

## CADTH REIMBURSEMENT REVIEW

# Patient Input

**budesonide (Jorveza)**

(AVIR Pharma Inc.)

**Indication:** Maintenance of Eosinophilic esophagitis in adults

**CADTH received patient input from:**

EOS Network (formerly FABED )

Food Allergy Canada

Gastrointestinal Society

**November 26, 2020**

**Disclaimer:** The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

## CADTH Drug Reimbursement Review Patient Input Template

Name of the Drug and Indication	Jorveza Budesonide
Name of the Patient Group	EOS Network (formerly FABED )
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	██
Telephone Number	██████████

### 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.

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

EOS Network is a British registered charity with a global reach

Our vision

Is of a world where everyone with an **Eosinophilic Gastrointestinal Disease** can eat without pain.

Our mission

Is to ensure that every person with an Eosinophilic Gastrointestinal Disease receives a prompt accurate diagnosis, the right treatment for them, and support to live with their condition.

What we do

- We provide information and support for people with Eosinophilic Gastrointestinal Diseases their families and carers, through our community hub, resources and events.
- We provide a global platform for clinicians and researchers to connect and share the latest research and best evidence-based practice.

- We provide educational resources and events for healthcare professionals to help them recognise symptoms, diagnose and treat Eosinophilic Gastrointestinal Diseases.
- We work with patients and their carers, **medical bodies**, manufacturers and funders to ensure the patient's voice is heard for decisions about treatment guidelines, the development and availability of medicines.

The roots of EOS Network go back to 2005 initially set up as a UK yahoo support group, FABED' Families Affected by Eosinophilic Diseases' became a registered Charity in 2011.

The eosinophilic community voiced the need to bring global research and growing medical knowledge to all sufferers, to improve their medical care.

In 2019 the Charity was restructured as EOS Network, strengthened by new trustee experience, a knowledgeable medical advisory board including an adult Eosinophilic patient with nurse experience and new working associations with professional British and Global medical institutions.

February 2020 we launched our new community's information hub and website.

On a personal level, I Amanda Cordell, Chair and Founder of EOS Network have two children born with Eosinophilic diseases now aged 13 and 17 this has inspired me to be an active Eosinophilic patient advocate for the past 16 years. During which I have attended and or participated in multiple Eosinophilic international conferences for patients and professionals and qualified as Eurordis patient expert for research and drug development within rare diseases.

## 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.

Over the years our organisation has used various tools to communicate with our community such as: blogs, Facebook groups, yahoo groups, surveys, educational days, family events and telephone support to discuss and learn about the experiences of living with Eosinophilic Oesophagitis.

In this report, we included:

- Statistics and quotes from our July 2020 UK Adult EoE patient experience survey, jointly undertaken with GUTS UK Charity. This survey was open to the public and our 2000+ followers on social media we received 39 completed forms.
- Our experiences as an Eosinophilic patient advocacy organisation.
- Quotes from patient/carer registration forms (Inc Canadian community)
- Past comments from social media

### 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?

Eosinophilic Oesophagitis (EoE) is an chronic inflammatory delayed response often to an unknown food substance, it causes symptoms such as: problems swallowing food, choking, mild to severe chest pain, regurgitation and food bolus obstruction (food stuck) meaning you are unable to swallow even water.

Without appropriate affective treatment long term damage can result in strictures (narrowing) reported in 69% of our survey participants which can then require regular dilatation (stretching of the Oesophagus) reported in 31% of our survey participants.

Survey participants also reported impact of the condition on social life (54%), eating (95%), travel (41%), diet (90%), work (46%), mood (74%), financial costs (39%).

Symptoms experienced include food sticking with or without mild to moderate pain (87%), with severe pain (49%), food bolus obstruction/impaction (74%), stricturing (narrowing) (69%), food avoidance (77%), weight loss (28%) and stretching of the oesophagus (31%).

This condition has an impact emotionally, socially, physically and financially to the patient and their family/carers. To be able to eat without pain is a human function we take for granted. Eating and sharing food is the center of all social events it brings us together in family and relationships, work meetings etc. It becomes isolating when you cannot eat the same food as your family, friends and colleagues.

Quote *“Affects relationship”*

The process of eating can be challenging, slower than others due to additional chewing and it may be difficult for the person to talk whilst eating.

Quote “Feeling scared to eat in front of others in case I ‘choke”

This affects everyone as the sufferer feels embarrassed upset and anti-social and the people around them feel embarrassed for them and awkward if they cannot share the same meal.

As this is non (IGE) delayed reaction there are no effective tests to indicate the foods to avoid only trial and error 78% reported food avoidance in our survey this becomes even more challenging when 29% of our survey found it difficult to access a dietician for treatment.

