



Canada's Drug Agency  
L'Agence des médicaments du Canada

## CDA-AMC REIMBURSEMENT REVIEW

# Patient and Clinician Group Input

relugolix, estradiol, and norethindrone acetate (Myfembree)  
(Pfizer Canada ULC and Sumitomo Pharma Switzerland GmbH)

**Indication:** Management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women.

February 18, 2025

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CDA-AMC in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings. **If your group has submitted input that is not reflected within this document, please contact [Formulary-Support@cda-amc.ca](mailto:Formulary-Support@cda-amc.ca).**

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## Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: relugolix, estradiol, and norethindrone acetate

Indication: Management of heavy menstrual bleeding associated with uterine fibroids

Name of Patient Group: CANFib Canadian Women with Fibroids

Author of Submission: Patricia Lee

### 1. About Your Patient Group

Established in 2012, CANFib provides a forum for Women in Canada with Uterine Fibroids to unpack their symptoms, talk to peers, find out more about Fibroids, discuss navigation of the Canadian Medical system while learning more about the treatments and medications approved by Health Canada for Uterine Fibroids.

CANFib also works with Canadian Pharmaceutical outreach, Research, Insurance Companies and Specialists to push for new ideas that become future treatments and solutions.

CANFib has 28,000 active followers on various Social Media platforms using a number of private discussion groups and customized platforms.

[www.CANFib.org](http://www.CANFib.org)

### 2. Information Gathering

CANFib has conducted surveys since 2012 as a way to establish best areas of involvement of CANFib itself in the patient community. In 2023 an extensive survey of more than 300 women was conducted, with some data designed to be compared to past surveys (as a means of tracking improvements/setbacks).

CANFib also conducted group call discussions with patients currently using Relugolix for additional context and followed up with a short survey to allow for better data collection. [Enter Response Here>](#)

### 3. Disease Experience

Uterine Fibroids exhausts a long timeline, and the condition often changes and worsens during its evolution.

Given the opportunity to provide information, most women said the primary symptoms they're controlling include heavy bleeding and pain.

Lost time at work, inability to function within a family unit, lack of social life or professional life, and eventual depression is a common chain of personal events as told in CANFib member discussions.

Caregiving to children often becomes a household issue, requiring more than proportional input from spouses (and the children themselves). So often women in CANFib discussion groups have talked about their sons and daughters having to help clean up the "crime scene" in the bathroom after a simple shower; few elements of the Uterine Fibroids patient are private any longer. Dignity is lost.

And while family balance is disrupted at every turn, and one's social and work life quickly dwindles as the symptoms of Uterine Fibroids becomes the most important issue; there is the need for constant open access to a bathroom, be that at work or at home

(and the cost/embarrassment of flooding office chairs, car seats and beds). There is absolutely no amount of consideration we can give to avoiding these calamities, that's enough to spare any dignity come the next instance.

Sexual relationships suffer under the immense pressure on women with Uterine Fibroids to carry on as if there is nothing wrong and the physical inability to do so.

And women who have opted for surgery seek ways to meet it with enough blood and energy to ensure those risks are mitigated.

No matter the stage of Uterine Fibroids, a woman with notable symptoms is experiencing, her life is very much narrowed to the above. <Enter Response Here>

#### 4. Experiences With Currently Available Treatments

There are currently a number of treatments and medications available for Uterine Fibroids., yet there is no cure other than surgical hysterectomy.

According to John Hopkins University, an estimated 1 in 3 women over the age of 30 has Uterine Fibroids, and according to Statistics Canada there are 5,349,309 women between the ages of 15 and 54. This suggests approximately 1,604,792 women in Canada are currently dealing with Uterine Fibroids.

Because Uterine Fibroids is extremely common among women over 30 and has varying degrees of tumor size, blood loss and other symptomology, the few treatments available do not offer all symptomatic patients their best path to relief.

Uterine Fibroids is not a "one size treatment fits all" condition.

Of the medications available, few offer a usage schedule offering the best window to full control effectiveness. For example, where one medication may require a two pill per day schedule, another requires a three-month commitment per dose (along with potentially harmful long-term effects during those three months).

