MedTech Passport to HTAs

What Is the Medical Technology HTA Process in Japan?

MT16

Mordin M,[1] Bhogal P,[2] Warttig S,[2] Gildea L,[2] Long J,[2] D'Souza V,[2] Kinderås M,[3] Ling C,[2] Hartley L[2]

[1]RTI Health Solutions, Ann Arbor, MI, United States; [2]RTI Health Solutions, Manchester, United Kingdom; [3]RTI Health Solutions, Ljungskile, Sweden

BACKGROUND

- Health technology assessments (HTA) of pharmaceuticals have been performed for some time. In recent years, HTA organizations 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 organizations is still developing, with no current consensus as to process and methods.[2] Therefore, HTA processes and methods for MT 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 Japan's HTA organization, Center for Outcomes Research and Economic Evaluation for Health (C2H), provides little information on the process and methods used to evaluate MTs.

OBJECTIVE

- To identify HTA processes and requirements for MTs globally.
  - More specifically, we sought to understand the process and methods for MT HTA used by C2H in Japan.

METHODS

- We reviewed publicly available information from the C2H 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 organizations worldwide, including C2H in Japan, in spring 2023.
- Quantitative and qualitative data were obtained and collated in Excel.

RESULTS

- The C2H website provides little information on the process and methods used to review MTs.
- C2H responses to the online survey revealed the following:
  - C2H reviews for HTA focus on invasive devices.
  - MTs are externally referred (e.g., by local government) to C2H for review.

For MTs selected for HTA:

- A general HTA process (e.g., the same process used for assessing pharmaceuticals) is used.
- C2H reviews clinical efficacy, safety data, and economic data. C2H does not consider opinions from healthcare professionals and patients in the assessment.
- C2H conducts systematic literature reviews to identify clinical data for the HTA and will consider published randomized controlled trials, real-world data, registry data, and unpublished data (i.e., confidential data).
- MT companies can submit evidence as part of the HTA, and C2H has a specific evidence submission template.
- Economic analyses that can be used in the HTA are cost-utility analyses. A fixed willingness-to-pay threshold of JPY 5 million per quality-adjusted life-year (QALY) (range, ¥5 million to ¥10 million per QALY).
- ¥5 million to ¥10 million per QALY for clinical efficacy and safety data as well as economic data are considered.
- A healthcare system perspective is used for economic analyses.
- It usually takes C2H ≥ 12 months to complete an HTA for MT.
- The outcome of the HTA is used for reimbursement price setting.

Survey Responses

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

- ☑ Randomized 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

What topics do the economic systematic literature review (SLR) cover?

- ☒ Utility
- ☒ Health resource use/cost
- ☒ Economic evaluations

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

If your organisation considers cost-utility analysis, do you have a willingness to pay (WTP) threshold?

Fixed WTP threshold is used

What is the willingness to pay (WTP) threshold your organisation uses?

¥5 million per QALY (range: ¥5 million to ¥10 million per QALY)

Perspectives for economic evaluations
Select all that apply.

- ☒ Societal
- ☑ Healthcare system
- ☒ Individual patient
- ☒ Target groups of specific services

Discount rates

Outcomes: *2% per year*

Costs: *2% per year*

CONCLUSIONS

- In Japan, only invasive devices are subject to review by C2H.
- 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 Japan, information about the process and methods used was limited on the C2H website.
- The wider project of which this is part showed that 42% of HTA organizations that undertake HTA on MTs do not have dedicated MT HTA processes and methods.
- Our results show that there is a general HTA process for MTs in Japan that is like that for pharmaceuticals but with MTs being externally referred to C2H for review.
- C2H considers a range of data sources for clinical evidence that includes RCTs, real-world evidence, and unpublished data, but information on the economic evidence required was sparse.
- However, it is not clear how much MT companies can influence the timing of HTA.
- MT companies should be prepared to contact HTA agencies directly to obtain information about HTA processes and methods to inform market access strategies and HTA submission plans.

REFERENCES

1 Ciani O, Federici C, Tarricone R. Current and future trends in the HTA of medical devices. In: Kyriacou E, Christofides S, Pattichis CS, editors. XIV Mediterranean conference on medical and biological engineering and computing 2016. Springer International Publishing; 2016. pp. 1345-1348. https://doi.org/10.1007/978-3-319-32703-7_258.

2 Ming J, He Y, Yang Y Hu M, Zhao X, Liu J, et al. Health technology assessment of medical devices: current landscape, challenges, and a way forward. Cost Eff Resour Alloc. 2022;20(1):54. https://doi.org/10.1186/s12962-022-00389-6.

CONTACT INFORMATION

Margaret Mordin, MS
Vice President, Market Access and Outcomes Strategy, RTI Health Solutions

Telephone: +1.571.294.0834
Email: mmordin@rti.org

Presented at: ISPOR 2024; 5-8 May 2024; Atlanta, GA, United States

RTI Health Solutions