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Do positive Health Technology Assessment outcomes guarantee reimbursement for specific oncology therapies in major European markets?

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Background

- Cancer is the second leading cause of mortality and morbidity across the EU, with >3.7 million new cases and 1.9 million deaths per year
- The age-standardized rate for all cancers in the United Kingdom (UK), Germany, and France was 340-350 per 100,000 in 2018
- Non-small cell lung cancer (NSCLC), colorectal cancer (CRC), and ovarian cancer (OC) are the most prevalent cancers
- Over the last 10 years, about 19 novel therapies were approved across these indications
- Most oncology therapies have multiple indications, and these drugs pose a particular dilemma regarding pricing and reimbursement considerations since they often provide different levels of clinical benefit across indications or patient sub-populations

Objectives

The objective of this research was to assess the HTA recommendations, reimbursement decision trends, and their association across 3 major EU HTA agencies (UK: NICE; France: HAS; Germany: G-BA) among oncology therapies approved in the last 10 years indicated for NSCLC, CRC, and OC.

Methodology

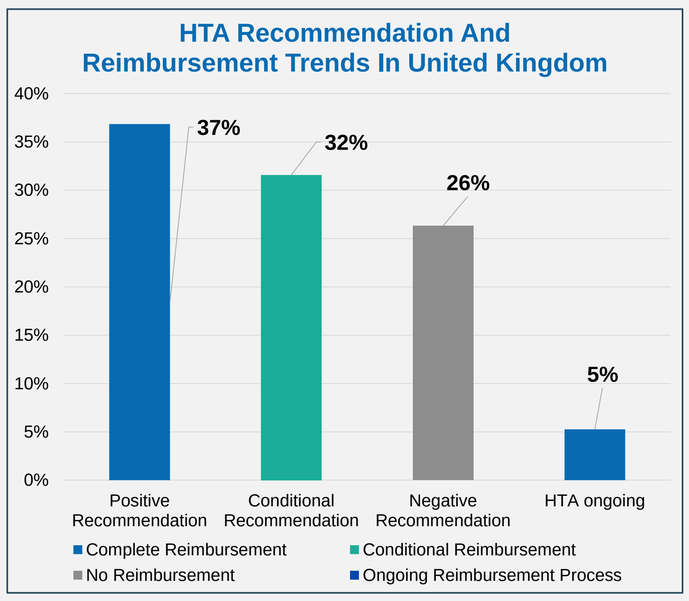
- Secondary research was conducted to identify therapies approved for use in NSCLC, CRC, and OC in the last 10 years along with the treatment line
- Included publicly available HTA recommendations and reimbursement data from the major European markets – UK, France (FR), and Germany (DE)
- As reimbursement policies and HTA agency guidelines differ among EU countries, the relationship between the type of recommendation and reimbursement status was assessed separately for each country
- The agreement between recommendations and reimbursement status was assessed using Cohen's kappa coefficient (k)
- The κ coefficient can range from -1 to 1, with values <0 denoting no agreement, 0 representing the amount of agreement by random chance, and 1 denoting perfect agreement

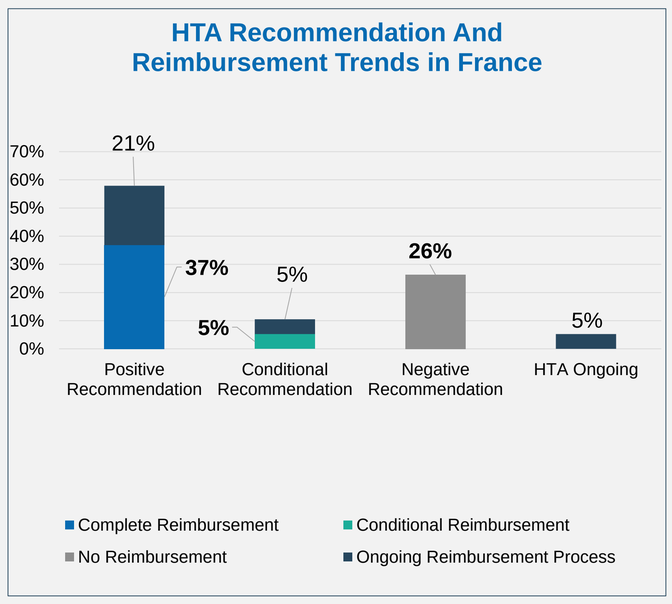
Study Limitations

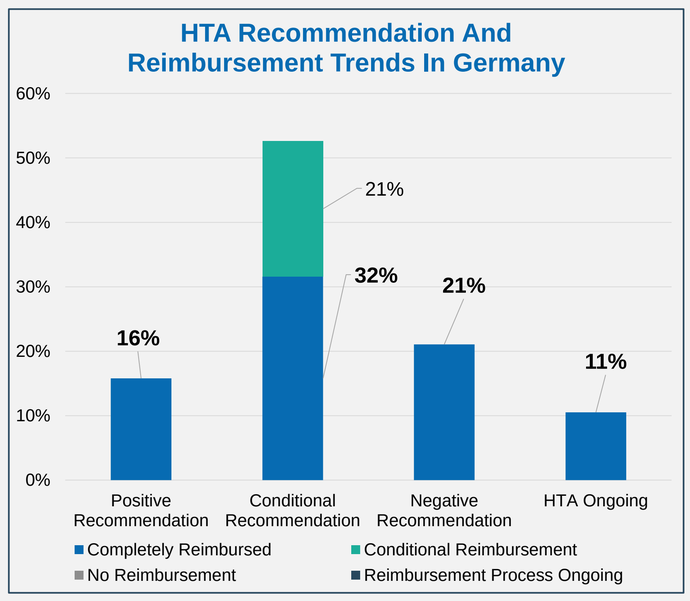
- Analyzed variables might affect the k-coefficient which is used to define the agreement between HTA recommendations and reimbursement, and thus treated as descriptive rather than inferential statistics
- This study only focused on specific oncology indications; might need further research across oncology therapies, irrespective of indications, to analyze reimbursement considerations