Often a sufferer’s diet can become extremely restricted whilst trying to discover safe foods 57 % eliminating 6 or more food groups from their diet i.e. (egg, dairy, wheat, soya, fish, nut and more). This becomes impossible for some to manage whilst others will withdraw from social activities in order to maintain their restrictions. Majority of sufferers will avoid eating out for fear of having a reaction and will choose to carry their own prepared food everywhere. Currently there are no standardised treatments resulting in random pathways of care, lengthy time to acknowledgment and diagnosis, leading onto a trial and error process of off label drugs and diet. This causes psychological distress for patient and carer.

*Quote “I have developed anxiety, physically shake at times, for 3 yrs the dr prescribed Acid reducing medication without establishing the cause, it was when I complained of food sticking and physical choking episodes did they ref me to an ENT specialist who diagnosed silent reflux, it’s a long slow process waiting for appointments which causes more anxiety. Stress makes the symptoms worse, I also stopped eating when at work for fear of choking. Ideally I’d prefer to attend a centre of excellence for this conditions and see drs specially trained in this area, to me it’s bonkers that different primary care trust use different methods to treat this disease”*

#### **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).

Currently there are no approved NHS treatments for Eosinophilic Oesophagitis (EoE).

### **PPI's Omeprazole, Lansoprazole or Esomeprazole**

92% (36) of our survey participants had been prescribed PPI's for their symptoms. 72% felt that the treatment did not improve their quality of life. 18% were satisfied with this as a treatment for EoE. Patients struggle to receive treatments beyond treating acid suppression symptoms due to lack of awareness and a reluctance to prescribe off label.

### **Fluticasone (Flixotide) Asthma Pump or Budesonide (Pulmicort) Slurry**

72% (28) of our participants had tried these as a treatment for their symptoms. 57% (16) felt these medications did improve their quality of life. These medications need to coat the Oesophagus like a topical cream on the inside, so you must not wash it away (food or drink) till it is absorbed ie a minimum of 30 minutes.

- Using an asthma pump to deliver steroid treatment such as fluticasone by swallowing instead of inhaling the substance is difficult and inaccurate.

*Quote" I had two prescriptions after diagnosis, the first was a normal asthma inhaler which was difficult to use, and I never knew when it had run out. The second came as a nasal spray so it was much easier to use. All in I only used Fluticasone for about two months. Then I went on an elimination diet."*

- Mixing budesonide Respules with Splenda or honey to make a slurry for swallowing is open to many wrong administrations from mixing incorrectly to ingesting incorrectly.

*Quote" This medication helped me as it improved my symptoms, but it was difficult to take and I was very unhappy taking 5 teaspoons of Splenda daily. I try to avoid artificial sweeteners and I was worried about the long term effects of taking Splenda. I also felt I put on weight whilst using Splenda."*

Both options require patient/carer to disregard the patient leaflet instructions and verbal or limited instructions from the prescriber are open to miss interpretation. 25% (7) of surveyed Patients or carers struggled to be compliant with these off-label techniques of administration as an organisation we regularly find patients are unclear as to how to correctly administer their medication.

There are no guarantees that the drug is delivered as needed to treat EOE but still carries the risk of the listed (steroid) side effects.

Quote *“I found it difficult to know whether I was swallowing enough to make any difference. It gave me oral thrush.”*

We have included our comments on dietary treatments under addition comments.

## Dietary Treatments

There are various forms of dietary restrictions the most common being the 6-food elimination diet (egg, dairy, wheat, soya, fish, nut) as per 32% of responders this was closely followed by 25% avoiding more than 6 foods.

This is a challenge financially, physically and emotionally for patients and their families/carers.

59% of respondents reported it as difficult to follow a diet when away from home i.e. work and travel, pleasure or social.

Quote *“It's very restricted and so most of the time you eat alone because you cannot eat what others are eating. It can be quite depressive as foods have an ability to lift your mood. Eating the same restricted meals all the time is not great.”*

Long term success of dietary treatment requires strict compliance to removal of foods that you are sensitised to. Global recommendations are to remove of 4 or 6 food groups, wait for symptoms to stabilise and then biopsy by endoscope to confirm remission. Once this is confirmed you can reintroduce one food at a time (approximately 6 weeks if no reaction) and then biopsy after each introduction to look for inflammation which can present even when symptom free. This treatment process requires multiple endoscopes.

Patients comments confirm this is not a standardised process in the UK.

