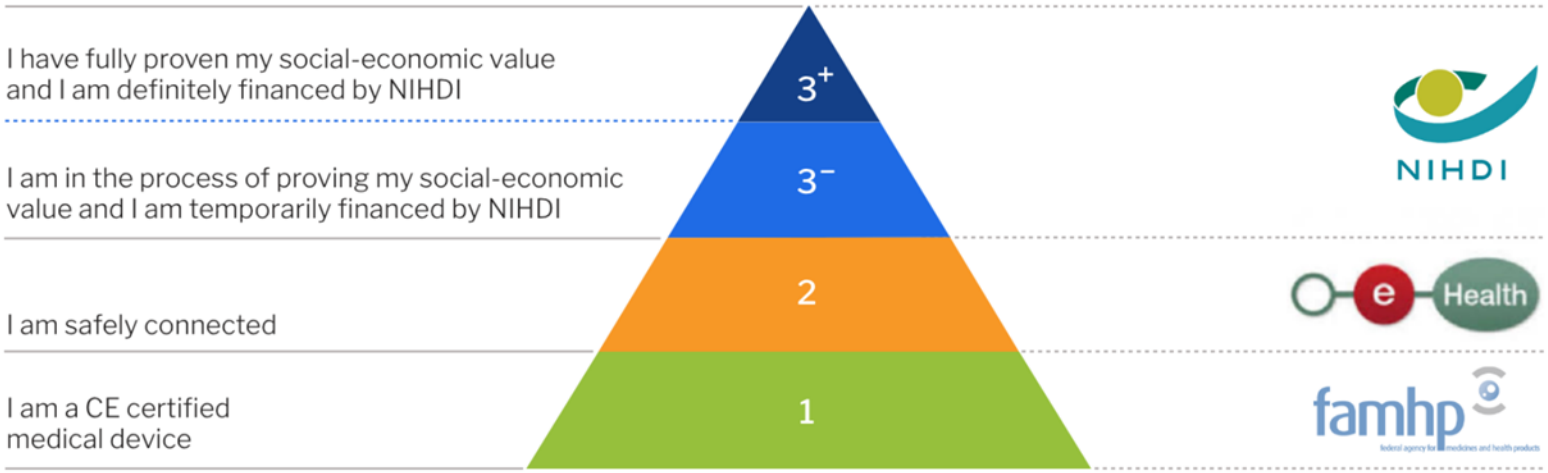
mHealth reimbursement Belgium

12-05-2026

BACKGROUND

2020-2023: mHealth validation pyramid



- Applications were evaluated by ad hoc working groups, but the existing concertation bodies were responsible for the development of reimbursement
- Lack of specific mHealth Budget

=> No actual implementation of reimbursements

2023: first reform

1. Publication on the (private) mHealthBelgium website no longer mandatory
2. The principles of the validation pyramid remain, but the visual and name are sort of retired.
3. Creation of a mHealth working group
   - Responsible for both the evaluation and the development of reimbursement proposals (which still need to be validated)
   - Multidisciplinary core group of members (HCPs, public insurers, hospitals, health economists + some observer members)
   - Ad hoc members added for each reimbursement application (HCP, patients, representatives of the relevant concertation bodies)
4. HCPs and hospitals can submit reimbursement requests.
   - Scientific or professional organisations, not individual HCPs

2023: first reform

5. Indicative timings
6. Temporary reimbursements possible
   - != financing of studies
   - Letter of support from a professional or scientific association mandatory
7. (limited) dedicated mHealth budget
8. Scope remains
   - Treatment, diagnostic or monitoring
   - Transmission of data with a HCP is required (>< DiGA)
   - Not limited to smartphone applications. Connected medical devices are also in scope.
9. New templates

CURRENT PROCEDURE

Templates

- Based on templates for implants and invasive medical devices
- Quite exhaustive: systematic literature searches required on epidemiology, clinical studies and health-economic studies
- Specific templates
  - Permanent or temporary reimbursement
  - commercial firm or HCPs/hospitals
- Reimbursement request must be submitted in French, Dutch or German depending on the location

