PHARMACOECONOMIC RESULTS OF HIGHLY INNOVATIVE DRUGS APPROVED FOR TEMPORARY REIMBURSEMENT IN THE CZECH REPUBLIC

Authors: Eva Ornstová¹, Monika Sebastianova¹, Tomas Milcoch¹, Klara Lamlbova¹, Tomas Dolezal¹

¹Value Outcomes s.r.o., Czech Republic

BACKGROUND

Highly innovative drugs (HDs) can be granted two plus facultative one year extension of temporary reimbursement (TR) to provide timely access and to collect additional real-world evidence by creating a HDs registry.

To obtain a HD status, drug needs to meet legally prespecified criteria such as treatment of highly severe illness plus no alternative reimbursed treatment available including drug resistance, inadequate controlling treatment or substantially better effectiveness or safety compared to the alternative (in terms of survival, severe complications, side effects, hospitalisation, drug interactions).¹

TR applicant does not need to comply with strict cost-effectiveness (CE) requirements and willingness-to-pay (WTP) when there are no sufficient data to support existing evidence. Through the reimbursement of medicines, the German DRG system was able to assess the effectiveness and cost of HDs in clinical practice.²

TR is approved by the Ministry of Health (MoH) on the recommendation of the permanent representation of the Payers Organization (PO) and the reimbursement of HDs is temporary.³

Authors:  Eva Ornstová¹, Monika Sebestianova¹, Tomas Mlcoch¹, Klara Lamblova¹, Tomas Dolezal¹

Highly innovative drugs (HIDs) can be granted two plus facultative one year extension of temporary reimbursement by the German DRG system.

RESULTS

Fourty individual procedures of HDs approved for TR were identified over 10-year period. The most commonly used legally prespecified criteria used in classification of HD status were absence of alternative treatment (90%), followed by unmet need (20%), better efficacy or safety than the alternative (80%), better than sufficient evidence (50%) and orphan status (20%). The most commonly used criteria in classification of HD status were unmet need and better efficacy (80%), followed by lack of alternative treatment (60%), better efficacy than sufficient evidence (50%), better than sufficient evidence (50%) and orphan status (20%). The most commonly used criteria in classification of HD status were unmet need and better efficacy (80%), followed by lack of alternative treatment (60%), better efficacy than sufficient evidence (50%), better than sufficient evidence (50%) and orphan status (20%).

Figure 1 presents the pathways of drugs from the time they entered temporary reimbursement. In cases where collected RWE has not yet been assessed or in cases where there is not enough data to support existing evidence, the first period of temporary reimbursement may be extended. This was the case for 25 (70%) drugs which did not have such data after two years. Ten (25%) drugs had an ongoing TR (first or extended) one. Thirty-five (75%) drugs approved for TR after the expiration of TR. Out of these, 35% had positive subsequent decision on PR and 65% did not manage to receive PR due to withdrawal or not reaching positive decision yet. Price negotiations with payers were present in 50% of cases.

Cost-utility analysis was used to present results of CE in 44% of TR approval procedures. The mean ICER was €38,200/QALY (€38,200/QALY) and does not play a role in decision process of TR. In cases where collected RWE has not yet been assessed or in cases where there is not enough data to support existing evidence, the first period of temporary reimbursement may be extended. This was the case for 25 (70%) drugs which did not have such data after two years. Ten (25%) drugs had an ongoing TR (first or extended) one. Thirty-five (75%) drugs approved for TR after the expiration of TR. Out of these, 35% had positive subsequent decision on PR and 65% did not manage to receive PR due to withdrawal or not reaching positive decision yet. Price negotiations with payers were present in 50% of cases.

An ICER of €38,200/QALY was reported in the subsequent PR procedure (WTP threshold is equal to €45,000/QALY vs. €16,688/QALY in TR).

CONCLUSIONS

Costly HDs accepted for a TR entered the system on average twice higher ICERs and higher netBI than usually accepted in PR procedures (WTP threshold is equal to €45,000/QALY vs. €16,688/QALY in TR). Ninety-two percent of TR drugs were successful in consecutive PR procedure and continue to be available to patients and their reimbursement. Length of approval process was shorter in PR compared to TR, which can also be due to earlier assessment (thus knowledge of the CE model and clinical data) and RWE data availability.

METHODS

All drugs along with their indications approved for TR until 2017 were identified (TR for HDs has been legally valid since 2000). Pharmacoeconomic settings and results in a type of analysis, ICERs, net benefit impact (NBIs) at the time of TR and consecutive PR application were analysed. We also examined these results (ATC, indication of interest, orphan status, type of HD according to legal criteria and compared the length of approval procedure of TR versus PR. We used publicly available databases of pricing and reimbursement procedures maintained by State Institute for Drug Control (SLUK) to access this relevant information.

We distinguished between fast TR procedure and an extension of TR by one year, which is usually allowed when RWE data are not mature for PR and HD status is still valid.

REFERENCES

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