Quote *“Hard following diet treatment as some consultants unwilling to scope or do not fully understand the condition.”*

29% of our patients find it difficult to access the essential knowledgeable dietetic support needed to use it as a treatment and are often left trying to work out how to self-manage food trials and dietary restrictions. Which can often cause further complications both physically and emotionally.

*Quote “I finally saw a dietitian when I was diagnosed with oral allergy syndrome, so I had a whole other food group to eliminate. The dietitian had never heard of eoe and oral allergy syndrome and didn’t really give any advice or follow up. Just to continue to try and avoid foods that trigger reaction.”*

*Quote “The dietitian didn't know about EoE or how to treat it /me, totally disregarded the information leaflet she gave me, and took 2 years to admit she didn't know what she was doing with me.”*

We report that 7% of our responders were on prescription elemental feed diets, usually used in the need for nutrition or in cases refractory to treatment. These medical feeds are broken down to be fully digested but avoid the hypersensitivity reactions causing the inflammation. Whilst they can provide full nutrition, they have poor palatability and may require an NG tube or more permanent MICI button or Peg to be surgically inserted for the patient to receive the necessary volume. The feed is then given by gravity or mechanical pump this has a huge impact on daily life for patients and carers and can need 24-hour support. Many suffer further complications of site infections.

## **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?



Eosinophilic Oesophagitis (EoE) is a chronic inflammatory delayed response often to an unknown food substance, it causes symptoms such as: problems swallowing food, choking, mild to severe chest pain, regurgitation and food bolus obstruction (food stuck) meaning you are unable to swallow even water

A recent patient experience survey identified the following::

Areas where Eosinophilic Oesophagitis has negatively affected quality of life include diet and eating, work, social life and travel.

Symptoms experienced include food sticking in the throat with or without mild to moderate or severe pain, stricturing (narrowing), weight loss and food avoidance.

One person describes the challenges of living with this condition:

*“I choke drinking water now. I’ve had this for the past 30 years and I think my oesophagus is really scarred and damaged. My consultant has discharged me because he doesn’t know what to do. I’ve asked for a PEG so I can have a break from the pain, inflammation, pain cycle but it was a no. I choke every time I eat and drink. I’m an ITU nurse and my best mates are nurses and doctors. When I choke and can’t swallow/ breath/ speak it even scares them. To the point that at work the other day someone was going to get the crash trolley. I drink at least a litre of water with every meal to push each mouthful of food down.”*

Current off label medications are part of a potluck standard of care. The benefits of approving Jorveza as a maintenance treatment would include:

- patients avoiding taking ineffectual medications
- reduced need for restricted diets and elemental tube feeding
- reduced GP, dietitian and hospital appointments
- reduced A and E visits due to Food Bolus Obstructions
- reduced medical procedures to remove food or (dilatation) stretching the oesophagus due to long term stricture damage
- reduced stress and anxiety caused by inconsistent care

Quote “I happened to speak with my Dr. about food getting stuck in my esophagus occasionally and he performed an endoscopy a couple years ago. I recently (last week) had an issue with food getting stuck and it didn’t pass for 72 hours so I went to emergency and had it removed. The GI doctor at the hospital has corresponded with my GI and I have been put on Rabepalozole to reduce acid in my stomach. My Dr. has suggested the 6 food elimination diet as I had already been cutting out 3 of 6 recommended restricted foods (egg, fish, and nuts).”

Jorveza orodispersible (Budesonide) tablet is a simple effective treatment that

dramatically increases the chance of efficacy and compliance, improving symptoms and quality of life for 8 out of the 10 Jorveza users in our survey.

## 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.

Jorveza has been approved by the EMA European Medical Agency and is available on prescription both privately and some government hospital trusts, in addition it has recently been recommended for acute and maintenance treatment by the SMC NHS Scotland.

As outlined in the improved outcomes Jorveza is a simple affective treatment and our survey showed 8 out of 10 (80%) patients felt Jorveza improved their quality of life.

Access to this treatment and its higher rates of efficacy and ease of compliance would improve both earlier and long term management of symptoms:

- Reducing GP and hospital appointments
- Reducing food bolus obstructions requiring A and E visits and emergency endoscopy procedures to remove food impactions (unable to swallow even water). Currently experienced by 74% of the survey participants.
- Reducing long term damage to the oesophagus (strictures) experienced by 69% in our respondents and 31% of respondents needing a dilatation to stretch their oesophagus.
- 

The oral - dispersible tablet is easy and discrete to administer even when away from home.

