CADTH

CADTH COMMON DRUG REVIEW

CADTH Canadian Drug Expert Committee Recommendation

(Final)

BUDESONIDE (JORVEZA—AVIR PHARMA INC.)
Indication: Eosinophilic esophagitis

RECOMMENDATION
The CADTH Canadian Drug Expert Committee (CDEC) recommends that budesonide be reimbursed for the induction of clinico-pathological remission in adults with eosinophilic esophagitis (EoE) only if the following conditions are met.

Conditions for Reimbursement

Initiation Criteria
1. Patients who have all of the following characteristics:
    1.1. Confirmed clinico-pathological diagnosis of EoE according to established diagnostic criteria:
        1.1.1. History of symptoms of esophageal dysfunction (at least one of the following: transient or self-cleared food impaction, dysphagia, chest pain, epigastric discomfort, vomiting/regurgitation)
        1.1.2. Peak eosinophils ≥ 15 in at least one high-power field (HPF); (magnification: 400x) found pathologically on endoscopy.
    1.2. No evidence of any other clinically evident causes for the patient's symptoms other than EoE.
    1.3. Failed an adequate trial of proton pump inhibitor (PPI) treatment. PPI failure is defined as refractory symptoms after four weeks of PPI treatment at a standard dose (omeprazole 20 mg/day, pantoprazole 40 mg/day, esomeprazole 40 mg/day, lansoprazole 30 mg/day, or rabeprazole 20 mg/day).
2. Budesonide should not be used in combination with other corticosteroids used to treat EoE.
3. The maximum duration of authorization of budesonide is six weeks.

Prescribing Conditions
1. The patient must be under the care of a specialist with experience in the diagnosis and management of EoE.

Pricing Conditions
1. Reduction in price.

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1. The patient must be under the care of a specialist with experience in the diagnosis and management of EoE.

Pricing conditions

1. Reduction in price

Reasons for the Recommendation

1. In one randomized, double-blind, phase III trial (Study BUL-1/EEA, N = 88) comparing the efficacy and tolerability of budesonide orodispersible tablets with placebo in adults with active EoE, treatment with budesonide 1 mg twice daily was associated with a statistically significant and clinically meaningful improvement in the percentage of patients who achieved clinico-pathological remission after six weeks of treatment (between-group difference of 57.6% in favour of budesonide; 95% CI, 38.2 to 72.0; P < 0.0001). In addition, at week 6, 93.2% of patients in the budesonide treatment group, but none of the patients in the placebo group, achieved histological remission (between-group difference of 93.2%; 95% CI, 86.8 to 99.6; P < 0.0001), and 59.3% of patients in the budesonide group achieved resolution of symptoms versus 13.8% in the placebo group (between groups difference of 45.5%; 95% CI, 27.8 to 63.3; P < 0.0001).

2. All patients in Study BUL-1/EEA were required to have a documented trial with PPIs to exclude PPI-responsive esophageal eosinophilia. Given the lack of evidence for using budesonide 1 mg in patients with EoE who are PPI naive, there is uncertainty in the benefits and safety of using budesonide in patients who have not previously been treated with a PPI.

3. At the submitted price, the drug acquisition cost of budesonide 1 mg orodispersible tablets is $462 for a six-week course of therapy, which is higher than other pharmacological therapies currently in use in Canada for the treatment of EoE. The cost-effectiveness of budesonide orodispersible tablets compared with relevant treatments currently used for EoE in Canada is unknown, but a CADTH re-analysis of the sponsor's economic model suggested that one six-week-long course of treatment with budesonide orodispersible tablets may be associated with an estimated incremental cost-effectiveness ratio (ICER) of between $24,422 and $74,129 per quality-adjusted life-year (QALY) compared with no treatment. A price reduction of up to 35% may be

required to achieve an ICER of $50,000 per QALY, although given the uncertainty associated with the ICER estimates, a higher price reduction would be more likely to ensure that treatment is cost-effective.

Implementation Considerations

- Reimbursement of PPIs for EoE may require Special Authorization in some jurisdictions.