Adding more options to the choice of medications addresses such setbacks for patients that experience them.

Ultimately, in the case of Uterine Fibroids the condition produces such a diversity of symptoms that choices and options is exactly what promises the most expedient successful outcomes.

By offering more expedient outcomes we inevitably reduce visits to health care providers, and this ultimately opens spaces for those currently waiting months for access.

In our 2023 Survey of more than 300 Canadian women with Uterine Fibroids, CANFib found the duration of patients experience with Fibroids was 8 years, matching the number of years in 2012. If we had all the treatments women need, one would expect this long wait for relief would be shorter by now.

#### 5. Improved Outcomes

First and foremost, CANFib would like to see all women have access to a treatment that works for her; currently that's not possible. According to the same 2023 Survey of Uterine Fibroids Patients, CANFib found that most visits to their care giver is to review her treatment because it's not addressing her symptoms.

The average wait time for a Uterine Fibroids patient to see her specialist is between 4 months and a year (depending on province and region) so it just makes sense that the right treatment should be found as soon as possible.

The ability to pivot to new treatments is important as the wrong one will affect her life even more adversely during the 4-12 months she waits with no help from her medication.

Having medications available that don't require 3-month dosage commitments that often cause a myriad of new symptoms associated with aging, or medications that come with twice a day schedules that when missed bring setbacks; having medications that are notably effective without these setbacks seems an ideal choice among those currently available.

And while there are a few medications that don't have these setbacks, if they were effectively serving the Uterine Fibroids patient community needs - then seeing her Specialist for a different medication would not be the top reason for return visits. <Enter Response Here>

## 6. Experience With Drug Under Review

CANFib talked to several women currently taking Myfembree for symptoms of Uterine Fibroids.

First, we met through a teleconference focus group. Later I spoke with individuals who had more information to offer.

All Uterine Fibroids patients I interacted with had used or was using Myfembree through Private Insurance or paid out of pocket.

Of the 32 who reached out, all but one were "very happy" with the results of Myfembree medication taken for symptoms of Uterine Fibroids (one was "indifferent"). The discussion of side effects was brief as the women concluded any they had, were "better than the symptoms left behind."

Two of the women told me they were able to do their jobs again, making it one less stress (one being a teacher who was taking more than 6 days per month off to accommodate her symptoms).

Having one's confidence back, being able to have family, social and professional life on course is the desired outcome and achieving that is invaluable.

Of the 32, 3 said they could/would continue to afford the medication for even a notable period. The rest indicated they will eventually revert to an affordable medication with fewer positive results, in-turn having to accommodate a less healthful and productive life.

In this small group, Myfembree was the medication allowing all the women (in CANFib's discussion) to lead a full life, be with family, give care to children and/or elderly parents, show up at work, and function without the debilitating pain, horrendous blood loss, ongoing depression (and often dangerous combinations of symptoms) of having Uterine Fibroids.

I was unable to find anyone using the medication that had discontinued or was unhappy with Myfembree, however, the user group is quite new, and I find it important to balance this information with the inevitability of those less enthused. As of yet though, none have materialized.

## 7. Companion Diagnostic Test

I'm unaware of the diagnostic testing so will politely opt out of this question.

## 8. Anything Else?

Yes. Imagine taking your car to the mechanic for repairs, but on the way home it breaks down again.

Now consider what it would be like to call the garage once you've limped home – to be told the mechanic can see your car in 8 months. (keep in mind there are no other mechanics available right now)

This is what care looks like for Fibroids patients. It's not new, this is how it's been for decades.

The key to avoiding such a life-consuming disaster is to get to that appointment with as much symptom information as possible and having the best treatment for one's own instance delivered as quickly as possible.

This avoids the potential failure of going home with high hopes for a treatment that is of no value to the symptoms at hand. And that means more women find relief sooner - in turn - opening appointment times for other Women with Fibroids.

This is a win-win we can actually achieve when the options for such a diverse symptomology are varied and accessible.

## Appendix: Patient Group Conflict of Interest Declaration

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.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.  
None what-so-ever.
  