*Quote "I have felt a big improvement in my symptoms since taking the drug Jorveza (budesonide), whilst it has not cured my disease it has made living with it easier. I feel this is due to the convenience and simplicity of taking the right dose of medication in a dispersible tablet, especially when away from home. I am still cautious about eating out in public due to my past experiences, but I feel I have had less episodes of choking on food since taking Jorveza.(budesonide) I know I have been fortunate to be put on this drug as its not widely available in the UK yet. I have had a long history of EOE for which my GP has experienced the difficulties in treating and therefore was able to prescribe it for me. I understand this is not the case for many other patients in the UK."*

Patients appreciate that there maybe be side effects when taking a steroid treatment but feel that the benefits of Jorveza out way the risk far more than the ineffectual off label use of steroids via slurries and asthma pumps.

*Quote "Taking Jorveza has much improved my quality of life in a positive way, in comparison to taking budesonide slurry with Splenda. Jorveza also fits in better with my lifestyle. It has transformed my life, I feel "normal" again."  
Having an effective standardised treatment and NHS guidelines would give structure to education and awareness of EoE, improving the patient's pathway of care and ultimately their quality of life.*

*Quote" I have yet to access this drug, my gastro consultant said ask your gp my gp says go ask your consultant it's insane I can't access the medication I need my gp is useless and has absolutely no idea what the drug is or what eoe even is. It's so not on gp's radar. Some have never even heard of it"*

As per our previous comments poorly managed or undiagnosed this condition affects every part of a patient and carers/family life: at home, work, sleep(coughing), pleasure and social interaction.

Receiving this treatment would mean:

Less hospital and GP visits, less time off work and traveling to appointments.

- *Quote "The fluticasone inhaler was a little tricky to initially use - e.g. swallowing and not breathing in, however I found that this medication really helped my symptoms, at the time I was choking often, my throat felt sore, hoarse voice, coughing at night and it stopped everything, I was also taking Mucogel at the time (my gp switched me from Gaviscon) and I also felt that helped. However, after the four weeks of prescribed medication the symptoms all returned, my gp prescribed another 4-week course and the same thing happened again so I was referred back to hospital to see the consultant"*

Being able to eat out socially without fear and eating together as a family.

- *Quote" It's been a long process and my husband gets annoyed with the limitations if he's cooking"*
- *Quote "It's hard as there is no change in your meals day in day out. Been on it now 6 months straight."*

Less stress in the family, better sleep for all, as no coughing in the night.

- Quote *“Unexplained coughing at night, wake coughing and choking, runny nose, migraines, thick head / brain fog, itchy mouth numerous times. However, whilst taking Jorveza zero choking or coughing episodes, still experience itchy mouths, runny nose at times”*

Being able to travel as a family without worrying about food or choking.

Reduce financial family burden for specialist foods.

## 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.

## 8. Anything Else?

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

We received reported side effects for all the treatments mentioned in the report.

Omeprazole: multiple reports of increased gastrointestinal problems forcing them to stop.

Quote *“Omeprazole for me in bigger doses give me stomach problems and seems to cause intolerance like symptoms. My sleep is massively effected.”*

Fluticasone Asthma pump / Budesonide Slurry: Multiple reports of oral thrush without benefit of the medication.

Quote *“Oral thrush and no benefit”*

We also received comments on Jorveza:

Brittle hair and nails, pancreatitis both patients also commented on their complexities and restricted diets.

One patient also made the following comment

*“It gives me an instant head rush when taking the tablet and I have been suffering with constant headaches. I have only been taking it for two weeks though”*

This patient has since updated us and confirmed that the headaches/head rush have stopped and the swallowing difficulties due to EoE have resolved, she is currently at week 4 of her Jorveza treatment

We have directed all patients to the Yellow Card to report their concerns.

## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH drug 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.

No

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.

The patient experience public survey was completed in conjunction with GUTs UK charity.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000

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: Amanda Cordell  
 Position: Chair and Founder  
 Patient Group: EOS Network  
 Date:

# CADTH Drug Reimbursement Review Patient Input Template

Name of the Drug and Indication	Jorveza (budesonide) for the induction and maintenance of clinico-pathological remission in adults with eosinophilic esophagitis (EoE).
Name of the Patient Group	Food Allergy Canada
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED] [REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

## 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.*

Food Allergy Canada is a national non-profit charity and Canada’s leading patient organization committed to educating, supporting, and advocating for the more than 3 million Canadians living with food allergy. We focus on improving the daily quality of life of individuals and families by providing education and support needed to effectively navigate food allergy, building informed and supportive communities, and acting as the national voice on key patient issues.

[foodallergycanada.ca](http://foodallergycanada.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.*

Food Allergy Canada conducted telephone interviews with patients from November 18-23, 2020. Patients were identified by staff based on previous interactions. The organization also sought to recruit patients with Jorveza treatment experience through online Facebook groups organized by eosinophilic esophagitis (EoE) patients, but without success.