Templates: technical file

- In addition to the technical admissibility requirements (M2 self-check)
- Questions provided by eHealth
- Questions on:
  - Cloud storage
  - Data transfers outside the EEA
  - Supported OS if a smartphone is involved
  - Whether any additional certificates are obtained (none are required)

Loads of additional questions could be asked but

- Would increase workload and require additional expertise
- Would make generic reimbursements impossible
- Repeating the work that has been done in the context of the CE-certification?

Templates: scientific file

a. Description of pathology and patient group, including a calculation of the potential target group size
b. Description of the current standard care pathway and other therapeutic options
c. Description of the proposed care pathway (both the medical device itself and the required associated health care services)
d. Scientific analysis:
   - Discussion of the identified publications, with a focus on the studies with the highest level of evidence of the most relevance
   - Both clinical improvements and organisational improvements are regarded as added value
   - Discussion of the applicability of the studies to the clinical practice
   - Recommendations by HCPs, patient organisations can be mentioned

Template: economical file

a. Overview of the different cost components (medical device, accessories and related health care services,
b. Reimbursements in other countries,
c. A budget impact analysis only considering direct cost and savings,
d. A budget impact analysis also considering future costs and savings (more uncertainty and more challenging to include into budget calculations)
e. Discussion of the health economic studies (if they exist)

Evaluation

1. Admissibility is checked
2. Internal evaluator will prepare a report
   - Other NIHDI experts may play a supporting role
3. Report is presented to the working group and adjusted based on their feedback. Questions to the applicant may be formulated
4. The report and questions are sent to the applicant. The applicant is asked to provide a written response to the questions
5. The applicant is invited to a meeting of the working group to offer additional clarifications (15 min presentation and Q&A)
6. The working group decides on a positive or negative evaluation
   - An additional meeting may be required

Development of reimbursement proposal

- Working group decides on a temporary or permanent reimbursement
- Bundled payment for both the medical device and the associated health care services
- Generic reimbursement: no list of accepted applications, but rather a list on minimal functionalities
  - Software evolves. When is a re-evaluation required?
  - Many similar applications exist. Working with lists of apps would increase workload immensely.

Validation, implementation and evaluation

- One or several of the existing concertation bodies have to approve the reimbursement proposal
  - Risk of previously obtained consensuses being called into question again.

- Depending on the form of the reimbursement, the implementation may take half a year or longer

- A temporary reimbursement will typically last three years or longer
  - Intermediary reports every 18 months

FUTURE

Improvements necessary?

- Only 3 applications received in 2.5 years
- Currently exchanging ideas with different stakeholders.
- The following options are just ideas, not current or future policy

Speeding up the process

A sufficiently exhaustive evaluation is considered essential. The evaluation is also not the longest step.

Validation and implementation timings are mostly out of our control.

This leaves the development of the reimbursement proposal, which also takes the longest.

Potential actions:

- Implementing generic reimbursement conditions for telemonitoring
- Implementing a modular system of fixed reimbursement rates
  - For example different rates for software, hardware, basic monitoring, extensive monitoring,…
  - Option to deviate from rates, either immediately or after some time should remain.

Adjusting hospital financing

- Hospital financing is based on patients being actually hospitalised. Discharging patients early but telemonitoring them intensely for a short period is financially disincentivised.

- Creation of a “remote hospital stay” could alleviate this issue without a risk of budget overruns, as hospital financing is a closed envelope.

- Challenging to change hospital financing, so a long-term option

Increasing clarity (and trust!)

- Organising yearly webinars and Q&As, publishing a FAQ, referring to best practices, improving the guidelines in our templates (in addition to the pre-submission meetings we already offer)
- More clarity on evidence requirements (European projects)
- Involving eHealth and the federal agency for medicines and health products.