Discussion Points

- CDEC acknowledged that budesonide orodispersible tablets is the first Health Canada approved treatment for EoE. The clinical experts consulted by CADTH indicated that other steroids are used but are often associated with uncertain delivery of drug to the site of action (such as inhalers) or require compounding. Patients expressed a desire for a more convenient treatment; intuitively budesonide orodispersible tablets may fill this need.
- CDEC acknowledged that current guidelines for the diagnosis and management of EoE recommend that either PPIs or topical corticosteroids could be first line pharmacological treatment; however, given that Study BUL-1/EEA required that all enrolled patients had undergone a documented trial with PPIs, it is uncertain whether patients who are PPI naive would respond to budesonide 1 mg in the same manner as patients included in Study BUL-1/EEA. Based on available evidence, it is not possible to predict who will respond to PPI treatment. Furthermore, PPIs have fewer adverse effects compared to corticosteroids. For these reasons, CDEC recommends that budesonide 1 mg be used only in patients who have failed an adequate trial of PPI.
- CDEC acknowledged that clinical practice has evolved since the BUL-1/EAA study was initiated and that some patients who have not demonstrated a response after six weeks of treatment may benefit from an additional 6-week course of treatment with budesonide for a total duration of twelve weeks. However, the efficacy of continuing treatment for an additional six weeks with budesonide (twelve weeks total) in the BUL-1/EEA study is uncertain due to the limitations associated with the open-label induction phase of the BUL-1/EEA study. Limitations include the open-label design, lack of randomization, the small number of patients (N= 23), subjective outcome measures, and lack of control group. Hence, further evidence is needed to support the use of budesonide for an additional six weeks of treatment.
- The clinical experts consulted by CADTH for this review indicated that patients whose symptoms have resolved after one six-week course of treatment with budesonide may experience recurrence of symptoms. However, there is no evidence to demonstrate whether patients who relapse would respond to a subsequent course of treatment with budesonide or in the same manner as they responded to the initial treatment course.
- CDEC discussed limitations associated with generalizability of the study population to Canadian patients with EoE. In Study BUL-1/EEA, fewer than half of the study population had tried a dietary intervention before enrolment. Further, the use of concomitant medication (such as biologics or immunosuppressants) were prohibited during the treatment period in Study BUL-1/EEA.
- CDEC discussed that the role of budesonide in the maintenance of EoE after induction is unclear, given that there is currently no evidence available for the use of budesonide as a maintenance treatment; this is under investigation in an ongoing study.

Background

Budesonide has a Health Canada indication for the induction of clinico-pathological remission in adults with EoE. Budesonide is a non-halogenated glucocorticosteroid, which acts primarily as an anti-inflammatory by binding to the glucocorticoid receptor. Budesonide is formulated as a 1 mg orodispersible tablet, and the Health Canada–recommended daily dose is 2 mg budesonide as a one 1 mg tablet in the morning and a 1 mg tablet in the evening. The usual treatment duration is six weeks.

Summary of Evidence Considered by CDEC

CDEC considered the following information prepared by CADTH: a systematic review of randomized control trials of budesonide orodispersible tablets and a critique of the sponsor's pharmacoeconomic evaluation. The committee also considered input from clinical experts with experience in treating patients with EoE, and patient group–submitted information about outcomes and issues important to patients.

Summary of Patient Input

Six patient groups provided input for this submission. One submission was from a Canadian patient group (The Gastrointestinal Society), and the other five submissions were from international patient groups (the Families Affected by Eosinophilic Disorders in the UK, the American Partnership for Eosinophilic Disorders, the Campaign Urging Research for Eosinophilic Disease in the US, ausEE Inc. in Australia, and the Spanish Association for Eosinophilic Esophagitis in Spain). Patient perspectives were obtained from a combination of published studies, self-reported data that patients or caregivers (including parents of patients) shared with various online platforms, and personal experiences shared by the patients and/or caregivers or members of the patient groups. The following is a summary of key input from the collective perspective of the patient groups:

- The symptoms of EoE vary among individuals and can include difficulty swallowing, choking, regurgitation, nausea, vomiting, fatigue, reflux, abdominal and/or chest pain, as well as malnutrition and failure to thrive in the case of young children.
- It was noted that living with EoE has a significant impact on the health-related quality of life (HRQoL) and the daily lives of patients and their families; socially, mentally, and financially. Dietary restrictions presents a significant burden on the lives of patients and/or caregivers, having a negative impact on activities such as holidays and/or family gatherings, social engagements, dining away from home, and travel.
- The patient groups reported that the dietary treatment approach is challenging given that restricted diets can result in nutritional inadequacies, many patients struggle to access knowledgeable dieticians, and compliance to a highly restricted diet is very difficult, if not impossible, on a long-term basis.
- The patient groups reported that corticosteroids generally resulted in remission; however, they are primarily asthma medications used beyond the Health Canada indication that are sprayed from an inhaler into the patient's mouth and then swallowed or mixed with sucralose or another thickener to form an aqueous gel, and the non-specific nature of drug delivery makes the effectiveness varied and uncertain.
- Patients expressed a need for a treatment specifically indicated for EoE that improves their day-to-day quality of life (i.e., eating, working, and socializing), resolves clinico-pathological symptoms and has minimum long-term complications. Patients also expressed a desire for convenience in medication administration as well as clear instructions to maintain compliance and provide for reliable administration.

Clinical Trials

The systematic review conducted by CADTH included one study (BUL-1/EEA). Study BUL-1/EEA (N = 88) was a pivotal, phase III, double-blind, randomized, multicenter, placebo-controlled study that compared the efficacy and tolerability of a six-week treatment period with budesonide orodispersible tablets to placebo for the induction of clinico-pathological remission in adult patients with active EoE. Patients enrolled in the trial were adults (18 to 75 years of age) with a confirmed clinico-pathological diagnosis of EoE, active symptomatic and histological EoE, and must have undergone a documented trial with PPIs in order to exclude PPI-responsive esophageal eosinophilia. Patients were assigned to receive either budesonide 1 mg orodispersible tablet (budesonide 1 mg) twice daily or placebo orodispersible tablet (placebo) twice daily by a central randomization procedure using a 2:1 allocation ratio. The budesonide 1 mg and placebo treatments were identical in physical appearance, which assured treatment blinding. No stratification of randomized treatment assignment was performed. The up to six-week screening period was followed by a six-week double-blind treatment period and an optional six-week open-label induction. Seven patients were prematurely withdrawn from double-blind treatment phase (all due to lack of efficacy), four (13.8%) patients in the placebo group, and three (5.1%) in the budesonide 1 mg treatment group.

Key limitations of Study BUL-1/EEA were the lack of the validity, test-retest reliability, and responsiveness of the outcome measures used, including the dysphagia numerical rating scale (NRS), pain during swallowing NRS, Physician's Global Assessment, and Patient's Global Assessment. The clinical assessment of symptom resolution and patients' HRQoL were based on patient-reported outcomes using a diary recording over a week or questionnaires and therefore subjective recall biases were highly likely. The use of systemic or topical glucocorticoids, biologics, or immunosuppressants (except for PPI) as concomitant medication or initiating dietary restrictions were prohibited during the study treatment period. However, in clinical practice, symptomatic patients often receive dietary or pharmacologic treatment. Hence, the beneficial treatment effect as observed in Study BUL-1/EEA may not be entirely generalizable to Canadian patients with EoE. Study BUL-1/EEA was not of sufficient duration to assess how long the remission

would be maintained. In addition, there is no evidence to demonstrate whether patients who relapse would respond to a subsequent course of treatment with budesonide 1 mg in the same manner as they responded to the initial treatment course.

Outcomes

Outcomes were defined a priori in CADTH's systematic review protocol. Of these, CDEC discussed the following clinical response, treatment failure, HRQoL, histologic response, EoE activity, and harms outcomes:

- Clinical response
  - Resolution of symptoms (i.e., not any or only minimal problems) — defined as a severity of less than or equal to two points on 0 to 10-point (0-10) NRS for dysphagia and a severity of less than or equal to two points on 0-10 NRS for pain during swallowing on each day of the week before week 6.
  - Dysphagia NRS — The dysphagia NRS is a 10-point rating scale where patients provide an assessment of the severity of dysphagia symptoms experienced in the past 24 hours or seven days. The scale ranges from 0 to 10 (0 represents no troubles to swallow, 10 represents the most severe troubles to swallow).
  - Pain during swallowing NRS — The pain during swallowing NRS is a 10-point rating scale where patients provide an assessment of the severity of pain during swallowing experienced in the past 24 hours or seven days. The scale ranges from 0 to 10 (0 represents no pain during swallowing, 10 represents most severe pain during swallowing).
- Treatment failure
  - Food impaction
  - Patients needing endoscopic dilation
- HRQoL
  - Modified Short Health Scale (modSHS) — The modSHS is a four-item questionnaire, representing each of four health dimensions: symptom burden, social function, disease-related worry, and general well-being. Patients respond to each of the following questions representing the four health dimensions, which is scored on a scale of 0 to 100: the severity of the symptoms from esophageal disease (0 represents no symptoms, 100 represents very severe symptoms), interfere with activities in daily life due to esophageal problems (0 represents not at all, 100 represents interferes to a very high degree), worry caused by esophageal disease (0 represents no worry, 100 represents constant worry), and general feeling of well-being (0 represents very good, 100 represents dreadful).
  - Adult Eosinophilic Esophagitis Quality of Life (EoE-QoL-A) questionnaire — The EoE-QoL-A is a self-reported 30-item questionnaire. The 30-item questionnaire (24-item scale with a six-question addendum for those on elimination diet therapies), is categorized according the following five dimensions: impact of the disease on eating patterns and diet, social impact, emotional impact, disease anxiety, and swallowing anxiety. Patients provide response based on their life over the past week that best describes their experiences with living with EoE. Each question had five answers ranging with 4 corresponds to "does not describes their experiences at all" and 0 corresponds to "extremely describes their experiences." Based on the responses, an overall score, and the five subscale scores are generated. Higher scores indicate better HRQoL.
- Histologic response
  - Histological remission — Peak of < 16 eosinophils (EOS)/mm^2 HPF.
- EoE Activity
  - The Eosinophilic Esophagitis Activity Index Patient Reported Outcome (EEsAI-PRO) — The EEsAI-PRO score is used to assess EoE activity over a seven-day recall period in adult patients and it consists of the following five items: frequency of trouble swallowing, duration of dysphagia episodes, pain during swallowing, visual dysphagia questions, and behavioural change strategies. The scores of each item are added to provide an overall score out of 100, with disease severity rated as: remission (0 – 20), mild (21 – 40), moderate (41 – 65), and severe (66 – 100).
- Harms were assessed as the occurrence of adverse events (AEs), serious adverse events (SAEs), withdrawal due to adverse events, deaths, and notable harms.

- Data were not available for relapse after remission. Also, the minimal important difference (MID) in the EoE population is not available for any of the patient-reported outcomes assessed.

The primary outcome in Study BUL-1/EEA was percentage of patients with clinico-pathological remission at week 6 defined as fulfilling both criteria histological remission and resolution of symptoms.

Efficacy

The percentage of patients achieving resolution of symptoms (dysphagia and pain during swallowing) in Study BUL-1/EEA was 59.3% in the budesonide 1 mg group versus 13.8% in the placebo group. The difference between the budesonide 1 mg and placebo groups was 45.5% (95% CI, 27.8 to 63.3; P < 0.0001), which was clinically relevant and statistically significant in favour of budesonide. The clinical experts indicated that using a questionnaire to assess resolution of symptoms is not common in clinical practice, they also indicated that the questionnaire used in the trial is simple to use. However, no studies validating the dysphagia NRS, and pain during swallowing NRS in patients with EoE were identified from the literature.

Food impaction needing endoscopic intervention occurred in only one patient in the placebo group and none in the budesonide 1 mg group, and no endoscopic dilation was needed in either group during the study. It is uncertain if treatment with budesonide 1 mg effervescent tablets would decrease the risk of impaction and the need for endoscopic dilation.

