Number of Submissions Needed to Reach a Positive Reimbursement Decision from SMC, CADTH and PBAC

Authors: Ashley Jaksa, MPH; Yin Ho, MD, MBA; Kermit Daniel, PhD

OBJECTIVES

Positive reimbursement decisions are frequently achieved only after multiple submissions. Multiple submissions can delay patient access to necessary therapies and be costly for the manufacturer. This study analyzes the number of submissions needed to gain a positive decision. For those drugs that were not recommended on the first submission but received a positive decision upon resubmission, this analysis determines the lag time between the first submission and a positive decision.

METHODS

The data, drawn from the Context Matters Reimbursement Risk Tracker™, included Health Technology Assessments (HTAs) from SMC, PBAC, and CADTH’s Common Drug Review. The 425 RRT™ reviews included in the analysis cover 23 disease conditions and were issued between 2005 and February 2013. Of these, 165 were issued by SMC, 187 were issued by PBAC, and 73 were issued by CADTH. Included are 334 HTAs that were initial submissions of the drug for reimbursement and 91 resubmissions.

RESULTS

A positive decision was achieved after the first submission in only 66% (219 reviews) of the HTAs analyzed. Of the 115 HTAs that resulted in a negative decision on the first submission, 62% (71 reviews) were never resubmitted. CADTH had the highest rate of negative decisions for HTAs that were never resubmitted: 79% as compared to SMC and PBAC (60% and 52%, respectively). At 1.39 submissions, PBAC had the highest average number of submissions required to achieve a positive decision. PBAC’s average was statistically higher than SMC’s (p < .05). On average, SMC and CADTH needed 1.16 and 1.17 submissions, respectively, to obtain a positive decision. Drugs that were resubmitted and eventually achieved a positive decision had the following mean lag times: SMC – 430 days, CADTH – 924 days, and PBAC – 1,089 days. The sample size is small for CADTH and SMC, and there is a lot of variability in lag times for PBAC. For SMC and CADTH, there appears to be a modest linear relationship between the number of resubmissions needed to obtain a positive decision and the number of unique drugs reviewed within the disease condition (correlation coefficient = .41 and .46, respectively). This relationship was not observed for PBAC (correlation coefficient = .01).

CONCLUSIONS

Only 66% of drugs submitted for review achieved a positive decision on the first submission. Of the drugs given a negative decision on the first submission, 62% were never resubmitted. CADTH had the largest percentage of reviews that were never resubmitted. The lower rate of resubmissions to CADTH could reflect a situation where reimbursement is achieved from the provincial governments in Canada instead of on the national formulary. Both SMC and PBAC require a positive recommendation for reimbursement. The percentage that chose not to resubmit for those jurisdictions was over 50%. A limitation to this analysis is lead-time sampling bias. PBAC required a greater number of submissions to gain a positive decision, and the lag time to a positive decision was longer as compared to SMC and CADTH. The number of submissions needed to gain a positive decision by CADTH and SMC were similar, but CADTH’s lag time was twice as long as SMC’s. A positive correlation was observed between the number of drugs reviewed in a disease condition and the number of submissions required to achieve a positive decision in reviews from SMC and CADTH.

1Data has been updated since abstract submission.
Number of Submissions Needed to Reach a Positive Reimbursement Decision from SMC, CADTH and PBAC

Authors: Ashley Jaksa, MPH; Yin Ho, MD, MBA; Kermit Daniel, PhD

COMPARISON OF RESUBMISSIONS TO TOTAL SUBMISSIONS

<table>
<thead>
<tr>
<th>First Submissions</th>
<th>Reviews Never Resubmitted</th>
<th>Reviews Resubmitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>334</td>
<td>71</td>
<td>44</td>
</tr>
</tbody>
</table>

115 Negative Decisions Upon First Submission
219 Positive Decisions Upon First Submission

MEAN NUMBER OF SUBMISSIONS NEEDED TO ACHIEVE POSITIVE DECISION, BY AGENCY

- PBAC: 1.39
- CADTH: 1.17
- SMC: 1.16

At .05, the difference between PBAC and SMC is statistically significant.

DAYS NEEDED TO ACHIEVE POSITIVE DECISION FOR A RESUBMITTED REVIEW

- PBAC: 2000
- CADTH: 1000
- SMC: 3000