

CADTH Drug Reimbursement Review Patient Input Template

Name of Drug: Maribavir

Indication: Post-transplant cytomegalovirus infection

Name of Patient Group: The Kidney Foundation of Canada

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1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

The Kidney Foundation of Canada is committed to achieving excellent kidney health, optimal quality of life, and a cure for kidney disease.

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 healthcare;
- Increasing public awareness and commitment to advancing kidney health and organ donation.

For more information, please visit: www.kidney.ca

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus

groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

Patient input was collected in February and March 2022 by the Kidney Foundation of Canada in both official languages via a self-administered questionnaire from people across Canada. The survey was directed at people living with a kidney transplant and their caregivers and inquired about respondents' lived experience with a kidney transplant and medications and expectations for new drug therapies in Canada. The survey posed a number of questions specifically about the drug under review, maribavir. Awareness about the surveys was generated through the Kidney Foundation's social media channels (Twitter and Facebook). It was also promoted on the Kidney Foundation's website and e-newsletter.

A total of 9 people responded to the survey with 7 completed and 2 partially completed surveys. 6 respondents identified as kidney transplant recipients and 1 identified as a donor and caregiver. Of the 7 people that responded to the question about their current age or the current age of the person they care for, 2 were 25 to 39 years old, 2 were 40 to 54 years old, and 3 were 55-69 years old. 7 respondents answered the question about how long they had lived with a transplant. 1 respondent reported living with a transplant for under 1 year, 1 for 3 to 5 years, 3 for 6 to 10 years, 1 for 11 to 20 years and 1 respondent reported more than 20 years with the disease.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

Kidney disease describes a variety of diseases and disorders that affect the kidneys. Most diseases of the kidney attack the nephrons and damage their ability to eliminate waste and excess fluids. Often, kidney disease is associated with other medical conditions such as diabetes, high blood pressure and heart disease.

Chronic kidney disease (CKD) is the presence of kidney damage, or a decreased level of kidney function, for a period of three months or more. Kidney disease can range from mild to severe and in some cases, lead to kidney failure (sometimes referred to as end-stage kidney disease, or ESKD). There are usually no specific symptoms of kidney disease until the damage is severe. When kidneys fail, waste accumulates in the body and dialysis treatments or a kidney transplant become crucial for survival.

A kidney transplant is generally considered the best treatment for most people with kidney failure. However, not everyone is a candidate for a transplant. People may not be eligible, for example, if they have other serious health issues in addition to kidney disease. Even if they are eligible for a transplant, a kidney donor may not be immediately available. Most people start dialysis while they wait for a kidney donor.

The advantages of a transplant include better quality of life with fewer limitations than dialysis. For example, a transplant won't take hours of treatment time out of a person's week, and they may feel physically stronger, able to work, travel and stay more active.

The main disadvantage of a transplant, in addition to the general risks of surgery, is that they will have to take medications every day, which may increase their risk of infection and have other side effects. A transplant is considered a treatment and not a cure since recipients will have to take medication for the rest of their lives to prevent their bodies from rejecting the new kidney.

Before being considered for a kidney transplant, all potential recipients must undergo a rigorous evaluation to determine if they are suitable transplant candidates. This is a detailed medical assessment that could include doctors' evaluations of the heart, lung, stomach, bladder and blood vessels. Many tests and procedures may be needed to make sure they are healthy enough for the transplant surgery and the medications needed to prevent rejection of the kidney. They may also need to see a psychologist or psychiatrist before the transplant surgery to explore their feelings about this treatment. The transplant work-up can take up to a year to complete.

Most respondents who participated in the survey spoke about how a transplant changed their lives. Some respondents talked about the positive effects such as returning to work, the ability to have a family and resuming their studies and travels. They said "my kidney transplant was fabulous!" while others were more guarded, "I have resumed a normal rhythm of life but with more worries and precautions".

Other respondents talked about their tiredness both prior to and following the transplant. "I have more energy than when I was on dialysis, but I still burn out faster than a healthy person." Others spoke of the effects of long-term chronic kidney disease, "I'm retired and have been beating (sic) kidney disease for 40 years. As a result, I have weak bones, try to exercise every day (sic). Some days are good others I need to take it easy".

Others spoke of side effects following the transplant "...but I have many side effects following the transplant and taking anti-rejections and cortisone: diarrhoea, abundant hair loss, diabetes... It's not always a pleasure".

Caregivers spoke of how it effects both the person with the condition and themselves "our life has forever changed. He was diagnosed with CKD (untreated high blood pressure). It was hard for both of us. He was always tired, felt sick, discouraged and no life (as he always say)". (sic)

Respondents also talked about their particular challenges of living with both a kidney transplant and cytomegalovirus (CMV). "...Still enjoy being intimate with my wife, but that all changed when we were told I had CMV. It is spread through blood, semen and saliva great (sic) my wife is scared of catching CMV".

