HTA155

The Impact of Phase 2 Clinical Trials on Reimbursement Recommendations in Oncology by Canadian Health Technology Assessment Agencies

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INTRODUCTION

- Reimbursement recommendations for drugs are issued by two health technology assessment (HTA) agencies in Canada: Institut national d'excellence en santé et services sociaux (INESSS) for the province of Quebec and the Canadian Agency for Drugs and Technologies in Health (CADTH) for all other provinces.
- Both organizations issue their recommendations based on the therapeutic and economic data submitted by drug manufacturers.
- In oncology, submissions are sometimes based on phase 2 clinical trials due to high unmet needs. However, it is not always clear to which extent phase 2 clinical trial results are sufficient to support a positive reimbursement recommendation.

OBJECTIVE

- This study aimed to assess the impact of phase 2 trials on reimbursement recommendations in oncology by CADTH and INESSS.

METHODS

- Searches were conducted on the INESSS and CADTH websites, where both agencies publish recommendations regarding drug reimbursement. No other websites, registries or grey literature were used.
- The search was limited to oncology reimbursement reviews from the past 5-years between 2018 and 2022. This time period was selected to best reflect the latest tendencies of HTA agencies.
- The final reimbursement recommendations issued for the same medication and indication from both agencies for an innovative oncology drug therapy were included
- Data concerning the approved indication by Health Canada, as well as key parameters used to assess the therapeutic and economic value were extracted.
- Disagreement between INESSS and CADTH implies a difference in the recommendation for the same indication reviewed by both HTA agencies (e.g., positive for INESSS and negative for CADTH).
- In cases where the year of recommendation was different for INESSS and CADTH, the most recent year was chosen for analysis purposes.

RESULTS

- Of the 500 oncology reimbursement reviews available on the INESSS and CADTH websites, between 2018 and 2022, 125 were included from each HTA agencies.
- The total 250 reimbursement recommendations were categorized according to the following:
  - Phase 2 clinical trials only (n=28, 11.2%)
  - Phase 3 clinical trial only (n=164, 65.6%)
  - Other clinical trial phases (n=58, 23.2%; i.e., combination for phase 2/3 clinical trials, phase 1 or 4 clinical trials).
- Overall, it appears that the likelihood for CADTH to issue a positive reimbursement recommendation (with or without clinical criteria and/or conditions) based on phase 2 trials (43.0%) is higher compared to INESSS (28.6%) (**Figure 1**).
- However, for phase 3 trials, it appears that INESSS issues more positive reimbursement recommendations (92.7%) compared to CADTH (81.7%) (**Figure 1**).

RESULTS

- For both CADTH and INESSS, reimbursement reviews based on phase 3 trials received more positive recommendations (87.2%) than those based on phase 2 trials (35.7%).

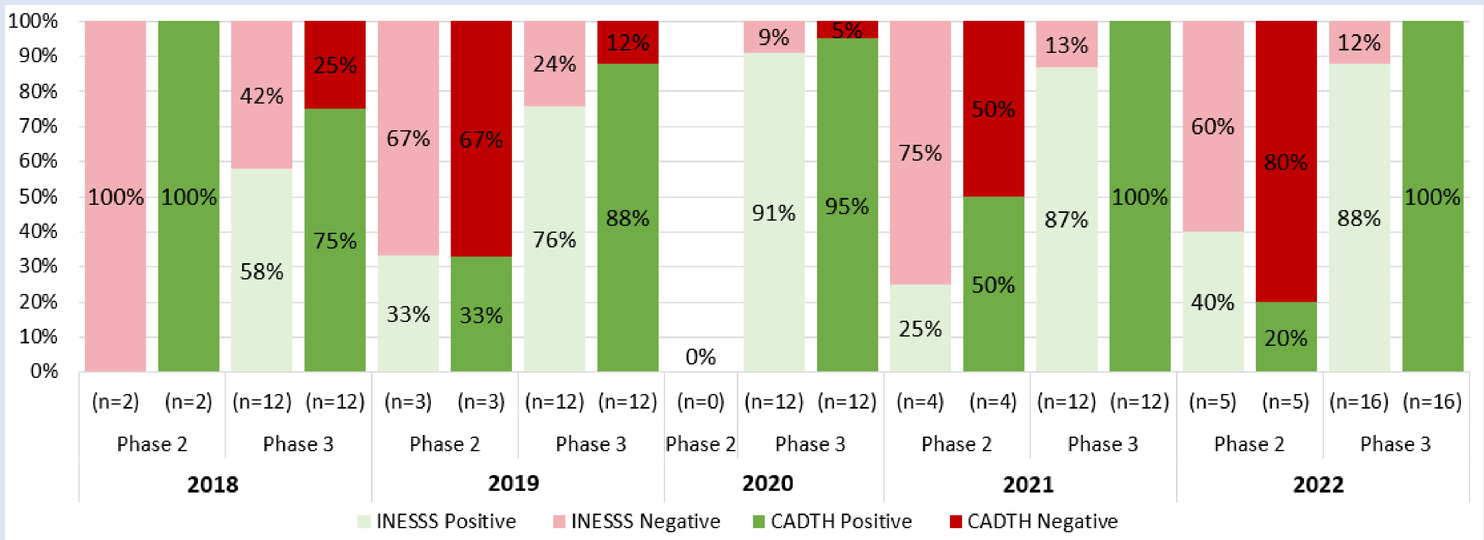

Figure 1. Reimbursement Recommendations of CADTH and INESSS from 2018 to 2022 based on Phase 2 vs. Phase 3 Trials (n=192)

- Among reimbursement reviews based on phase 2 trials, CADTH and INESSS made discordant recommendations for 42.9% of reimbursement reviews (**Figure 2**).
- However, for phase 3 trials, 11.0% of recommendations were discordant between the two HTA agencies (**Figure 2**).

