WTP THRESHOLD: A REVIEW OF INTERNATIONAL APPROACHES AND INSPIRATION FOR CULTIVATION OF CURRENT SITUATION IN THE CZECH REPUBLIC

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Background & Objectives

The willingness-to-pay threshold (WTP-T) is an integral part of the health technology assessment process, where health economic aspects are taken into account. In the Czech Republic, the WTP has been applied since 2008 with new legislation. Since 2011, the WTP-T has been an integral part of medicinal products' appraisal process in Czech Republic, initially set at 3-times GDP/capita/QALY.

Since 2017, the decision-making process has set the WTP-T at fixed value of 1.2 million CZK/QALY (≈€50,000/QALY). Currently, this one WTP-T is applied to all medicinal products, except orphan and highly innovative medicinal products at their first temporary reimbursed launch.

The fixed WTP-T (now equivalent to ≈1.86x GDP/capita) may not reflect the product's full value and the unmet medical need in a given disease, nor does it take into account the economic growth of the society or inflation.

Methods

A review of international WTP-T practices was conducted to provide a potential basis for future WTP-T cultivation and to apply an equity approach that captures the value of products and unmet needs across all (medicinal) interventions.

The following countries were included. These countries are generally known to have a well-developed HTA system and can therefore serve as inspiration for Czech Republic:

- Anglo-Saxon countries: United Kingdom (NICE), Scotland (SMC), Canada, USA, Australia
- Nordic countries (Denmark, Norway, Sweden, Finland)
- Other selected EU countries of interest (France, Netherlands, Belgium, Slovakia).

The literature review extraction template (2015-2023) registered within PROSPERO (CRD42023395813) protocol and relevant health-economic guidelines addressed the specific domains:

1. Applicability of WTP-T & its impact on the final decision
- The number of WTP-T and their level(s)
- Increased WTP-T for special types of interventions and/or diseases (rare/ orphan diseases, end-of-life treatment, high unmet medical need, absence of comparators, etc.)
- Advantages/ priority launch for interventions with ICER significantly below the WTP-T

2. How and to what should the level of WTP-T be anchored
- Related to GDP/capita or other economic index (e.g. wage)
- Implicitly derived
- Valorisation of WTP-T over time

3. Definition of added value & unmet medical need in relation to WTP-T
- Unmet medical need & lack of alternatives
- Incremental QALY gain
- Relative clinical benefit & curative potential, life extension
- Severity of disease/ condition & impact on quality of life

4. Exceptions, where WTP-T is not applicable
- Type of intervention, defined by target population size or orphan status
- Level of net budget impact

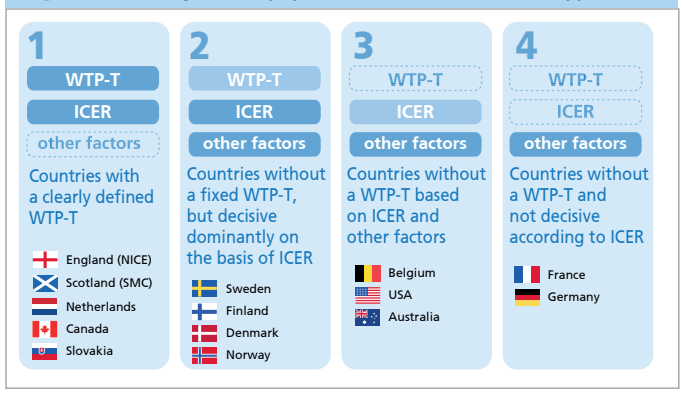
5. Budget impact results & its impact on final decision/ Innovation launch

Results

The literature review shows that the use of a fixed WTP-T is a completely unique approach. In the countries studied, there are usually multiple WTP-T, reflecting other factors, i.e. the added value of the intervention, the level of innovation, the lack of alternatives (clinical benefit, impact on quality of life, QALY increment), the severity of the disease, the unmet medical need, the uncertainty of clinical data/outcomes, the rarity of the disease & the budget impact results, respectively.

