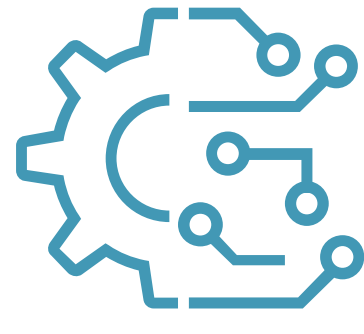


An evaluation of the NICE Early Value Assessment: What is the opportunity for digital therapeutics?

Victor Moran, David Carr, Richard Macaulay; Global Pricing, Market Access and Analytics, PRECISIONadvisors
For further information, contact david.carr@precisionvh.com or visit us on <https://www.precisionadvisors.com>

Objectives



To assess how digital therapeutics (DTx) have been evaluated by the National Institute for Care and Health Excellence (NICE) in the Early Value Assessment (EVA) process

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 20-June-2023 were analysed for evidence submitted and reimbursement outcomes

NICE assessments

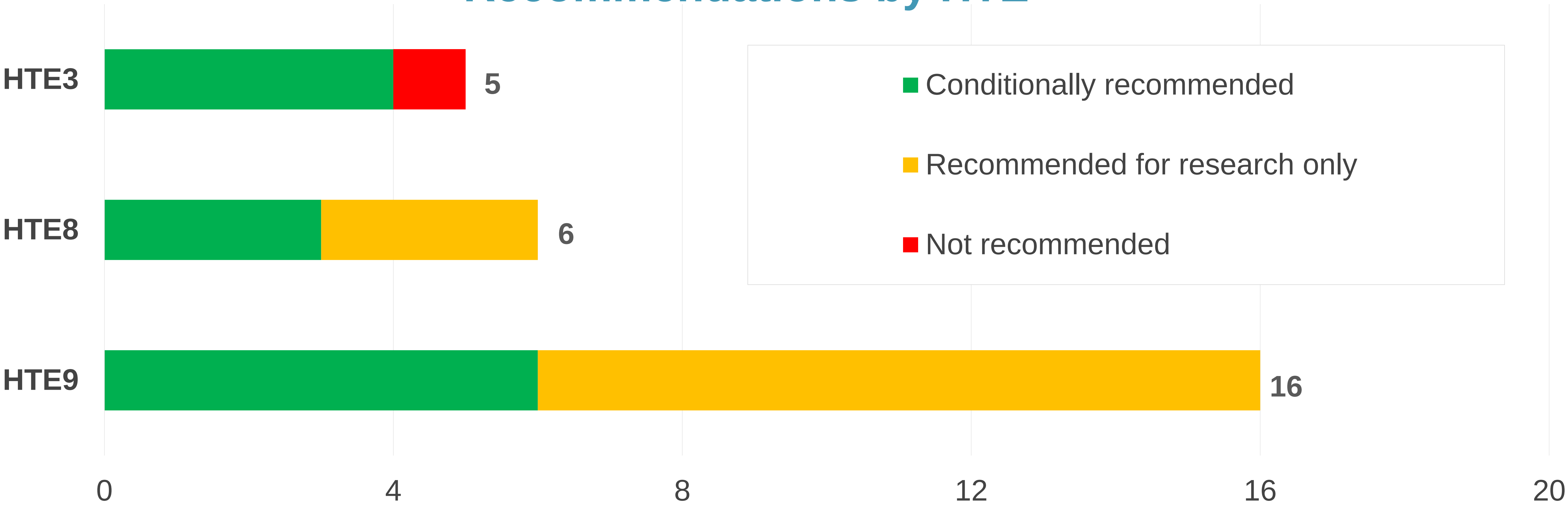
	HTE 3	HTE 8	HTE 9
Date	Feb 2023	May 2023	May 2023
DTx evaluated	5	6	11
Disease area	anxiety / low mood in children	depression in adults	anxiety disorders in adults
Evidence base	9 articles (1 RCT)	46 articles (14 RCTs ^a)	19 articles (4 RCTs)

Results

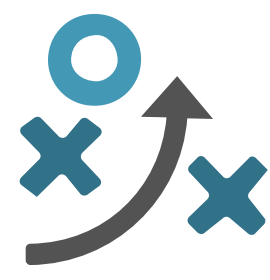


In summary, among the 27 recommendations, 48% were conditional recommendations, 48% for research only, and 4% not recommended. Additionally, of the total evidence submitted, 32% of studies came from RCTs

Recommendations by HTE



Discussion & conclusions



The EVA process allows rapid assessment of DTx by NICE for clinical effectiveness alongside recommendations on additional evidence to be generated



Whilst NICE recommendations of DTx under EVAs are not legally binding, these are expected to improve local access in England. Additionally, they may have positive effects in markets that look to NICE guidance



However, by submitting early and potentially less mature data, an 'only in research' recommendation is possible. Manufacturers must consider this trade-off of speed versus access in product development

Strategic roadmap



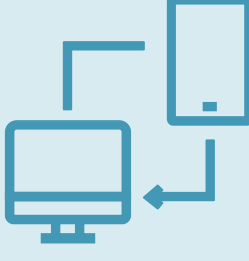
Engage early with NICE
Establish a relationship with NICE early on to understand their evaluation criteria



Target the right indications & populations
Demonstrate significant benefit in conditions with recognised national unmet need



Balance speed and evidence maturity
Be strategic about when to seek NICE evaluation



Conduct the right studies
Develop appropriate evidence generation plans to demonstrate value for money

Notes, a. 46 papers reporting on 32 studies; References, NHS England; NICE; Pharmaphorum; Abbreviations, DTx, digital therapeutics; EVA, Early Value Assessment; HTE, Health Technology Evaluations; NICE, National Institute for Health and Care Excellence; RCT, randomized controlled trial;