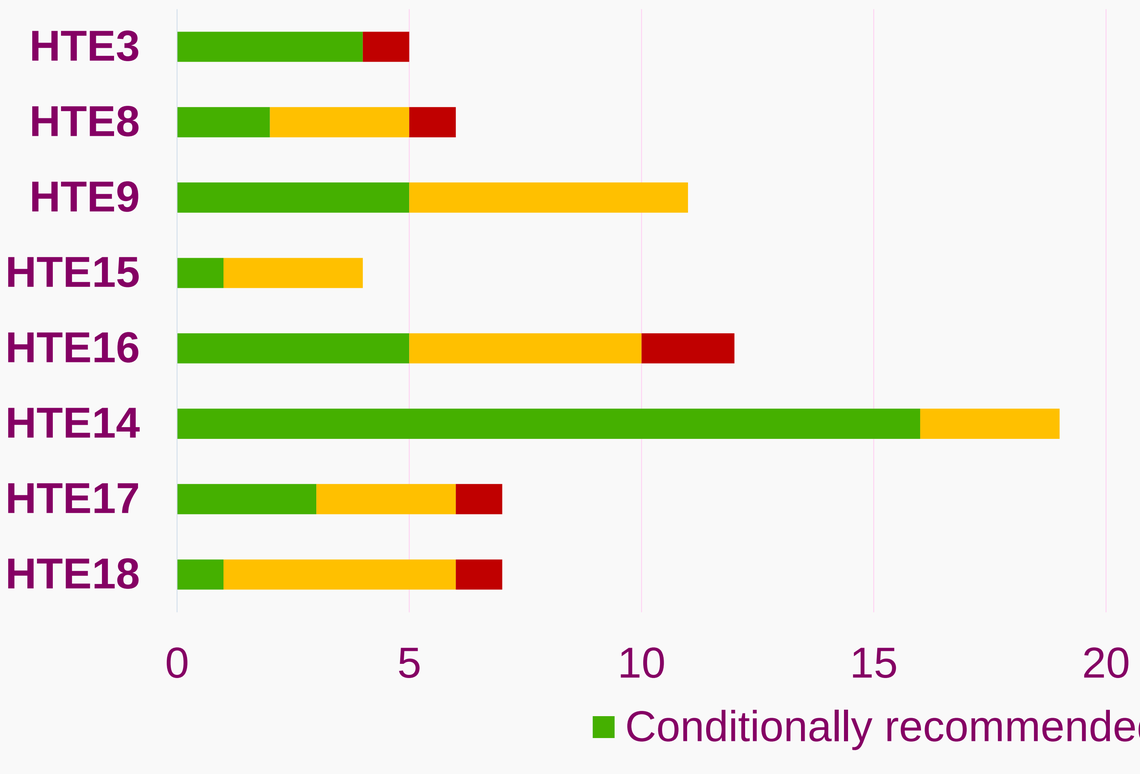
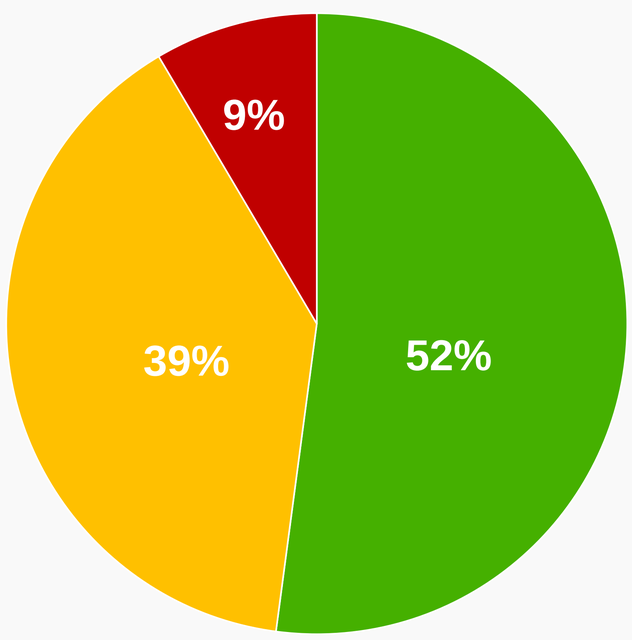


Figure 2: Overall recommendations



CONCLUSIONS

- Achieving a conditional recommendation is challenging, as almost half of the recommendations are for research only or not recommended, highlighting the risk of submitting to EVA without a robust evidence package.
- Even with a conditional recommendation, technology developers must adhere to evidence development plans and implement local access strategies to gain uptake.
- From an HTA policy perspective, the EVA sets out a standardized national-level pathway for DTx, positioning NICE as a key influencer in this space.
- For DTx manufacturers, the EVA process provides a pathway for early access and the opportunity to improve the evidence package, but it is not without challenges.

QUESTIONS FOR DTX MANUFACTURERS

- How does your value proposition specifically address the health challenges identified by NICE?
- Which stakeholders, such as regional NHS entities and advocacy groups, are essential to ensure adoption?
- What insights and lessons can be leveraged when entering other European markets?

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