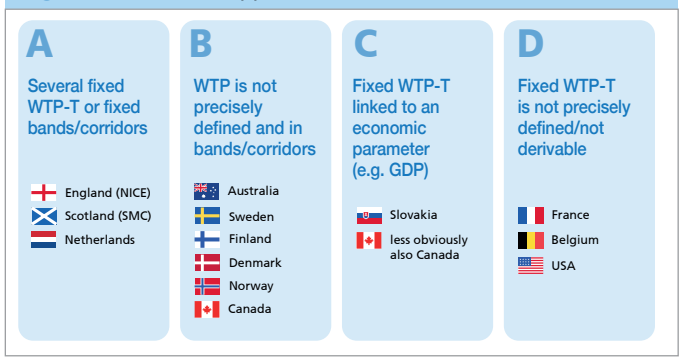
The countries' approaches to WTP-T can be broadly grouped into four categories (**Figure 1**).

Figure 1. Willingness-to-pay threshold countries archetypes



In the United Kingdom, the Netherlands, and Slovakia the level of WTP-T is not defined at one specific value. It varies according to disease severity, unmet need, or defined by QALY (incremental or QALY shortfall: absolute or proportional), see **Figure 2**.

Figure 2. Countries' approaches to WTP-T definition/levels



In general, the lower the ICER, the more favourable reimbursement position and access to interventions has (faster process, or less stringent budget impact requirements).

Countries where valorisation of WTP-T is mandatory are Slovakia and Canada, as the level of WTP-T is based on GDP per capita, which reflects both economic growth and price levels (inflation).

For several countries, the level of budget impact (BI) is also used in the decision-making process. These BI levels determine (i) the obligation to submit CEA/CUA analyses (no need to submit CEA/CUA, in case of low BI), or (ii) the need of appraisal within another body (entering the negotiations with health care payers and negotiate the limitation of costs).

It should be noted that the BI levels are always "permeable" in the sense that it is possible to cross them and it is rather an "entry point" to appraisal phase/ negotiations, e.g. in the United Kingdom (NICE), the Netherlands, Norway. Most countries probably operate in this way, but it is not possible to systematically track the specific values of the BI limits, which are very specific and may result from negotiations between payers and manufacturers.

Discussion & recommendations for WTP-T cultivation in the Czech Republic

In the case of efforts to cultivate the Czech WTP-T so that it transparently reflects both the therapy added value & the unmet medical need in a health condition, there are a number of inspiring approaches. We believe that these approaches can maintain the current framework of the ICER/ QALY-based decision-making process:

I. Quantitative evaluation of therapy added value/benefit & unmet medical need

a. Adjustment according to the proportional or absolute reduction in QALYs (reference to UK, Netherlands)

b. Adjustment according to QALY increment (intervention vs. comparator) as more relevant approach vs. adjustment according to type of intervention (ATMP, orphans, etc.), or ideally a combination of both approaches

Note: This approach would require further/deeper analysis of the existing local HE evaluation results to appropriately select the individual criteria of increment/ decrement (absolute, proportional) QALY.

II. Valorisation/adjustment aspect of WTP-T over time

a. Explicitly link the baseline WTP to an economic indicator and to index it on an annual basis (GDP growth, inflation rate, wage growth, etc.)

b. Or regular adjustment (every 2-3 years) of the calculation of the WTP amount with respect to updated knowledge and practice

III. Determining the baseline level/anchoring of the foundations for WTP-T

a. Based on current decision-making practice (€50,000 / QALY)

b. Or linked to an economic indicator (multiples of GDP according to WHO recommendations, multiples of wages or valorisation of inflation rate)

IV. Faster/wider access to patients in case of low ICER vs. WTP threshold

Conclusion

The future of WTP-T cultivation in the Czech Republic should include:

1. **Stratification of WTP-T reflecting disease severity, unmet medical need, and intervention added value, defined ideally through QALY (incremental QALY gained, QALY shortfall – absolute and/or proportional) as opposed to qualitative/softer evaluation.** Czech Republic is a country with more than 15 years of QALY-based HTA experience. The QALY approach is well established in the Czech system and could be extended/enriched by other factors taking into account not all technologies or disease areas are the same.
2. **Valorisation of WTP-T according to economic growth, increased healthcare demand, monetary reasons (inflation).**

