



PBAC Secretariat - MDP 952
Department of Health and Ageing
GPO Box 9848
Canberra ACT 2601

22 September 2021

Re PBAC Budesonide (Jorveza®) submission for use in EoE (Eosinophilic Oesophagitis)

Allergy & Anaphylaxis Australia welcomes the opportunity to lodge our comments in support of the application for Pharmaceutical Benefits Scheme (PBS) listing of JORVEZA® for both induction of remission and maintenance of remission in adult patients with Eosinophilic Oesophagitis (EoE).

EoE currently affects about 1 in 1000 Australians¹ (both children and adults). It is a debilitating disease that has no cure. The symptoms of EoE are varied and include difficulty swallowing and food sticking in the oesophagus and can result in permanent scarring and narrowing of the oesophagus. Although more is known about the disease now thanks to increasing research, there is still much to be understood. People with EoE often have a poor quality of life so any treatment that improves their wellbeing is welcomed.

Currently, the goal of treatment is to improve symptoms by eliminating or reducing the number of eosinophils in the oesophagus. To date, medications used for other allergic conditions such as allergic asthma have been used to treat EoE. Asthma steroid medications such as Flixotide (Fluticasone propionate) and Pulmicort (Budesonide) have been sprayed into the mouth and/or swallowed to try to get the steroid medication to the oesophagus, and steroid liquid has been mixed into a slurry and swallowed.

Despite being beneficial for EoE, none of these asthma medications (inhalers and nebulisers/respules) have been indicated for EoE by the Pharmaceutical Benefits Advisory Committee (PBAC). People with EoE who are already marginalised by their condition, must pay full cost of inhaled steroids that their treating specialist prescribes for EoE if they do not also have asthma. It is important that people with rarer disease states that greatly impact on health and wellbeing have access to a range of medications (proven to improve the rare disease state such as EoE) to treat their medical condition.

JORVEZA® is a new medication that contains Budesonide (the same medication in Pulmicort) in tablet form that dissolves in the mouth and can be swallowed, therefore coating the oesophagus.

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A&AA strongly supports PBS listing of JORVEZA® as it is the only medication specifically formulated to target the oesophagus. The steroid aerosols and slurries currently used to treat EoE have improved the condition, so a disintegrating tablet specifically for EoE should help compliance and management. Having EoE often means people have difficulty eating so having a medication that is easy to take, targeted and affordable can improve eating challenges for people with EoE who often have many restrictions.

We understand that the submission is for PBS approval for treatment of EoE in adults, for both induction of remission and maintenance of remission, with JORVEZA® 1 mg BID regimen for induction treatment and either the JORVEZA® 1 mg BID or the JORVEZA® 0.5 mg BID regimen for maintenance treatment. A&AA strongly supports the approval of both doses for maintenance treatment so that doctors can prescribe the most suitable dose for each individual patient. In general, using the lowest effective dose of corticosteroid is preferred, and this will be an option if both the 1mg and 0.5mg tablets are approved. Pleasingly, based on the 48-week maintenance study², it seems that both doses are safe and efficacious.

As a consumer advocacy organisation, A&AA has heard from many people about the difficulty in managing EoE and so we welcome the opportunity for them to have access to proven medication that is easy to use, safe and efficacious at improving their symptoms and quality of life. We therefore also ask that the government make other medications such as Budesonide respules and Neocate Spoon (sometimes used to mix Budesonide respule into a slurry to be swallowed) to be made available to consumers with EoE via the PBS as some people may not be able to have JORVEZA®. It is important people with allergic disease and their treating doctors have a choice of treatments and doses that best suit the disease state and the person taking it.

Yours faithfully,

Maria Said
CEO
Allergy & Anaphylaxis Australia

Reference

1. ASCIA www.allergy.org.au/patients/food-other-adverse-reactions/eosinophilic-oesophagitis
2. Straumann et al. Budesonide Orodispersible Tablets Maintain Remission in a Randomized, Placebo-Controlled Trial of Patients With Eosinophilic Esophagitis. *Gastroenterology* 2020;159:1672–1685

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