



The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC24-007492

Ms Susan Templeman MP
Chair
Standing Committee on Petitions
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Dear Chair *Susan*

Thank you for your correspondence of 14 May 2024 regarding petition number EN6026 on behalf of patients with Von Hippel-Lindau (VHL) disease regarding access to Belzutifan (Welireg™) on the Pharmaceutical Benefits Scheme (PBS).

I am sorry to learn of the difficulties patients with VHL disease face affording suitable treatment. The information provided below may not provide an immediate solution, but I hope it is helpful.

The PBS is the main mechanism through which the Australian Government subsidises the cost of medicines for the treatment of Australian patients. Under legislation, a new medicine cannot be listed by the Government on the PBS unless the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, makes a recommendation in favour of listing. When considering a medicine proposed for PBS listing, the PBAC is required by that legislation to consider the effectiveness and cost of the medicine, including by comparison with alternative treatments.

The PBAC's consideration is generally initiated by the pharmaceutical company responsible for a medicine making a submission to the PBAC. This is because pharmaceutical companies usually hold the scientific data and other information necessary to inform the PBAC's considerations.

As noted, Belzutifan is not listed on the PBS. Merck Sharp & Dohme (Australia) Pty Ltd (MSD), the responsible pharmaceutical company, recently applied to the PBAC for the consideration of Belzutifan for VHL disease at the July 2024 PBAC meeting. A list of submissions that will be considered at this meeting is available at www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda/july-2024-pbac-meeting.

Patients are welcome to provide comments for consideration by the PBAC alongside the information submitted by the responsible pharmaceutical company for a medicine. The views of the public and peak bodies form an important part of the PBAC's decision making process. More information about how to submit consumer input is available at www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-consumer-comments.

Please note consumer comments for the July 2024 meeting closed on 29 May 2024. Should Belzutifan for VHL disease receive a positive PBAC recommendation, which is an essential requirement in the process of a PBS listing, other processes will need to be completed before it can be approved for listing. This includes pricing negotiations with the manufacturer, finalisation of the conditions for listing, quality and availability checks, and consideration by Government. The Government is committed to listing every medicine that is recommended by the PBAC where the pharmaceutical company agrees to the terms of listing.

The Department of Health and Aged Care works to finalise arrangements with the company and proceed to a PBS listing as quickly as possible once the necessary documentation has been submitted by the pharmaceutical company. Outcomes from the July 2024 PBAC meeting will be made available on the PBS website on 23 August 2024
www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes.

The Medicine Status Website enables one to search and monitor the status of a medicine as it progresses through the PBS listing process. The website is updated monthly and can be found at www.pbs.gov.au/medicinesstatus/home.

Subsidising clinical treatments is not the responsibility of the Government alone. The Government provides funding to the states and territories to assist with the costs of operating public hospitals, which can include assisting patients with the cost of medicines. Patients may wish to discuss with their treating doctor whether it would be appropriate to apply to the drug and therapeutics committee of a local public hospital for assistance with the cost of treatment.

A patient's treating doctor may also wish to contact MSD to request access to Belzutifan at reduced cost through a compassionate access or expanded access program. Decisions to grant access to these programs occur at the sole discretion of the pharmaceutical company concerned.

Where a medicine is not listed on the PBS, private health insurers are free to pay benefits under general treatment cover, for the full price of the medicine. A health insurer may choose to offer this as a value-added feature of its policies, subject to any terms and conditions it chooses to set. This is a commercial decision for each health insurer.

Thank you for writing on this matter.

Yours sincerely

Mark Butler

17 Oct / 2024