LEVERAGING REAL-WORLD DATA FROM THE PRIVATE PAYER PRIOR AUTHORIZATION PROCESS TO OPERATIONALIZE OUTCOMES-BASED AGREEMENTS IN CANADA

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BACKGROUND

Access to novel therapies in Canada:

Timely access to novel therapies has become increasingly challenging due to the rising number of therapies with limited but promising evidence, due to the nature of the disease, coupled with long reimbursement timelines. Outcomes-based agreements (OBAs) are a potential solution to enable early access for patients to therapies with limited evidence and clinical uncertainties, while mitigating the risk for payers of non-performance in the real world. One key barrier to the adoption of OBAs in Canada is the availability of appropriate real-world data (RWD) to support such agreements. It is important to note that not all therapies are appropriate for OBAs, and simple market access agreements should be used when possible.

Private payers and specialty drugs:

Private payers paid 36.9% of the total drug spend in Canada (compared to public spend representing 43.6%) in 2021. 32% of total private payer drug costs were devoted to specialty drugs. Specialty drugs are defined as drugs with a cost of $10K or higher per patient per year. For higher-cost drugs, private payers may insert a step called prior authorization (PA) to ensure a good fit between product and patient.

Research objectives:

This study sought to evaluate if existing prior authorization (PA) processes used by private payers could be leveraged to support OBAs.

RESEARCH QUESTION

Could real-world data from the private payer prior authorization process be used to operationalize an outcomes-based agreement?

METHODS

A selection of publicly-available prior authorization (PA) forms were reviewed to identify health outcomes currently being collected. Qualitative interviews were then conducted with private insurers and PBMs in Canada from May to October 2022, via Microsoft Teams. 14 organizations were invited to participate; 8 organizations participated, with 15 individuals in attendance. 20 interview questions were discussed across 4 themes: PA, OBAs, OBAs and PA, and OBA financial models.

RESULTS

What is the purpose of the prior authorization (PA) process?

For higher-cost drugs, private payers may insert a step called prior authorization as a cost containment mechanism, to ensure a good fit between product and patient. PA criteria are established by payers and requires patients or their physicians to submit medical evidence to justify the use of a drug prior to dispensing.

The PA process

- Teams with clinical expertise determine which drugs go on PA and define the evaluation criteria.
- More than 20 health outcomes are currently collected in private payer prior authorization forms **(Figure 1)**.
- At present, there are an estimated 100-300 drugs on PA. The volume of drugs on PA has been increasing and is forecasted to continue growing.
- The basic PA process includes completing a form by answering a series of questions including clinical markers, prior lines of therapy, etc., then assessing the information against drug criteria and rendering an approval decision as per each private payer's internal processes.
- Private payer resources include teams of adjudicators, nurse case managers, pharmacist consultants, and medical doctor consultants.
- Multiple stakeholders and touchpoints are involved throughout the process.
- There is no standard PA form or approach.
- PA is a highly manual process.
- The process is working well for payers and meeting its intended purpose.

Technology and data

- PA forms are received by the payer primarily in PDF format, by fax or email.
- Forms either stay as a hardcopy, are scanned to PDF, and/or data is keyed into internal databases.
- Data is sometimes used for volume or operational analyses. Data has not been used for real-world evidence (RWE) generation at present.
- 6 of the 8 private payers/PBMs rated the effort level as high to use the PA process to collect data to support OBAs **(Figure 2)**.

OBAs

- All 8 private payers and PBMs saw the need for OBAs. However only 3 considered them a priority **(Figure 3)**.
- 4 of the 8 private payers and PBMs have implemented OBAs.
- Implemented OBA models cited had elements of free drug for a period and non-responder rebate with trial period (i.e., 6 months) for patients.

Figure 1: Selection of health outcomes data collected and reviewed in private payer prior authorization forms

CATEGORY	HEALTH OUTCOMES
1. Clinical event or measurement	1. Number of relapses, attacks or hospitalizations within last 12 months 2. Reduction in the number and/or severity of attacks and/or relapses 3. Body mass index (BMI) 4. Weight
2. Lab tests and scans	5. LDL-C 6. Liver function tests (ALT, AST, bilirubin) 7. T2 Gandolinium-enhancing lesions (MRI) 8. Lesions (MRI) 9. C-reactive protein (CRP) value
3. Performance scale	10. ECOG Performance Status Scale 11. Tiffeneau-Pinelli Index (FEV1) 12. CFQ-R Respiratory Domain Score 13. Expanded Disability Status Scale (EDSS) 14. Hammersmith Functional Motor Scale Expanded (HFMSE) Score 15. Crohn's Disease Activity Index (CDAI) 16. Harvey-Bradshaw Index (HBI) 17. Mayo score (Endoscopic sub-score; Rectal bleeding sub-score) 18. ALSFRS-R Score 19. Spirometry report 20. Dermatology Life Quality Index (DLQI) 21. Psoriasis Area Severity Index (PASI)
4. Other	22. Return to work

Figure 2: Effort level to enable the PA process to collect data to support OBAs

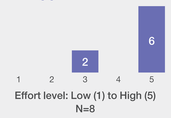

Figure 3: Is there a need for OBAs and are they a priority within your organization?

CONCLUSIONS

1. The private payer PA process in its current state is not usable to generate RWD to support OBAs.

The PA process and infrastructure could provide an option for data collection in the future but is not set up for that purpose today. It would take a significant amount of effort and cost to enable the PA process to support data collection. A process improvement milestone in the short term would be the digitization of the PA process (also called electronic PA or ePA) and the standardization of PA forms, however there is currently not a clear path to getting there.

2. Rare disease drugs could be a catalyst for PA data and infrastructure to be used for data generation to support OBAs in the private payer space.

In its current state, the PA infrastructure could potentially be used to manually track outcomes to support an OBA for rare disease drugs with limited patient populations. This may be an area where private payers gain experience in using the PA process to generate data to support OBAs for therapies with limited evidence and clinical uncertainties.

DISCUSSION

Private payers have limited experience with OBAs, with some short-term OBA models in place. OBAs are not a priority as there currently are limited incentives to leverage OBAs as a solution to support listing negotiations. It is anticipated that a few leaders will continue to investigate OBAs and RWD using the PA infrastructure.

THE MISSION OF THE ***RWE & OBA WORKING GROUP*** IS TO ADVANCE THE OPPORTUNITY FOR THE USE OF REAL-WORLD EVIDENCE AND OUTCOMES-BASED AGREEMENTS IN CANADA, TO THE BENEFIT OF ALL STAKEHOLDERS IN THE CANADIAN HEALTH-CARE SYSTEM. FOR PREVIOUS PUBLICATIONS AND ADDITIONAL INFORMATION FROM THE WORKING GROUP, PLEASE VISIT **https://www.20sense.ca/obas** OR CONTACT **info@20sense.ca**.

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