Despite these efforts, Food Allergy Canada had great difficulty finding patients with the appropriate experience, partly due to the low prevalence of this condition. Further, it is important to note that the organization's contacts in the EoE community are predominantly pediatric patients who are not included in the indication under review, and the perspectives provided in this submission represent a few patients and may not be representative of the entire population of adult EoE patients. In total, 7 patients with EoE were interviewed for this submission as well as one caregiver. All respondents were from Canada. Patients were diagnosed between 2000 and 2020.

### 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?*

**Symptoms of EoE:** Patient descriptions of their experience with EoE were highly variable. Acid reflux and dysphagia (swallowing difficulties) were the most commonly-cited symptoms of EoE (n=4). Impaction (catching food in your throat), choking, chest pain, vomiting, anaphylactic symptoms and scar tissue rings in the throat were all identified as symptoms by multiple patients.

The most severe EoE symptoms included chronic stomach pain that prevented the patient from working or attending school, choking that lasted so long that it led to vomiting and patients who lost weight because of their inability to eat without the fear of choking.

While these patients could be very well-adjusted in light of their experience, these symptoms still had a significant effect on their lives. Many patients cited fear of these symptoms or embarrassment that they would present while in public leading to social isolation. These symptoms can also impair patients ability to work or attend school:

- "I can't enjoy communal meals. It's difficult to socialize, difficult to go out with groups of people. I'm always worried that I'll be embarrassed by my reactions to food."
- "I'm scrawny because there are days where I don't eat much beside liquids."
- "I have a lot of fear about eating."

### 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).*

**Current Treatment for EoE:** There are currently no approved drug therapies for the induction and maintenance of adult EoE in Canada. All drugs are prescribed off label. Although current treatments may provide symptom relief, they also create serious side effects, may be difficult to use or require a surgical procedure with additional recovery time.

All 7 respondents provided information about the treatments they had received since their diagnosis. All patients had made significant dietary changes and most had received endoscopies. Three patients had received different forms of budesonide.

Treatments Received	n	Treatments Received	n
Dietary Changes	7	Budesonide Inhaler	1
Endoscopy Dilation	5	Flovent	1
Prevacid	2	CDB Oil	1
PPI	2	Codeine Syrup	1
Ranitidine	1	Unidentified probiotic	1
Oral Viscous Budesonide	1	Colonoscopy	1
Budesonide Capsule	1		

**Current Therapy Symptom Management:** When patients were asked to rate how much their current therapies were able to manage their EoE symptoms on a scale of 1 (Strongly Disagree) to 10 (Strongly Agree), the average score was 6.7 suggesting these patients were partially satisfied with their current symptom management. Patient comments include:

- “It took time to realize that I was feeling better than before.”
- “I eliminated the top 8 food groups and within two weeks I wasn’t coughing when I ate. I wasn’t vomiting. I put on weight because I could keep my food down.”
- “The elimination diet helps. I get more symptoms if I eat eliminated foods.”
- “The Prevacid doesn’t feel like it’s working, but it helped in the past. I’m afraid to not take it.”
- “With the Prevacid, I was taking it twice daily, but I noticed after about a year, it wasn’t helping. Now, I take it as needed. I feel like I don’t need it anymore. I didn’t feel 100% taking it every day.”
- “With dilations, it was pretty standard – helped with my swallowing on a regular basis. I didn’t need to drink water with every bite that I took - nothing but positive.”
- “Current treatments are not fully effective.”

**Side Effects of Current Therapies:** Patients identified a variety of side effects from current treatments. Comments included:

- “With Prevacid and ranitidine, my heart is jumpy. I have had heart arrhythmia. I feel wound up, jumpy and caffeinated. I went off ranitidine due to the heart arrhythmia.”
- “I seem to react more to foods after treatment.”
- “PPI made me more sick. I learned I was allergic to the pill.”
- “Budesonide made my esophagus softer but gave me really bad heartburn and reflux until I stopped taking it.”

**Additional Problems with Current Therapies:** Patients also identified practical difficulties associated with current therapies:

- “Eating is hard enough. Restricting appealing foods is sometimes more harmful than useful even with pain relief.”

- “It’s difficult removing dairy because it’s in a lot things. Due to my lack of access to kitchens, I can’t make my own meals (*Patient is a university student living in a dorm*). There are limited social opportunities when eating out.”
- “Strict diet was [a] big lifestyle change. I have [food] allergies so it was difficult to eliminate even more from my diet.”
- “[Oral viscous Budesonide] tasted terrible. It was hard to hold down.”
- “I had dilations every three or four months, lost a ton of school [time] and recovery is difficult.”
- “I need to find a new gastroenterologist to get a new scope and I have to wait for a new appointment.”
- “Using the budesonide was a pain in the butt. I had to do it 2 or 3 times a day. I often forgot. It took a lot time and it’s not convenient to carry.”
- “Losec (*one of the PPIs*) was expensive.”

