ALAN
Acute Leukaemia Advocates Network

Health Technology Assessment and Reimbursement: What is the Difference?

Health Technology Assessment (HTA) and Reimbursement: What is the Difference?

Once a new oncology medicine is developed, it must first be evaluated by the European Medicines Agency (EMA). This agency decides whether the medicine can be used in the 27 EU Member States, as well as Iceland, Liechtenstein, and Norway.

The EMA grants a marketing authorization only if it decides that the medicine's benefits outweigh its risks.

But approval from the EMA is not enough. Before patients can access the medicine through their public healthcare system, two more questions need to be answered:

- How is this medicine doing comparatively to existing treatments?
- Will the national health system pay for it?

1. HTA: How is this medicine doing comparatively to existing treatments?

This is the main question answered through health technology assessment (HTA). It is a process used to evaluate a new medicine and how it compares to existing treatments. HTA looks at:

- How this medicine works
- Whether it is safe
- Whether the additional benefits it offers are worth the cost.

HTA has two main parts:

- **Assessment:** This is the scientific review. Experts analyze the quality of the trial data — how the trials were conducted, what the results show, and whether the medicine was compared to the right alternatives. This part is focused only on the evidence, not on context (such as who will use the medicine).
- **Appraisal:** This is where the evidence is interpreted. Decision-makers use the findings from the assessment to decide how the medicine is doing comparatively to existing treatments, and in what situations. In this part, context matters — for example, whether the treatment is for children or for a rare disease.

EUnetHTA defines HTA as:

"A multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused, and seek to achieve best value" (EUnetHTA 2007).

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2. Reimbursement: Will the national health system pay for it?

Even if a medicine is approved by the EMA and has a positive HTA, it won't be accessible until it also receives a positive reimbursement decision.

The reimbursement process is conducted by health authorities, often different from the HTA bodies, at the national and/or regional level. They decide:

- If the medicine will be covered by the public system
- For which patients
- Under what conditions (e.g., hospital use only)
- At what price

Price negotiations take place between the health authorities and the pharmaceutical company. It is only after this step that the medicine becomes available to patients through the healthcare system.

In summary

- HTA provides scientific and clinical evidence.
- Reimbursement determines if and how patients can access the medicine.

3. Why engage patients in HTA and reimbursement?

Patients have unique knowledge based on their lived experience. They understand what matters most in daily life — like quality of life, side effects, or treatment burden — and can identify priorities that may be missed in clinical studies.

By contributing to different stages of the HTA process — from early planning to reviewing draft reports — patients help make decisions that are more realistic, relevant, and patient-centered.

Want to Learn More?

Read our companion factsheets:

- How Medicines Are Evaluated in Europe?
- Involvement of French Patients in Health Technology Assessment
- Involvement of German Patients in Health Technology Assessment

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