Table 1. High-level summaries for each country/ group of countries

England (NICE) The most robust system is currently applied by the English NICE (and therefore the English NHS), which updated its methodology in 2022 after years of debate. The NICE assessment is characterised by the fact that it is dominated by the ICER value, which is decisive. The baseline WTP-T is set at two fixed levels (Ł20,000/QALY or Ł30,000/QALY) according to the uncertainty of the input data and the pharmacoeconomic analysis. This WTP-T can be increased up to Ł50,000in the case of high disease severity, measured by the so-called absolute QALY shortfall in patients or proportional QALY shortfall, if the QALY gain is rewarded in two other bands (QALY gain times 1.2 or times 1.7). For highly specialised technologies (HRT: e.g. orphan drugs or other highly specialised technologies), the WTP-T is then increased to a baseline of 100,000Ł, which can then be further increased to a maximum of Ł300,000 based on incremental QALY gains (10-30 incremental QALYs).	**Slovakia** Similarly, Slovakia applies several fixed WTP thresholds that are linked to Gross Domestic Product (GDP). The basic WTP-T is set at 2-times GDP (currently €36,000/QALY) for interventions with a QALY gain of up to 0.33. This threshold can be increased to 3-times (for interventions with a QALY gain of > 0.33). For orphan drugs and advanced therapy medicinal products (ATMPs), it ranges from 3.5 to 10 times GDP, depending on the innovativeness of the therapy measured by the QALY gain (up to 0.33, up to 0.50 and above 0.5 QALY gain). Of all the WTP countries studied, only Slovakia has a threshold that is linked to another valid „metric", namely GDP. The advantage of GDP indexation is that it not only reflects the increasing (or decreasing) productivity (wealth) of the country, but is also calculated in given prices, i.e. it directly reflects the increasing (or decreasing) price level.
Scotland (SMC) The Scottish SMC also applies WTP-T of Ł20,000 and Ł30,000 as NICE, but WTP-T modifiers are applied beyond the standard WTP-T that can increase WTP above this threshold (e.g. unmet need for treatment, impact on quality of life and survival, etc.) (Patient and Clinician Engagement (PACE) process).	**No explicitly defined WTP-T: Nordic countries (Sweden, Finland, Denmark, Norway)** Another group of countries do not have an explicitly defined WTP-T and make decisions within a certain ‚band' based on other factors, but the results of the cost-effectiveness analysis are dominant (Sweden, Finland, Denmark, Norway). WTP-T is then influenced by the following factors: severity of the disease, unmet need for treatment (either unspecified or succinctly through QALY shortfall), clinical benefit of the therapy (QALY gain), rarity of the disease, lack of alternatives, etc. Exceptions to the WTP system are rather rare, but are usually applied to orphan drugs or other special technologies that by definition cannot meet the WTP-T (Denmark).
The Netherlands Since 2015, the Dutch ZIN has used an approach to WTP-T similar to NICE's, where disease severity is also assessed using proportional QALY shortfall. This is probably where NICE was also inspired. The Netherlands defines three WTP-T values as follows: €20,000, €50,000 and €80,000 €/QALY, at proportional QALY shortfall values up to 0.4; up to 0.7 and above 0.7 respectively.	
Canada Another country with multiple WTP-Ts is Canada, which has WTP thresholds of 100 – 150 – 200,000 CAD/QALY. The WTP threshold is related to the unmet medical/patient need for the intervention in a given disease, innovativeness, quality of the underlying evidence, magnitude of the clinical effect, resource savings, and/or added value of new drug technologies. The benefit of the intervention vs comparator (at the clinical and incremental QALY level) is then an essential element reflecting the relevant threshold of WTP.	**No direct application of WTP-T: Belgium, USA, France, Australia** The last group of WTP countries does not directly apply the WTP-T in the process or only has an informative character (Belgium, USA, France, Australia). These countries tend to make decisions on a „commission" basis based on a wide range of information, such as data on efficacy, safety, disease severity, unmet treatment need, disease rarity, and budgetary impact. In the case of the USA, the WTP is monitored, but the decision to reimburse a particular therapy is always entirely at the discretion of the insurance company; however, in general, the richer the insurance company (higher premium payments to the insured), the more expensive the technology it can afford to pay, and therefore the higher the WTP-T.

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