## 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?*

Patients would like on-label treatments that can be effective, lack or at least minimize side effects, are easy to consume and whose long-term safety has been tested.

**Greatest Treatment Need:** When patients were asked about their greatest EoE treatment need, these were some of their responses:

- “Something that gets the symptoms under control. Something that doesn’t require 9 packages of Splenda a day (*oral viscous budesonide*) – there’s no research on whether that’s harmful.”
- “Fewer side effects from Prevacid and ranitidine, fewer effects on [food] allergies.”
- “Understanding the long-term effects of my diet and medications.”
- “Lower cost of medication.”
- “Pre-mixed budesonide - that would encourage me to use it more.”

## 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.

Food Allergy Canada was unable to identify any patients who fit the indication for this review and had treatment experience with Jorveza.

## 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.*

Not applicable.

## 8. Anything Else?

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

**Other Patient Concerns:** Multiple patients expressed concern about a lack of knowledge about EoE among healthcare providers. They were unable to find specialists with the expertise to treat their symptoms or to recommend appropriate treatment.

**Caregiver Feedback:** One caregiver was also interviewed for this submission – the mother of an adult EoE patient. She described some of the challenges of caring for someone with EoE:

- “It’s frustrating, emotional, disappointing, stressful because you need to deal with multiple specialists so you end up bouncing around. There is a lack of communication between healthcare providers. You never know if existing treatments will work – let’s try it – 4 to 6 weeks - didn’t work, let’s try this – more time passes.”

She was also asked about the most helpful type of support for an EoE caregiver:

- “Dietary therapy, support for the emotional challenges of EoE, coordination for specialists when testing foods from the elimination diet.”

**Key Points:**

1. There are currently no approved drug therapies in Canada for the induction and maintenance of adults with EoE.
2. EoE can cause severe symptoms that inflict pain and suffering on patients as well as restricting daily activities and impacting quality of life.
3. Current treatments are only partially effective. They also create side effects that may cause patients to discontinue or restrict their use.
4. Taking budesonide in its current oral viscous form is cumbersome and sometimes nauseating.
5. EoE patients profiled in this submission would support any new therapies that can reduce the severity of their symptoms.

## 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.

Adam Waiser, an independent consultant, conducted the patient interviews, analyzed the data and prepared the submission with the assistance and oversight of Food Allergy Canada staff.

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.

Adam Waiser, an independent consultant, conducted the patient interviews and analyzed the data with the assistance and oversight of Food Allergy Canada staff.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Williams Wilson Sherport Foundation	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: Joni Huang  
 Position: Director, Education and Healthcare Initiatives  
 Patient Group: Food Allergy Canada  
 Date: November 26, 2020

## Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Jorveza® (budesonide) for eosinophilic esophagitis in adults
Name of the Patient Group	Gastrointestinal Society
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

### 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.*

As the Canadian leader in providing trusted, evidence-based information on all areas of the gastrointestinal tract, the GI (Gastrointestinal) Society is committed to improving the lives of people with GI and liver conditions, supporting research, advocating for appropriate patient access to healthcare, and promoting gastrointestinal and liver health.

The GI Society is a national charity formed in 2008 on the groundwork of its partner organization, the Canadian Society of Intestinal Research (CSIR), which was founded in Vancouver in 1976. We receive national and international attention, simply because we have earned the respect of both the gastrointestinal medical community and Canadians who battle GI and liver issues daily. During 2019, we had more than 4.4 million **unique** visitors to our English ([www.badgut.org](http://www.badgut.org)) and French ([www.mauxdeventre.org](http://www.mauxdeventre.org)) websites.

All our programs and services focus on providing Canadians with trusted, commercial-free, medically-sound information on gut and liver diseases and disorders, including obesity, in both official languages. Our BadGut® lectures (currently on hiatus due to the pandemic), quarterly *Inside Tract®* newsletter, pamphlets, and educational videos (4 new ones just added) arm Canadians with the information they require to better understand and manage their specific needs. We also work closely with healthcare professionals and governments at all levels toward system-wide improvements in care and treatment.

### 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.*

Data for this submission came from a variety of sources, including contact with patients and patient caregivers as well as the results of published studies.