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

57% of respondents have taken medication for CMV. Of those taking medication for CMV, 50% had taken ganciclovir, 75% had taken valganciclovir and 1 (25%) reported taking maribavir.

2 people reported being "very satisfied", 1 person indicated that they were "satisfied" with the medication they are currently taking for high CMV, and 1 was "neither satisfied nor unsatisfied". From those who responded about what they liked or didn't like about the medications they took for CMV, their effectiveness in treating CMV and eliminating symptoms of the virus.¹ respondent said "they were effective in curing me of the disease fairly quickly. The cost of going ahead was a negative as was the IV administration while working." Another said, "My CMV numbers dropped like a rock. Did eight weeks and CMV was undetectable. So happy !! (sic) On no (sic) three weeks later it was back."

Respondents also reported changes they had experienced as a result of current medication compared to previous therapies. 25% reported about the same change in taste, diarrhea, nausea or vomiting, feeling weak or tired and urinary changes while 75% didn't know. 100% of respondents didn't know if there were changes to fever, chills or sore throats or unexplained bruising or bleeding.

When asked about what factors were "very important" or "important" in choosing transplant medications in general, the following factors were identified as "very important" or "important" by the majority of respondents: tiredness, interference with sleep, foot edema, effect on mood, interference with other medications, changes in appetite, cost and length of time on the medication. One respondent stated that edema was neither important or unimportant, two respondents stated change in appetite was neither important or unimportant, one respondent also stated that cost was unimportant.

Additionally, patients were asked what else was important to them when taking transplant medications. A number of responses included side effects, impact on health, effectiveness and

interactions with other medications and cost. A respondent stated “Ensure that it is compatible with the rest of the medication and that it is available at a reasonable cost to the patient” while another said, “We live in Saskatchewan and all my husband's meds are covered (because he's a kidney transplant). This is most important to us, and it should be to any transplant recipients”.

Patients also spoke of lowered immunity following a transplant and its effects, especially with COVID-19 in mind, “with Covid (sic) in mind protecting myself and still being able to see family and friends. Being on dialysis ties you down. Getting that kidney should allow you some freedom but the lowered immune (sic) makes it difficult”.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Most respondents spoke about medication side effects when asked about their expectations when choosing a drug therapy. They also spoke about cost and having a better quality of life. Patients said, “that they are effective, simple to administer, and do not interfere with other medicines” and “no contraindications and no interaction with immunosuppressants. Side effects that are minimal or easily managed”. They also spoke about quality of life, “that these medicines have fewer side-effects for a better quality of life” and about medication costs “all meds (sic) are covered by the government, and it should be the same nationwide”.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

1 respondent reported taking or having taken maribavir, while one person did not know if they had taken maribavir. One of the respondents had switched from another medication and accessed it through a clinical trial. 3 people responded to the question about how their health changed on maribavir compared to before, although 2 of those responses answered with “I don’t know” to all the questions. The one respondent said that changes in tastes, diarrhea, upset stomach or vomiting, urinary changes, fever, chills or sore throat had, or unexplained bruising, had remained the same and that feeling tired or weak was worse.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

This question is not applicable to this submission.

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

Every year, thousands of Canadians wait for a life-saving transplant and of those, hundreds will die while on the transplant waiting list. For those patients who receive a new organ, many will experience challenges navigating through the complex Canadian health care system and will need to learn to live with the difficulties of being an organ transplant recipient.

Tens of thousands of Canadians currently live with an organ transplant and many experience challenges with mental health, financial strain, and the uncertainty of how long this new organ will last. For all the benefits of transplantation, the reality for someone receiving an organ transplant is that they are a transplant patient for life. To live with a transplant means a lifetime of immune suppressing medication, managing the side effects of these medications, and a

lifetime of check-ups, medical tests and concerns that they may one day lose their transplant and begin the journey all over again.

In many instances, transplantation is the only life-saving option available for patients with end-stage organ failure. For others, transplantation leads to better outcomes than alternative and more conservative treatments and offer significant savings to the health system. For example, kidney transplantation is widely considered the best treatment for people with kidney failure. A transplant enables people who would otherwise be on dialysis at least three times a week for four to five hours at a time, to live a relatively normal, healthy, and productive life, while providing a less costly option for the health care system compared to dialysis. The total annual cost of dialysis ranges from \$56,000 to \$107,000 per patient. The cost of a transplant is \$66,000 in the first year, then \$23,000 in subsequent years. For each kidney transplant patient, the health care system saves up to \$84,000 annually.

Those living with a kidney transplant experience additional health and financial challenges. Many would benefit from effective, affordable treatments that they can access equitably and in a timely manner. Maribavir may help people to achieve better health outcomes and improve their quality of life. For this reason, it should be available as an option for people living with a transplant and CMV.