2. 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.  
I used only members of CANFib to collect the data for this submission.
  
3. 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
Pfizer			X	
Godaddy			X	
Bayer		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:** Patricia Lee

**Position:** Founder/President

**Patient Group:** CANFib Canadian Women with Fibroids NPO

**Date:** Feb 26, 2025

January 29, 2025

Re: CDA Reimbursement Review relugolix, estradiol, and norethindrone acetate (Myfembree)  
Call for patient/clinician input

Dear Sir/Madam

**Attached is CANFib's submission regarding the CDA Reimbursement Review – relugolix, estradiol, and norethindrone acetate (Myfembree)**

Since 2012, CANFib works to empower women in Canada to speak of, hear about and understand more about uterine conditions that may affect them throughout life. CANFib works with women, physicians, insurance companies and research to promote more open dialog and provoke exuberant interest in working towards solutions.

Within this submission is data and discussion notes from the combined input and experiences of 1000s of women in Canada with Uterine Fibroids, as well as comments from incoming SOGC President Dr. Nicholas Leyland and endorsement from The Women's Health Coalition.

In short, recommendation of Myfembree will increase choices, improve options, and strengthen outcomes for women with uterine fibroids while offering a burdened system a potentially wider path of Patient access.

Thank you for taking the time to consider patient input via CANFib's submission.

Patricia Lee,  
Founder/President  
CANFib Canadian Women with Fibroids

[REDACTED]  
[www.CANFib.org](http://www.CANFib.org)

## A little about the numbers

According to John Hopkins University, an estimated 1 in 3 women over the age of 30 has Uterine Fibroids, and according to Statistics Canada there are 5,349,309 women between the ages of 15 and 54. This suggests approximately 1,604,792 women in Canada are currently dealing with Uterine Fibroids. The National Institute of Health tells us up to 50% of Uterine Fibroids instances bring notable symptoms – leaving hundreds of thousands of Canadian Women to navigate a complex system with an extremely discouraging condition.

In a recent survey of Fibroids Patients in Canada, a common thread is still *the unfortunate time from Diagnosis to resolution* (currently averaging 8 years).

Throughout the 8 years (on average) most women deal with Uterine Fibroids, symptoms rarely remain the same, but all too often symptoms increase so gradually that no “alarm bells” go off. This gradual elevation has the effect of leading women with Uterine Fibroids to “accommodate” new burdens in her day; adjusting how things are done, how work is navigated, what clothes are worn and how social life will be lead.

## The Ever-Shrinking Box of Life

A healthy outgoing hard-working woman will often, over 8 years, “accommodate” her way into becoming a depressed woman living in black trackpants, with no social life and an innate fear of being out of the circumference of a bathroom. It’s a very small box.

By year 8, often that box has almost no room for normal life at all, and the affected woman is still trying to integrate new or elevating Fibroids symptoms into her life.

1	Less than 1 month	11
2	1-2 months	38
3	3-6 months	57
4	7-12 months	98
5	13+ months	89
6	N/A	22



## Times and Waits

Adding significantly to this shrinking box is the time Women with Uterine Fibroids will wait to see their specialist.

The shown 2023 Survey by CANFib of 315 Women revealed 59% of respondents wait between 7 and 13+ months to see their Provider.

## Repeat visits for discussing

A: new symptoms and B: a current medication not working were the top reasons given in the same survey for wanting to return to the Specialist.

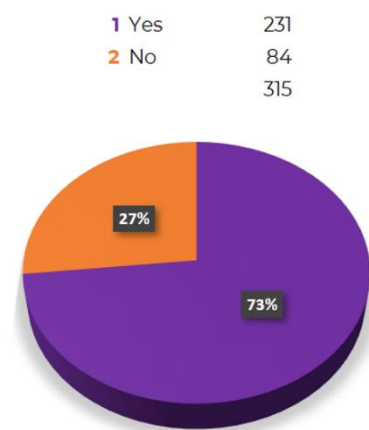
## If Uterine Fibroids was a car

Imagine taking one's car to the mechanic for repairs, but toward home the car breaks down again.