### 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?*

Eosinophilic gastrointestinal disease (EGID) is a **rare chronic disease** characterized by persistent inflammation in the gastrointestinal (GI) tract caused by a higher than normal number of eosinophils without evidence of other causes (e.g., infections, cancer). Physicians classify the disease according to the body

tissue where the eosinophils accumulate. Each type of the disease requires long-term treatment. **There is no cure for EGID.**

Eosinophilic esophagitis (EoE) is the most common type of EGID, where there are large numbers of eosinophils found in the esophagus, the tube that carries food from the mouth to the stomach. It can affect people of all ages and ethnic backgrounds, although there appear to be sex and genetic factors associated with the disease, in that males account for the majority of cases.

Although the etiology of EoE is not yet known, evolving research points to evidence of allergic, environmental, and genetic components. The fact that there is a high response rate to food elimination diets, especially amino acid–based elemental diets, along with the frequent recurrence of disease with food reintroduction, suggests that EoE is mediated by immune sensitization to foods.

EoE is a challenging disease to diagnose, treat, and manage.

Many individuals with EoE unfortunately go for many years without a proper diagnosis. Symptoms of EoE – vomiting, reflux, abdominal pain, and/or chest pain – are often associated with other more common ailments frequently seen by family physicians. As a result, patients are bounced around from one specialist to another, needing to run through a battery of tests in search of answers, creating frustration and a lot of anxiety. These visits are also time consuming, requiring individuals to take time off work or school.

The only test to definitively diagnose EoE is an endoscopy. The physician inspects the lining of the esophagus to see if there is inflammation, swelling, narrowing, and/or white spots. Given some patients with EoE will have an esophagus that looks normal, multiple biopsy samples are taken of the tissue in the esophagus. That tissue is then examined under a microscope for eosinophils, with an official diagnosis occurring when there is a peak of >15 eosinophils in a least one high-power field.

Once a diagnosis is determined, it can be a very difficult journey to get EoE symptoms under control. Access to a knowledgeable gastroenterologist who is willing to work with an allergist may require an individual to travel far distances. Even among the gastroenterology and allergy physician community, knowing how to manage and treat EoE is not well understood. Another complexity is having knowledgeable pathologists capable of accurately analyzing biopsy slides for a proper diagnosis.

The harsh reality for individuals with EoE is that after a considerable amount of time and hard work they can have a short period of remission but will frequently experience symptoms again once treatment stops.

Living with EoE has a significant impact on an individual's quality of life, including financially, socially, and mentally. Dietary restrictions associated with having EoE mean that individuals always need to be on high alert for possible food triggers in situations we too often take for granted – eating with friends and family, having dinner at a restaurant, traveling. Even if remission is achieved, dietary restriction is typically a very challenging therapeutic option.

Untreated EoE may lead to malnutrition, poor growth, and anemia. In some patients, EoE is complicated by the development of narrowing in the esophagus (strictures) that can cause issues with swallowing and choking.

This disease requires a long-term convenient medication treatment option specifically indicated for EoE that will not only help with getting symptoms under control but also keep them under control on an ongoing basis to minimize the risk of known long term complications.

#### **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).*



Through the journey to get EoE symptoms under control and managed, given the chronic nature of the disease, there are three available treatment options for physicians to consider. The decision on where to start is based on each individual's unique situation.

### **Elimination Dietary Therapy**

Individuals with EoE often have high rates of food allergies, and those allergies may be contributing to a high accumulation of eosinophils. Therefore, dietary therapy involves the elimination of what is suspected to be possible trigger foods. These diets can be extremely restrictive. Most EoE patients will start treatment with a six-food elimination diet, requiring them to completely stop eating the top allergenic foods – milk, eggs, nuts, wheat, soy, and seafood (fish and shellfish).

Once eosinophils are clear and symptoms improved (4-6 weeks), each food is slowly introduced one at a time. After one or more foods are reintroduced, the individual will undergo a repeat endoscopy to see if the eosinophils have returned. If the eosinophils have returned, those foods are again removed. The food reintroduction process continues through this cycle of 4-6 week intervals until it is clear what food(s) are causing the allergic reaction. Once the food(s) causing the symptoms are identified, the person must permanently eliminate those foods from his or her diet.

In cases where compliance with 6 foods could pose a problem, consideration is given to a less restrictive diet by only starting with two to three foods being eliminated. This approach however may still require a significant amount of time and resources to find the trigger foods as the first two to three foods selected may not be the culprit.

Any elimination diet is challenging to follow and very time consuming to find answers.

Access to timely and frequent endoscopies in Canada is also a real and significant challenge. If a physician won't agree to the necessary intervals for repeat endoscopies to test if the elimination of a particular food has been successful, or travel poses a burden to access the procedure, there is no point in pursuing this treatment option for EoE.

