



**Submission on
2022 Proposed Update
to PMPRB Guidelines**

December 5, 2022



About The Kidney Foundation of Canada

The Kidney Foundation of Canada is the leading charity committed to eliminating the burden of kidney disease through:

- Funding and stimulating innovative research for better prevention, treatments and a cure;
- Providing education and support to prevent kidney disease in those at risk and empower those with kidney disease to optimize their health status;
- Advocating for improved access to high quality health care;
- Increasing public awareness and commitment to advancing kidney health and organ donation.

Response to 2022 Proposed Update to PMPRB Guidelines

Access to medicines is a critical component of patient treatment throughout the kidney disease journey. Early access to new medication options for chronic kidney disease (CKD) can delay kidney failure for many years, vastly improving health and quality of life for patients, as well as saving the health care system significant costs associated with kidney failure.

Should CKD progress to kidney failure, the available treatments include dialysis, transplant, or conservative kidney care, all of which require access to high quality, innovative medications. In 2020, approximately 7900 Canadians started renal replacement therapy because of kidney failure, with a total of 23,708 people on dialysis. The total number of people receiving chronic dialysis has nearly doubled in the last 20 years. This costs the health care system \$56,000 to \$100,000 annually per person in dialysis costs alone and far outweighs the cost of treating the early stages of CKD. There are also considerable hospitalization costs in this patient population, and additional out-of-pocket costs for patients themselves.

Any step that would delay access to new medicines, including in the context of clinical trials, will have both a profound effect on the health and quality of life of kidney patients throughout their journey and a significant impact on health care costs. Meaningful consultation with patients and caregivers will ensure that those most affected by these decisions have the opportunity to influence the policy and process.

Therefore, the Kidney Foundation of Canada respectfully recommends that the implementation of the new guidelines be delayed until the following recommendations are properly addressed:

- That an independent third party be engaged to review the potential and real-time impacts of the guideline changes on access to medicines, including clinical trials, in Canada. Kidney patients and their families rely on access to medications that improve their health outcomes and have an impact on their quality of life.
- That the PMPRB formalize mechanisms to meaningfully and continuously engage patients and their representatives in its decision-making and process to ensure that patient voices are represented. The PMPRB website clearly articulates that the Board is “committed to listening to the voices and views of Canadians and including them in decision making,” yet to date no formal mechanism exists for meaningfully engaging Canadians outside the current consultation process. This engagement is necessary to allow the PMPRB to fulfill its mandate, deliver programs, launch new initiatives, and build public trust.
- That the consultation process allow for respectful consideration of stakeholder feedback prior to implementation of the guidelines. The short time frame from the closure of consultation on December 5th, 2022 to the proposed implementation of the guidelines on January 1st, 2023 limited the time available for in-depth, meaningful consideration of stakeholder feedback, especially from patients and patient groups. This may result in inequity, as these groups may require different timeframes for discussion and input.
- That changes to investigative criteria will not inadvertently put patients in the kidney community at a disadvantage, resulting in further delays in accessing new medicines. These medicines can change the course of kidney disease and have a profound impact on patients and families throughout their treatment journey. Equity of access to new treatments is essential to vulnerable communities who may have fewer therapeutic options currently available to them.

References

https://kidney.ca/KFOC/media/images/PDFs/3-2-1-NAT-Burden_of_Out-of-Pocket_Costs.pdf

Canadian Institute for Health Information. High Risk and High Cost: Focus on Opportunities to Reduce Hospitalizations of Dialysis Patients in Canada. Ottawa, ON: CIHI; 2016.

Canadian Institute for Health Information. [Trends in end-stage kidney disease in Canada, 2020 — Infographic](#) [infographic]. Accessed November 30, 2022.