

Patient Input for CADTH Reimbursement Review

Name of Drug: difelikefalin

Indication: Adult hemodialysis patients with chronic kidney disease (CKD)

Name of Patient Group: The Kidney Foundation of Canada

Author of Submission: Carrie Thibodeau

1. About Your Patient Group

Over nearly six decades, the Kidney Foundation of Canada has been guided by the fundamental principles of innovation, leadership, and collaboration, and has been committed to excellent kidney health, optimal quality of life for those affected by kidney disease, and a cure.

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.

For more information, please visit [kidney.ca](https://www.kidney.ca).

2. Information Gathering

Patient input was collected via independent surveys in September 2022 by the Kidney Foundation of Canada. Each survey was a self-administered questionnaire directed at people living with chronic kidney disease, as well as their caregivers. The surveys inquired about respondents' lived experience with pruritis and chronic kidney disease, including questions on medications and expectations for new drug therapies in Canada. Awareness about the surveys was generated through the Kidney Foundation's website and social media channels (Twitter and Facebook).

A total of 19 people responded to the survey; 10 questionnaires were fully completed and 9 were partially completed. 10 respondents identified as being a person living with kidney disease, 1 is a kidney transplant recipient, and 1 is a caregiver.

3. Disease Experience

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. In the early stages of CKD, self-management strategies may slow or prevent further damage to the kidneys. These lifestyle strategies may include engaging in regular physical activity, maintaining a healthy body weight, stopping smoking, reducing sodium, and managing other medical conditions and medications.

There are usually no specific symptoms of kidney disease until the damage is severe. In some cases, chronic kidney disease can lead to kidney failure (also called end-stage kidney disease, or ESKD). When the kidneys fail, wastes accumulate in the body and dialysis treatments or a kidney transplant are needed to survive.

Canadians with kidney failure and their families face significant out-of-pocket costs regardless of the treatment they receive. This financial burden is further compounded by the loss of income that is often associated with starting dialysis, which is the most common treatment for kidney failure. Because poverty is an important determinant of health, patients and their families who live in poverty may not be able to achieve optimal management of their kidney disease.

One of the most common symptoms experienced by kidney patients is pruritis, or itchy skin. Studies show that pruritis is present in about 40% to 84% of patients with end-stage kidney disease¹. Over 90% of the respondents to The Kidney Foundation of Canada's survey reported that they have experienced itchy skin as part of their kidney disease. 50% said they experience itchiness every day, 40% said they experience it several times per week, and 10% said they experience itchiness occasionally.

In terms of the duration of time patients have been experiencing itchiness, 60% reported that they had been living with pruritis for 1-2 years, while 20% said they'd been living with it for 2-5 years, and 20% over 5 years. 80% of respondents described their itchiness as moderate or severe.

Several respondents reported that they develop scabs and/or sores as a result of their itchy skin:

"I often put of (sic) things like going out or getting a haircut as the itching is so bad I scratch until there are sores."

"Scratching so often that I end up with scabs."

"[...] I would scratch and bleed VERY easy (sic). I had scabs, I would bleed on clothes and bedsheets, and I had to use expensive creams (protopic) to control it. Quite ugly and often had to use multiple bandaids all over my legs."

Many respondents also reported that they have trouble sleeping as a result of itchiness, with one person saying that they sometimes take Benadryl to help them sleep. Another said *"I'm unable to sleep and be intimate with my partner."*

4. Experiences With Currently Available Treatments

33% of survey respondents reported taking medication to treat itchiness associated with kidney disease. The types of treatments used to control itchiness that were cited by survey respondents were:

- Antihistamines (e.g., Benadryl, Claritin, Alerius, Atarax, etc.)
- Corticosteroid creams or ointments (e.g., hydrocortisone, betamethasone)
- Moisturizing creams or ointments (e.g., Uremol, Cetaphil, Vaseline, etc.)

67% of respondents said that they paid out of pocket for these treatments, while 33% had their treatments covered by their provincial drug plan. When asked how satisfied they are with their current medication/combination of treatments, most said they were satisfied, with 33% saying they were neither satisfied nor unsatisfied.

In terms of the challenges or difficulties experienced with existing treatments, one respondent had this to say:

“Cost. I don’t use it that often. But paying \$25 for a small jar of cream for the pharmacy to make up and insurance does not cover.”

The current medication/combination of medications taken by respondents were largely reported to leave skin itchiness about the same. Over 66% of respondents said they didn’t know whether their skin appearance was improved. One person reported that their itchiness symptoms disappeared after transplant.

5. Improved Outcomes

When asked about their expectations for CKD therapies in general, respondents rated certain questions as important or very important, including: “Does it interfere with my sleep?”, “How much does it cost?”, and “Does it interfere with my other medications?”.

All survey respondents said that they hoped that new medications would increase their well-being or quality of life, and 90% said that they hoped for increased energy. Other expectations included fewer hospital visits and less medication overall.

In talking about what else is important when choosing medication for kidney disease, several respondents mentioned side effects and efficacy. One respondent said:

“Cost, making sure thee (sic) isn’t a whole lot of work to get something covered [...]”

6. Experience With Drug Under Review

None of the those surveyed reported experience with difelikefalin.

7. Companion Diagnostic Test

Not applicable to this submission.

8. Anything Else?

Living with chronic kidney disease can involve not only health and quality of life challenges, but significant financial challenges as well. People may experience a decrease in income if they must limit their working hours due to their symptoms, and out-of-pocket costs increase as they change their diet, follow up more often with their health care team, and use recommended non-prescription treatments.

Those living with kidney disease also tend to be part of a low income and high cost population, and government coverage and financial support varies across jurisdictions, which can lead to inequities.

The burden of chronic kidney disease means that many would benefit from effective, affordable treatments that they can access equitably and in a timely manner. Itchy skin is a very common symptom for kidney patients, especially for those on dialysis, therefore difelikefalin should be available as an option for people living with kidney disease.

¹ Swarna SS, Aziz K, Zubair T, Qadir N, Khan M. Pruritus Associated With Chronic Kidney Disease: A Comprehensive Literature Review. *Cureus*. 2019 Jul 28;11(7):e5256. doi: 10.7759/cureus.5256. PMID: 31572641; PMCID: PMC6760874.

Appendix: Patient Group Conflict of Interest Declaration – The Kidney Foundation of Canada

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

- Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.
There was no external assistance in completing this submission.
- Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.
There was no external assistance with data collection or analysis for this submission.
- List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Alexion Pharma Canada Corp		X		
Amgen Canada				X
Astra Zeneca Canada				X
Bayer		X		
GlaxoSmithKline Inc.			X	
Horizon Pharma Inc.				X
Janssen Pharmaceutical Companies				X
Otsuka Canada Pharmaceutical Inc.				X
Paladin			X	
Takeda	X			

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Elizabeth Myles

Position: National Executive Director

Patient Group: The Kidney Foundation of Canada

Date: September 23, 2022