In the BUL-1/EEA trial, HRQoL was assessed using EoE-QoL-A and modSHS. The mean change from baseline to week 6 were higher in the budesonide 1 mg group than in the placebo group for both the EoE-QoL-A 30-items total scores and for each of the six subscales (Eating/Diet Impact 10 items, Eating/Diet Impact four items, Social Impact, Emotional Impact, Disease Anxiety, Swallowing Anxiety). Of note, the between-group difference in subscales “eating/diet impact 10 items” (0.50, 95% CI, 0.17 to 0.82) and “eating/diet impact four items” (0.49, 95% CI, 0.13, 0.86) were improved in favour of budesonide 1 mg, whereas these differences were less evident in the other four subscales in which the 95% CIs of the differences were all crossed zero. Similarly, the modSHS also showed a consistent change from baseline to week 6, with between-group difference improved in favour of budesonide 1 mg for social function and disease-related worry questions of the modSHS, but not for symptom burden and general well-being. An MID for the EoE-QoL-A and modSHS was not identified for patients with EoE. Also, the analysis of modSHS and EoE-QoL-A were not specifically tested for statistical significance with methods adjusted for multiplicity, despite a reporting of 95% CI. It is likely, however, that budesonide 1 mg may have substantially improved patients’ eating and/or diet; whereas, the clinical importance of the magnitude of improvement on other outcomes is uncertain.

Fifty-five of the 59 patients (93.2%) in the budesonide 1 mg versus none of the 29 patients (0%) in the placebo group achieved histological remission at week 6 (between-group difference was 93.2% [95% CI, 86.8 to 99.6; P < 0.0001]).

The primary end point in the in Study BUL-1/EEA was the percentage of patients with clinico-pathological remission, this end point encompasses both histological remission and patient-reported symptom resolution, this outcome is a composite measure of efficacy outcomes identified in the CADTH review protocol. Thirty-four of 59 patients (57.6%) in the budesonide 1 mg versus none of the 29 patients (0%) in the placebo group achieved clinico-pathological remission at week 6. The difference between the budesonide 1 mg and placebo treatment groups on this composite outcome was 57.6% (95% CI, 38.2 to 72.0; P < 0.0001) in favour of budesonide. Results from the primary end point and its main criteria (resolution of symptoms and histological remission), indicate that almost every patient who achieved resolution of symptoms was also in histologic remission, but not vice versa. The clinical experts indicated that these results underscore the imperfect relationship between esophageal symptoms and the biological activity of EoE.

Harms (Safety)

In Study BUL-1/EEA, a higher proportion of patients reported treatment-emergent AEs (TEAEs) following treatment with budesonide 1 mg (37 patients, 62.7%) in comparison to patients treated with placebo (12 patients, 41.1%). The most frequently reported TEAE in the budesonide 1 mg group were suspected AEs of candidiasis, which occurred in 14 patients (23.7%) in the budesonide 1 mg treatment group and in none of the patients in the placebo group.

Of the 14 patients (23.7%) affected with local fungal infection in the budesonide 1 mg treatment group, 10 patients (16.9%) had esophageal candidiasis, three patients (5.1%) had oropharyngeal candidiasis, two patients (3.4%) had oral candidiasis, and two patients (3.4%) had candida infection. Some patients had more than one fungal infection in different subcategories.

No death and no SAE occurred during the study in any of the treatment groups. One AE in the placebo group and none in the budesonide 1 mg group led to discontinuation of the treatment. The one AE leading to discontinuation of treatment in the placebo group was an esophageal food impaction that was severe and needed endoscopic intervention.

There were 17 suspected AEs of candidiasis in the budesonide 1 mg treatment group versus none in the placebo group. Only four events (three esophageal candidiasis events and one oral candidiasis) in three patients (5.1%) were histologically confirmed and showed endoscopic and clinical signs.

Indirect Treatment Comparisons

No indirect evidence was submitted by the sponsor. An independent search conducted by CADTH did not find any published indirect evidence that met the inclusion criteria of the CADTH review protocol.

Cost and Cost-Effectiveness

The recommended dose of budesonide orodispersible tablets is 1 mg twice daily for a usual duration of six weeks. At the submitted price of $5.50 per tablet, the cost per six-week course of budesonide orodispersible tablets is $462 per patient.

