HTA351

A targeted review exploring how English and German Health Technology Assessment agencies differ in their appraisal of Digital Health Apps

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Introduction

- As the range of prescribed digital health apps expands, the need to evaluate an app's value has become an important consideration
- An increasing number of manufacturers seek to undergo a form of appraisal to certify the clinical and economic value of their apps; however, the type of health technology assessment (HTA) and the evidence required differ between agencies
- In England, Medical Technologies Guidance (MTG) reports published by the National Institute for Health and Care Excellence (NICE) have recently been used to assess healthcare apps
- In Germany, the fast-track Digital Health Applications (DiGA) directory by the Federal Institute for Drugs and Medical Devices (BfArM) is a well-known pathway for healthcare apps. This pathway has also served as a blueprint for the assessment of healthcare apps in other European countries
- This review was conducted to understand how HTA agencies in England and Germany assess prescribed digital health apps from the perspective of process and evidence considerations

Methods

- MTG reports published by NICE and assessments from the DiGA directory by BfArM were analysed to identify apps in the same therapy area that had undergone review in both countries
- A targeted search was conducted for assessments published between May 2020 and May 2023, which identified:
  - **Chronic obstructive pulmonary disease (COPD) apps:** myCOPD in England and Kaia COPD in Germany
  - **Insomnia-focused apps:** Sleepio in England and Somnio in Germany

Results

- The potential assessment outcomes between England and Germany differed, with NICE granting either a positive or negative recommendation, and BfArM granting either a positive, negative or a provisional recommendation (trial phase)
- **COPD:** The appraisal of myCOPD by NICE resulted in a negative recommendation with a suggestion for further evidence generation, whilst the appraisal of Kaia COPD by BfArM resulted in a provisional recommendation for one year (subject to further data collection)
- **Insomnia:** Somnio and Sleepio both received positive recommendations by NICE and BfArM
- **Clinical evidence:** The evidence required by the two agencies differed; where NICE required larger study sample sizes, longer study duration and real-world evidence alongside randomised clinical trial (RCT) data, whilst BfArM placed an emphasis on data from RCTs
- **Economic evidence:** NICE required substantial cost modelling data in its appraisal, while in the DiGA assessment, no economic evidence was required at the assessment stage
- **Other considerations:** The assessment by NICE considered factors relating to the app itself, such as ease of use, training requirements, and whether it helped with patient engagement; such factors were not considered in the BfArM assessment

Conclusions

- Whilst there are now established HTA pathways for the assessment of prescribed digital health apps in England and Germany, the factors considered in assessments differ between the HTA agencies
- As other European countries develop pathways for the appraisal of prescribed digital health apps, we are likely to see further evolution in HTA processes, with potential divergence in evidence requirements and final recommendations for reimbursement
- Manufacturers of healthcare apps will need to consider the evolving appraisal processes to develop evidence generation plans to support reimbursement and uptake of their apps

Technology	Outcome	Clinical evidence and key measures	Economic evidence	Other considerations	Key appraisal comments
COPD **myCOPD[1]**	**Not recommended** (further research required)	4 — Four studies, including three RCTs and one observational study *Key measures: CAT score and 6MWD*	2 — Two cost models, including analysis of eligible patient population and hospital discharge	! — Training, implementation and usability	• **Clinical evidence is uncertain** due to the short trial lengths and populations studied • **Cost savings uncertain** due to lack of information about how myCOPD affects healthcare resource use
COPD **Kaia COPD[2]**	**Provisionally recommended** (trial phase December 2022 – December 2023)	2 — Two studies, including one RCT and one observational study *Key measures: CAT score and 1-MSTS*	0 — No cost models submitted	0 — No other considerations	• **Reassessment** using additional evidence collected from another RCT
Insomnia **Sleepio[3]**	**Recommended**	12 — Twelve RCTs, in addition to non-randomised studies and RWE *Key measures: insomnia symptoms*	3 — Committee analysed 3 models (out of 12 submitted), including eligible population and comparisons vs standard of care	! — Training, treatment pathway and drop-out rates	• **Sleepio is recommended as a cost saving option for treating insomnia** for people who would otherwise be offered sleep hygiene or sleeping pills • **Option for additional research** through RWE studies to compare Sleepio with face-to-face CBT-I
Insomnia **Somnio[4]**	**Recommended**	1 — One RCT with 12-month follow-up *Key measures: insomnia symptoms*	0 — No cost models submitted	0 — No other considerations	• The clinical study has shown that Somnio can **reduce the symptoms of insomnia effectively and in the long term**

Table 1. Summary of HTA assessments for COPD and insomnia in England and Germany.

Abbreviations

CAT=COPD assessment test; CBT-I=Cognitive behavioural therapy for Insomnia; COPD=Chronic obstructive pulmonary disease; RCT=Randomised controlled trial; RWE=Real-world evidence; 1-MSTS=One minute sit to stand test; 6MWD=6-minute walk distance test.

References

1. National Institute for Health and Care Excellence. myCOPD for managing chronic obstructive pulmonary disease (MTG68). Available at: https://www.nice.org.uk/guidance/mtg68. Accessed: May 2023. 2. Federal Institute for Drugs and Medical Devices. Kaia COPD: My active COPD therapy. Available at: https://diga.bfarm.de/de/verzeichnis/01329. Accessed: May 2023. 3. National Institute for Health and Care Excellence. Sleepio to treat insomnia and insomnia symptoms (MTG70). Available at: https://www.nice.org.uk/guidance/mtg70. Accessed: May 2023. 4. Federal Institute for Drugs and Medical Devices. Somnio. Available at: https://diga.bfarm.de/de/verzeichnis/00508. Accessed: May 2023.

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