MedTech Passport to HTAs

MT26

HTA Requirements for Medical Technologies in Germany

Caoimhe Leonard,[1] Liesl Gildea,[1] Sheryl Warttig,[1] Margaret Mordin[2]

[1] RTI Health Solutions, Manchester, United Kingdom; [2] RTI Health Solutions, Durham, NC, United States

BACKGROUND

- Health technology assessments (HTAs) of pharmaceuticals are the industry standard for evidence-based value assessment. In recent years, HTA organisations have also started to assess medical technologies (MTs) to a greater extent.[1] As a result, MT companies may be required to provide different types of evidence, such as health economic models, that were previously not required.
- However, the assessment of MTs by HTA organisations is still developing, with no current consensus regarding process and methods.[2] Therefore, the HTA process and methods for MTs, and the types of evidence considered, can vary globally and within countries.
- In addition, information on HTA processes and requirements for MTs is not always clearly available. Therefore, it can be difficult for MT companies to work out what is required.
- The website for Germany's HTA organisation, the Federal Joint Committee (G-BA), provides some information on the process and methods used but is limited in relation to MTs.[3]

OBJECTIVE

- To identify HTA processes and requirements for MTs globally.
  - More specifically, we sought to understand the process and methods for MT HTAs used in Germany.

METHODS

- We reviewed publicly available information from the G-BA website and supplemented findings with results from an online survey.
- We developed an online survey to request information on the selection process, general submission process, and types of evidence considered part of the clinical and economic assessment of MTs.
- The survey was sent to 55 HTA organisations worldwide, including the G-BA in Germany, in spring 2023.
- Quantitative and qualitative data were obtained and collated in Excel.

RESULTS

- Although the G-BA website indicates MTs are considered, the focus of information is about pharmaceuticals, so it is unclear if MTs are handled in the same way as pharmaceuticals or if different processes and methods apply.
- Responses to the online survey revealed that:
  - The types of MTs G-BA can consider for HTA include invasive and noninvasive devices, diagnostics, and digital technology such as apps or software.
  - For the MTs selected for an HTA:
    - A general HTA process is used (e.g., the same process used for assessing pharmaceuticals).
    - Clinical efficacy and safety data and opinions from patients are considered. Economic evidence is not required as part of the assessment and is performed separately.
    - MT companies can submit evidence as part of an HTA, including confidential data, and G-BA has a specific evidence submission template.
    - After regulatory approval, it usually takes G-BA > 12 months to complete an HTA for an MT.
    - The outcome of the HTA is a recommendation or conclusion, which is mandatory for the healthcare system to follow. The G-BA, however, does not engage in pricing negotiations for reimbursement of the MT.
- The G-BA is required to assess additional benefit, impacting reimbursement of the statutory health insurance funds in Germany.
- The 2025 G-BA review found that methods for high-risk MTs are evaluated within 6 months.

Survey Responses

What types of clinical evidence are considered as part of the health technology assessment (HTA) process for medical technologies?

- ☑ **Randomised control trials (RCT)**
- ☐ **Real-world data (RWD)**
- ☐ **Registry data**

Does your organisation conduct clinical systematic literature reviews (e.g., safety and efficacy) as part of the health technology assessment (HTA) process for medical technologies?

- ◉ **Yes** ○ **No**

Does your organisation conduct economic systematic literature reviews (e.g., resource use) as part of the health technology assessment (HTA) process for medical technologies?

- ○ **Yes** ◉ **No**

Does your organisation consider economic evaluations as part of the health technology assessment (HTA) process?

- ○ **Yes** ◉ **No**

What kind of economic evaluations does your organisation consider?

- ☒ **Cost-utility analysis (CUA)**
- ☒ **Cost-effectiveness analysis (CEA)**
- ☒ **Budget-impact analysis**
- ☒ **Cost-benefit analysis (CBA)**
- ☒ **Cost-minimisation analysis (CMA)**
- ☒ **Price comparison analysis**

CONCLUSIONS

- A major challenge for MT companies is establishing whether a technology requires or is eligible for HTA in different markets, and if so, which types of clinical, economic, and other types of evidence are considered and what the likely outcome of HTA will be (e.g., a mandatory recommendation that healthcare services must follow or advice and information that is optional for healthcare services to use or follow).
- In Germany, limited information on the processes and methods used to review MTs was available on the G-BA website.
- Our survey results indicate that the G-BA applies a general approach to the HTA of MTs, which does not differ from the process and methods used for pharmaceuticals. For MTs, the HTA process is limited to clinical efficacy data, safety data, and opinions from patients, with no economic evaluation required as part of the assessment, and this is performed separately.
- MT companies should be prepared to contact HTA agencies directly to obtain information about the HTA process and methods to inform market access strategies and HTA submission plans.

REFERENCES

1. Ciani O, et al. IFMBE Proc. 2016;57:1345-1348.
2. Ming J, et al. Cost Eff Resour Alloc. 2022;20(1):54.
3. G-BA. 2025. https://www.g-ba.de/.

CONTACT INFORMATION

Caoimhe Leonard, MSc
Research Associate, Value and Access

RTI Health Solutions
2nd Floor, The Pavilion
Towers Business Park
Wilmslow Road
Didsbury, United Kingdom
Phone: +44 (0) 161 447 6037
Email: cleonard@rti.org

Presented at: ISPOR Europe 2025; 9-12 November 2025; Glasgow, Scotland, United Kingdom

RTI Health Solutions®