The sponsor submitted a cost-utility analysis comparing budesonide orodispersible tablets to no treatment in adults diagnosed with EoE who were refractory to PPI treatment, over a time horizon of 52 weeks. The sponsor's three state Markov model assessed non-response, response, and recurrence, where response was defined as clinic-histologic remission. Patients started in the non-response state and could move to the response state after any of the first six weekly cycles; after which, patients who were responders had a risk of recurrence. Patients who entered the recurrence state at any point between week 7 and week 52 were not retreated and remained in this state for the remaining duration of the 52-week model. Data from the BUL-1/EEA trial were used to inform response, recurrence, and AE data inputs. Health utilities were assumed consistent with moderate gastroesophageal reflux disease (GERD), while recurrence was represented by the utility of mild GERD. Patients also visited a gastroenterologist at varying periods dependant on the health state.

CADTH identified several key limitations with the model submitted by the sponsor, including:

- The one-year time horizon did not adequately reflect the chronic, recurrent nature of EoE, or the need for repeated treatment. Clinical practice was not appropriately reflected within the one-year time horizon.
- Relevant comparators, such as dietary modifications, off-label PPIs, and off-label inhaled steroids (topically administered), which budesonide orodispersible tablets may displace or be added to, were not included.
- Due to a gap in evidence, the modelled population, based on patients in the BUL-1/EEA trial who were all refractory to PPIs, represented only a subset of the population captured in the Health Canada indication. No data are available for patients who are not refractory to PPIs.
- Utilities were not specific to EoE, and the proxy values appear to have been overestimated in some health states, increasing uncertainty with the results.

Due to limitations with the submitted model and gaps in the available evidence, CADTH was unable to provide a reliable estimate of the cost-effectiveness for budesonide orodispersible tablets over a relevant time horizon for either the Health Canada-indicated population or the modelled population. Furthermore, CADTH was also unable to estimate the cost-effectiveness of budesonide orodispersible tablets compared with relevant comparators already in use for the treatment of EoE in Canada.

CADTH undertook exploratory analyses to estimate the cost-effectiveness of budesonide orodispersible tablets compared to no treatment over the single EoE flare period (considered to range from six to 12 weeks), which CADTH considered the model adequately represents. At the maximum duration of therapy of six weeks (the "usual duration of therapy" specified in the product

monograph), budesonide orodispersible tablets were associated with an ICER of $24,422 per QALY compared to no treatment over a 12-week time horizon. When considering a shorter time horizon of six weeks, or an increased maximum duration of treatment with budesonide orodispersible tablets (12 weeks for initial non-responders), the ICER increased to $74,129 per QALY and $31,133 per QALY respectively.

The cost-effectiveness of budesonide orodispersible tablets compared to other therapies used in the treatment of EoE in Canada is unknown, as is the cost-effectiveness compared to no treatment over longer time horizons or with repeated use. At the submitted price, the drug acquisition cost of budesonide orodispersible tablets is more expensive than other pharmacological therapies currently in use in Canada for the treatment of EoE.

May 20, 2020 Meeting (Initial)

CDEC Members

Dr. James Silvius (Chair), Dr. Ahmed Bayoumi, Dr. Bruce Carleton, Dr. Alun Edwards, Mr. Bob Gagne, Dr. Ran Goldman, Dr. Allan Grill, Mr. Allen Lefebvre, Ms. Heather Neville, Dr. Rakesh Patel, Dr. Danyaal Raza, Dr. Emily Reynen, Dr. Yvonne Shevchuk, and Dr. Adil Virani.

Regrets

None

Conflicts of Interest

None

October 21, 2020 Meeting (Reconsideration)

CDEC Members

Dr. James Silvius (Chair), Dr. Ahmed Bayoumi, Dr. Sally Bean, Dr. Bruce Carleton, Dr. Alun Edwards, Mr. Bob Gagne, Dr. Ran Goldman, Dr. Allan Grill, Mr. Allen Lefebvre, Ms. Heather Neville, Dr. Danyaal Raza, Dr. Emily Reynen, Dr. Yvonne Shevchuk, and Dr. Adil Virani.

Regrets

Two CDEC members did not attend.

Conflicts of Interest

None