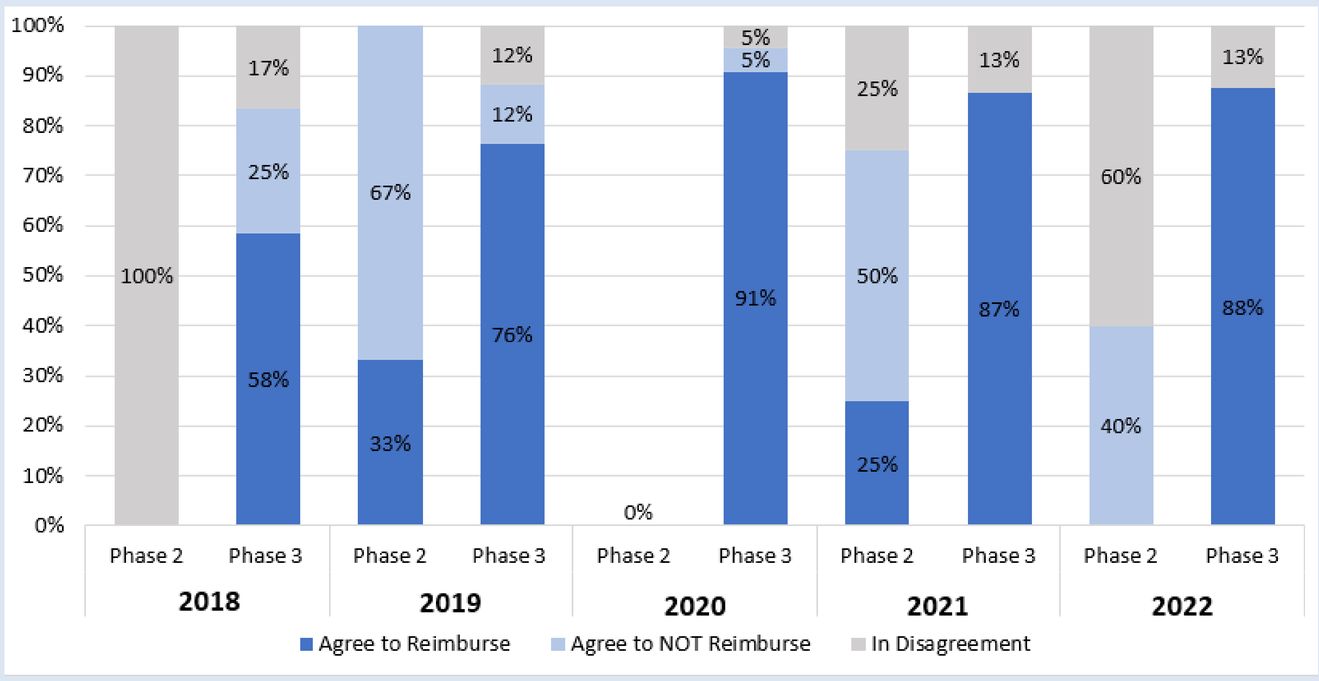

Figure 2. Agreement Status Between CADTH and INESSS on Reimbursement Recommendations from 2018 to 2022 based on Phase 2 vs Phase 3 Trials (n=192)

DISCUSSION / CONCLUSIONS

- This study indicates that reimbursement reviews in oncology based on phase 2 trials are less likely to receive a positive recommendation than reviews based on phase 3 trials, from both Canadian HTA agencies. In fact, phase 3 trials offer a more robust study design, more relevant active comparators, and longer survival follow-up data which justifies why HTA agencies accept them more than phase 2 trials.
- Disagreement on reimbursement recommendations between both CADTH and INESSS is more prominent for recommendations based on phase 2 trials versus phase 3 trials. Appreciation of therapeutic value was the main conflicting component between HTA agencies.
- The majority of recommendations in disagreement have a negative recommendation from INESSS.
- CADTH recently announced the introduction of time-limited reimbursement (TLR) recommendations, a new HTA review process whereby recommendations would be issued based on a phase 2 clinical data assessment. The reimbursement recommendations will be time-limited and contingent upon a future reassessment of additional evidence (i.e., phase 3 clinical data) completed within a three-year period from the initial recommendation.
- The TLR process represents a positive step forward for early access to medicines with promising value and alignment between CADTH and INESSS on this initiative will be important to ensure equal patient access in Quebec.

DISCLOSURES

Author Disclosures:

- Catherine Beauchemin is a partner at PeriPharm Inc., a company that has served as a consultant to AbbVie and has received funding from AbbVie.
- Monika Ham, Mathieu Pelletier and Kimberly Guinan are employees of PeriPharm Inc.
- Ariane Gosselin, Nancy Paul Roc and Stephane Barakat are employees of AbbVie Corporation. Employees of AbbVie may hold equity.
- Monika Ham, Mathieu Pelletier, Kimberly Guinan, Ariane Gosselin, Nancy Paul Roc, Stephane Barakat and Catherine Beauchemin have participated in the study conduct, data interpretation and preparation of the poster.

AbbVie Disclosures:

- No author has received funding for developing the poster. AbbVie participated in the design and provided financial support for the study. AbbVie reviewed and approved this publication.

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