Now consider what it would be like to call the garage after limping home – to be told the mechanic can see the car in 4 months. (keep in mind there are no other mechanics available right now, and no questions are taken over the phone)

This is the nightmare scenario most Women with Fibroids face. *For, on average, 8 years.*

## Everyone loses



Of the 315 Respondents in CANFib's 2023 Survey, 266 said pain was the top reason for seeking medical help, followed by excessive bleeding from 249.

In the same survey, these symptoms lead 73% of the respondents to take at least 2 days extra off per month, and among these respondents alone this adds up to 5544 workdays per year lost in the Canadian Productivity model; the math for a near million symptomatic patients in Canada is devastating to the economy, to the

businesses and services involved - and indeed to the women carrying the burden and families they are supporting.

## What Women know and don't know

In the absence of timely access to Medical Professionals, of the 315 Respondents, 261 said they consulted the internet for information on Uterine Fibroids relief and once consulting a Medical Professional 84% felt they left the consultation still "uninformed" about the condition while 86% felt they were not given the full list of Health Canada approved Treatments and Medications.

This information gap ferments during up to 8 months wait between visits to their Specialist and effectively sets the stage for the necessity of Canada to recognize the advantages of having more Treatments available and approved for insurance coverage.

Not only does a having number of solutions benefit patients, but finding one early on that works well reduces the need for follow up appointments (and ultimately this lack of repeat visits lowers wait times for other patients to access medical help). While the symptoms are similar among Fibroids patients, the solutions are not "one size fits all."



## Why Medications change the game

1. Because Fibroids is not a "one size fits all" treatment, full access to any treatments available is top priority. Finding the right treatment can help those Women through potentially long waiting periods.
2. Often Women with Uterine Fibroids are awaiting access to a treatment or surgery that involves hospital access; medication that works for the Patient can help her remain productive and less symptomatic for that pending treatment or surgery.
3. On waiting for treatments or surgery some medications can help maintain or improve the patient's health status, making her more suitable for a successful surgical process.

## Adding Options to the list

- Given medications not working is a top reason for return specialist visits
- Given the waits for appointments is often quite long
- Give the long wait from diagnosis to possible treatment or surgery...

... the advantages of having a number of different medication options is clear. A large "option map" allows more women to benefit from "something" - and coverage of them all allows all women a better chance to find their best solution expediently.

## It can't be overly repeated, we can also help create open spaces with Specialists.

When more women find a viable medication early on to help them through the Uterine Fibroids medical process, it conversely means less women will require return visits to discuss other potential medications. This opens much needed spaces for women who have been waiting months for access.

## Uterine Health Specialists agree



### Dr. Nicholas A. Leyland,

BASC,MD,MHCM,FRCS and incoming President of the **Society of Obstetricians and Gynecologists of Canada (SOGC)** agrees, not only with the concept of access to several types of medication, but Leyland also confirms the

currently considered product for treating Uterine Fibroids symptoms (Myfembree) to be advantageous to the landscape.

***In a recent discussion of the Myfembree medication with Dr. Leyland, he offered the following:***

“GnRH antagonists such as Myfembree (Relugolix plus add-back) have great advantages over existing medical options for women with symptomatic fibroids (and endometriosis patients).

Women suffering from heavy menses and low blood counts can rapidly improve their symptoms with this oral medication to avoid surgery or to prepare themselves for simpler, less invasive techniques now available.

The single pill with "add-back"- estradiol and norethindrone acetate work to ameliorate the potential side effects of the GnRH antagonist component,” Leyland added.



### **Please, let's not forget the Patients**

CANFib talked to several women currently taking Myfembree for symptoms of Uterine Fibroids.

Of the 32 who reached out, all but one were “very happy” with the results of Myfembree medication taken for symptoms of Uterine Fibroids (one was “indifferent”).

However, From this group of women with Fibroids, only 2 had access to Myfembree by extended insurance coverage.

30 of the Women at CANFib’s discussion said they were paying out of pocket by giving up other household needs or personal activities to meet the expense.