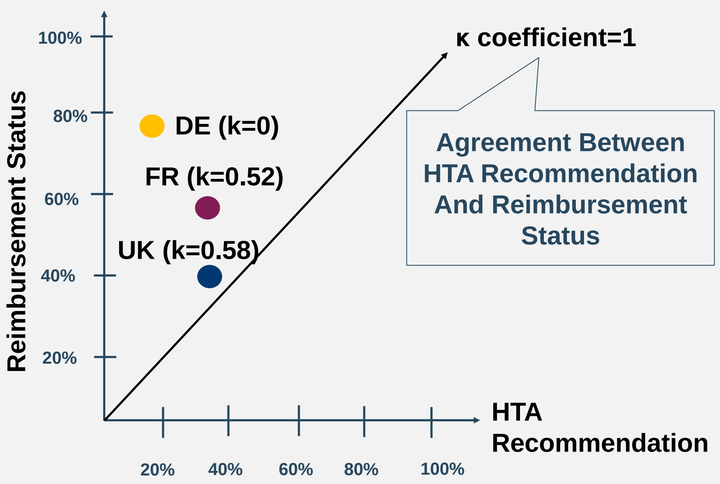
Findings

- Given the high prevalence of these cancers, patients should be able to access the novel treatments currently available in the market – best care at the best price
- A total of 19 therapies were included in this study to analyze the HTA recommendations and reimbursement trends in the major European markets
- Overall HTA recommendation trends – 37% recommended; 32% recommended conditionally; 26% no HTA submissions; and 5% HTA ongoing
- The share of completely positive HTA recommendations was 37% for the UK, 16% for Germany, and 58% for France; the highest in France while Germany had the lowest
- The share of completely reimbursed drugs was 42% in the UK, 79% in Germany, and 37% in France; the highest in Germany while France had the lowest
- Sensitivity analysis revealed that the agreement between recommendations and reimbursement status was 0.58 and 0.52 for the UK and France, respectively
- Results from UK and France portrayed a moderate agreement between HTA recommendation and reimbursement status (κ coefficient >0), implying a possibility of reimbursement with a positive recommendation from HAS and NICE
- In Germany, contradictory to G-BA's benefit assessment decisions, most of the oncology therapies were generally reimbursed upon receiving marketing authorization which might be due to conditional approval and orphan designation; HTA recommendation was not connected to a reimbursement status (κ coefficient=0)
- Complete correlation is not possible with different existing pricing and reimbursement policies across the systems, especially with the availability of specialized oncology funds









Conclusion

Heterogeneity was observed in coverage recommendations and decision making across the major European markets. The reimbursement and treatment access concerns go beyond clinical benefit assessments or economic evaluations that are captured in the evaluation process. So, it is imperative to understand each system and tailor the clinical development strategy for novel therapies to the requirement nuances to achieve optimal HTA and reimbursement decisions.

References

1. World Health Organization [Internet]. Cancer data and statistics; [reviewed: 2021 Nov 6; cited: 2021 Nov 10]. Available from: https://www.euro.who.int/en/health-topics/noncommunicable-diseases/cancer/data-and-statistics
2. World Cancer Fund Research International. Global cancer data by country; [reviewed:2021 Nov 7; cited: 2021 Nov 10]. Available from: https://www.wcrf.org/dietandcancer/global-cancer-data-by-country/
3. World Health Organization [Internet]. Cancer; [reviewed: 2021 Nov 6; cited: 2021 Nov 10]. Available from: https://www.who.int/news-room/fact-sheets/detail/cancer
4. European Medicines Agency [Internet]. Medicines; [reviewed: 2021 Nov 8; cited: 2021 Nov 11]. Available from: https://www.ema.europa.eu/en/medicines
5. National Institute for Care and Excellence [Internet]. Technology appraisal guidance (UK); [reviewed2021 Nov 8; cited: 2021 Nov 15]. Available from: https://www.nice.org.uk/guidance/published?ngt=Technology%20appraisal%20guidance&ndt=Guidance
6. Haute Autorité de santé [Internet], Drug Opinions and Decisions (France);); [reviewed: 2021 Nov 8; cited: 2021 Nov 15]. Available from: https://www.has-sante.fr/jcms/p_3281266/en/avis-et-decisions-sur-les-medicaments
7. German: Gemeinsamer Bundesausschuss [Internet]. Benefit assessment of drugs (Germany);); [reviewed: 2021 Nov 8; cited: 2021 Nov 15]. Available from: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/

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