

Revisiting the Willingness-to-Pay Threshold: Integrating QALY Shortfall to Reflect Disease Severity and Unmet Medical Need

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Background

- The current Willingness-to-pay threshold (WTP-T) in Czechia has not been updated since 2013 (≈€49,000/QALY).
- Traditional ICER/QALY approach has inherent limitations and does not always adequately capture the true disease severity or unmet medical need.
- QALY shortfall metrics – absolute shortfall (AS), proportional shortfall (PS) and the ratio of incremental QALYs to AS (Δ QALY/AS) – can better reflect disease severity, unmet medical need, and societal preferences in reimbursement decisions allowing equity and innovation to be quantified.

Methods

- A retrospective analysis of 73 reimbursement decisions (2022–2024) in Czechia. The year 2022 was selected because it marked the most recent major legislative changes in medicines reimbursement, including the introduction of a new pathway for orphan medicines.
- **Standardized QALY shortfall calculator was developed** by the Czech Pharmacoeconomic Society (ČFES) and applied to compute (**Figure 1**):
 - Absolute shortfall (AS)
 - Proportional shortfall (PS)
 - **Ratio Δ QALY/AS**
- We introduce a novel measure of innovation using **ratio Δ QALY/AS** that reflects the added value of a new intervention. It combines the incremental QALY gain delivered by the technology with the absolute QALY shortfall, effectively indicating the extent to which the new treatment restores health toward the level observed in the general population without the disease.
- Analysis was stratified by procedure type: Standard, Highly Innovative Medicinal Products (HIMP), Orphans.
- Benchmarked vs. NICE (UK), ZIN (Netherlands), NOMA (Norway).

Figure 1. QALY shortfalls and incremental QALYs

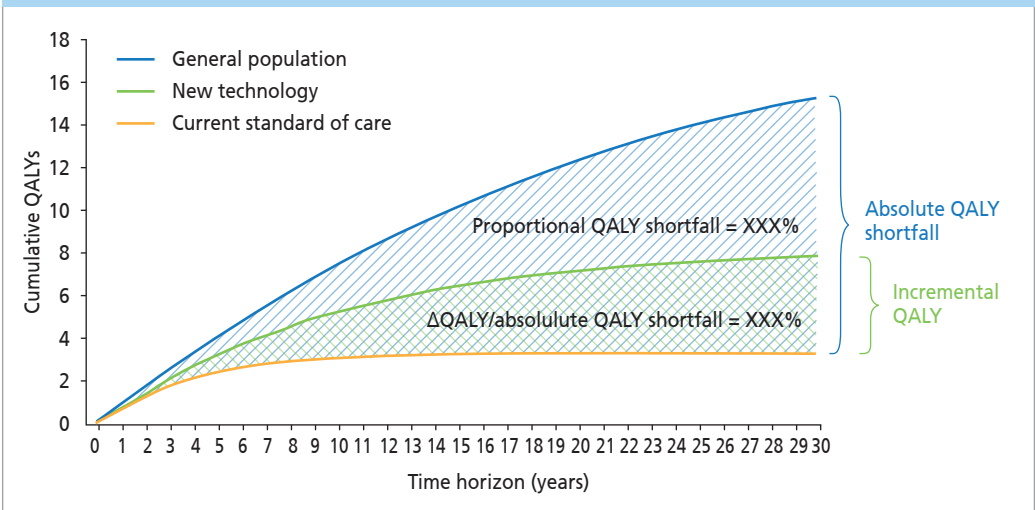


Figure 2. Comparison of QALY shortfalls and incremental QALYs, stratified by reimbursement type					
Reimbursement type	Median ICER	Median QALY gain	Median proportional QALY shortfall	Median absolute QALY shortfall	QALY gain / abs. shortfall ratio
Standard	37,040	15.18	47%	6.51	7%
HIMP	118,078	12.79	87%	10.70	9%
Orphan	193,119	19.52	73%	12.51	15%
ALL	72,207	15.39	71%	8.89	9%

Results

- Median ICER: ≈€72,000/QALY; only 37 % of cases fell below WTP-T.
- **Median QALY shortfalls: Absolute 8.9 QALYs, Proportional 71%, Δ QALY/Absolute 9% (Figure 2).**
- Orphans: highest AS 12.5 QALY, highest Δ QALY/AS 15 %
→ Orphans proved strongest Innovation potential
- Highly Innovative Medicinal Products (mainly oncology): highest proportional shortfall 87% due to high mortality of cancers.
- We present all 73 reimbursement decisions and their QALY, QALY gained by new technology and disease QALY loss (**Figure 3**).

Conclusions

- **QALY shortfall robustly quantifies disease burden & unmet need.**
- **Newly introduced parameter Δ QALY/Absolute QALY shortfall represents an innovative measure of therapeutic value as it shows additional information value in disease burden, unmet medical need and level of Innovation, it shows the „level of healing“.**
- **Implementation within the current framework is feasible without additional administrative burden.**
- **Further dialogue on threshold differentiation or QALY weighting based on shortfall in Czechia is recommended.**

Figure 3. Reimbursement decisions measuring QALYs, stratified by reimbursement type