Not having dietary therapy to resolve the symptoms and manage the disease puts an even greater emphasis on the need to have an approved medication for EoE for not only initiation but also for maintenance.

### **Medication**

There is currently no medication specifically approved by Health Canada for EoE maintenance therapy. However, corticosteroid medications, primarily used for asthma, are widely used "off-label" to find a solution for how to reduce the number of eosinophils and improve symptoms. The two most frequently prescribed medications include: budesonide, a liquid medication mixed with a thickening agent (e.g., sucralose) and fluticasone contained inside an asthma puffer. In both cases, these medications are intended to be swallowed 30 minutes before each meal to coat the esophagus.

Neither of these options provides a convenient, reliable method of administration to ensure a consistent dose of medication to manage the disease.

### **Elemental Diet**

If a patient doesn't improve with an altered diet or medication and is severely symptomatic, a physician may recommend an elemental diet. In this case, all regular foods and drink are removed from the diet. Individuals on this treatment are placed on a liquid diet consuming a cocktail of amino acids, sugars, vitamins, minerals, and fats for approximately four to six weeks.

If an individual is not able to consume enough calories, or does not tolerate the elemental diet, then a feeding tube is required to manage EoE. There are cases of EoE where individuals are no longer able to tolerate food and are permanently on a feeding tube in order to survive.

## **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?*

Currently, there are almost no treatments available to treat EoE. For patients, this means that they have little hope of having their disease-state improved and managed over the long term. Jorveza® is the first corticosteroid with an indication for EoE, and it can help those with EoE have a chance at reducing their symptoms and improving quality of life when taken as maintenance therapy.

## **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?*

Studies find that budesonide is an effective treatment option for EoE. In one such study, budesonide treatment resulted in reduced symptoms as well as endoscopic and histologic improvement when compared with placebo. Other studies show similar results, as well as a considerable reduction in eosinophil count. We know that this medication is an effective option for a condition physicians have been treating with off-label medication. Jorveza® can offer patients a safe medicinal option that reduces symptoms and improves quality of life.

In addition, Jorveza® is an easy medication to take. Patients take one pill twice daily for six weeks (or up to twelve weeks if they do not respond adequately) in order to reduce eosinophil count to a more appropriate level.

Budesonide is effective for EoE; data supporting the recommendation for initiation of treatment with Jorveza clearly shows it works. Knowing that EoE is chronic, and symptoms resume when treatment is stopped, this medication should be recommended for ongoing use as a maintenance drug otherwise patients will have to revert back to using off-label, inferior options.

## **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.*

There are no laboratory tests that provide information about how effective a particular drug is performing with respect to the treatment of EoE or how severe the disease is at any moment in time. The only way to diagnose and assess the severity of EoE to know if treatment is working is to perform an endoscopy and measure the eosinophils from biopsies of the tissue in the esophagus.

## 8. Anything Else?

*Is there anything else specifically related to this drug review that CADTH reviewers or the expert*

In 2014, the Federal Government passed *Protecting Canadian's from Unsafe Drugs (Vanessa's Law)*, in order to amend the *Food and Drugs Act*. This legislation has raised the bar for patient safety and concern regarding off-label use of drugs and medical devices in Canada. For a disease like EoE, where physicians are forced to prescribe drug therapy options off-label, they are put in a precarious position.

The Canadian Medical Protective Association has issued guidelines for physicians about how to minimize the risk of liability when using medications off-label.<sup>1</sup> For #2 below, the rationale today for physicians in Canada needing to treat EoE patients with an off-label medication is because they don't have access to any other options.

1. Determine if the proposed use of the medication or device constitutes an off-label use.
2. Consider if there is sufficient support from the medical literature (e.g. guidelines from medical specialty organizations) for the off-label use of the medication or product. Is the use in keeping with the present standards of practice?
3. Document the rationale for using the medication or device off-label.
4. Obtain a detailed history from patients and examine them to determine if they have a condition that would place them at increased risk of potential side-effects from the off-label use of the drug or device.
5. Obtain and document patients' consent after an appropriate discussion of the potential risks and benefits, and after a discussion about the medication or device being used in an off-label fashion.
6. Document any questions asked by patients and the answers provided.
7. Carefully monitor patients for side-effects during or following on an off-label treatment

### Appendix: Patient Group Conflict of Interest Declaration

*To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, 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.*

No.

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.*

No.

3. *List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.*

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
none				

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:** Gail Attara

**Position:** Chief Executive Officer

**Patient Group:** Gastrointestinal Society

**Date:** 2020-11-24

<sup>1</sup> <https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2012/risk-management-when-using-drugs-or-medical-devices-off-label>