Of the 32, only 3 said they could continue to afford the medication for any notable period. The rest indicated they will eventually revert to a medication with fewer positive results, in-turn having to accommodate a less healthful and productive life.

Here, Myfembree is the medication allowing all the women (in CANFib’s discussion) to lead a full life, be with family, give care to children and/or elderly parents, show up at work, and function without the debilitating pain, horrendous blood loss, ongoing depression (and often dangerous combinations of symptoms) of having Uterine Fibroids.

### **This is just not necessary**

There is no point nor advantage to a health system that asks women to lose personal health, lose time from family, abandon time as care givers and take (often unpaid) time off work while experiencing potentially years of depression, all while viable options are placed out of reach.

## **My name is Patricia Lee**

In 2012 I was in year 6 of my 8-year long battle with severe Uterine Fibroids.

With 8 years already behind me, I learned a lot about the condition. Sure, I understood clinically what Uterine Fibroids entails, but by year 8, I also understood the point to never leaving the house unless one knows where the closest bathroom will be at any given destination. I understood the depression that comes with one's own body acting in astonishing betrayal with no provocation. I understood what it meant to go to emergency only to find myself with 70% of my body's blood having been aggressively shed over a matter of 3 days.

When a nurse giving me a blood transfusion explained my dalliance with organ shutdown, what I knew for sure is I had to have surgery quickly (and did).

But what I never understood, in all those years, was how so many women could have the same condition, and we never met. Where were they all? Why were we not talking? Why does no one know what Uterine Fibroids (a common condition) is... until they are affected by it?

One day I stood in the line at the bank and counted women in the same line. My math told me there were 4 women in my line that needed to get out of the building as urgently as I. 4 women were feeling my exact pain. 4 women were suffering in silence.

It was then I began building a patient group using organized communication. This effort quickly became a living, breathing, motivated group of affected women who also longed for and needed a place to unpack their Uterine Fibroids Suitcases.

In building this group I also quickly recognized the importance and benefits of collaborating with Patients, Physicians, Insurance Companies, Health Canada and, indeed, the Pharmaceutical companies in Canada offering and producing effective products for Women's Health.

Over 13 years, CANFib moved from a popular grass roots collective to Not for Profit Organization in Canada, here to help ensure as few women as possible suffer the length of time, nor the dangerous and ongoing loss of blood, confidence *and hope* that I did.



Patricia Lee, Founder

CANFib Canadian Women with Fibroids



January 17, 2025

**CDA Reimbursement Review – relugolix, estradiol, and norethindrone acetate (Myfembree)  
Call for patient/clinician input - Women's Health Coalition of Canada Society**

The Women's Health Coalition of Canada Society (WHC) is committed to advancing a movement to speak openly, learn, and engage, to address barriers, gaps, and biases in menstrual, reproductive and sexual health. We are enabling advocacy, awareness and education in gynecological, uro-gynecological, menstrual, uterine, and reproductive health, through all the ages and stages of a woman's life.

**The WHC is pleased to support the CANFib recommendation for access and reimbursement for Myfembree as a therapeutic option for heavy menstrual bleeding associated with uterine fibroids.**

The WHC is highly committed to ensuring that women have access to the right treatment and support at the right time, for improved health outcomes. Patients dealing with symptoms of uterine fibroids are often dismissed in the health system for years. Uro-gynecological health is not well understood and is underserved in the health system. Patients are often not provided with therapeutic options for conditions associated with uterine fibroids such as heavy menstrual bleeding.

In addition, when reimbursement is not available, clinicians may not offer a new therapy, resulting in the most current and preferred treatments only being accessible to women with private health coverage and/or personal wealth.

Recommendation of Myfembree will improve treatment options, choice, and access for women with uterine fibroids and may raise clinician awareness of the importance of treating heavy menstrual bleeding. An improvement in therapeutic choice/access will benefit women physically and improve quality of life.

We welcome the opportunity to address this matter with you in greater detail. Should you wish to speak with us, please e-mail us at [REDACTED]

Sincerely,



Chair/President, Carmen Wyton  
E-mail [REDACTED]  
Website: [theWHC.ca](http://theWHC.ca)