15 December 2023

PBAC RECOMMENDS KALYDECO (Ivacaftor)
Extension for Ages 4 Months and Older, Including Additional Gene Mutations

Your voice has been heard and today we are delighted to share the great news that the Pharmaceutical Benefits Advisory Committee (PBAC) has provided a recommendation for the expansion of Kalydeco (also known as Ivacaftor).

Thank you to everyone who made submissions, including our members, it is evident that we have been heard.

Not only will Kalydeco be available from the age of 4 months (previous access to 12 months and older), but it will now be available for more gene mutations. This is something we have been relentlessly advocating for and today's outcome is significant progress to ensure that all Australians living with cystic fibrosis have access to the therapies they need.

The table below shows the full list of gene mutations that will benefit from this listing, as per the TGA website, KALYDECO (tga.gov.au) see page 17.

CFTR gene mutations that produce CFTR protein and are responsive to Ivacaftor

There are approximately 100 people in Australia that will benefit from this decision. This recommendation provides an extension of the existing listing to include a younger age range and gene mutations that will respond to Kalydeco. Consequently, this expansion grants access to modulator therapy for individuals who have not had this option before.

Whilst Cystic Fibrosis Australia welcomes this recommendation, I request that all stakeholders now expedite the discussions so that the listing of Kalydeco will be made available on the Pharmaceutical Benefits Scheme (PBS) without delay.

Thank you to the PBAC for your support of our community.

You may have seen on social media that our CEO, Jo Armstrong, met with Jo Watson, Deputy Chair of the PBAC, this week and she was very encouraged by their discussion especially as Jo Watson reiterated that they are working hard to ensure no one is forgotten.

The meeting of the Jo's!

Today's announcement is another great win for the CF community. In fact, in 2023 we have seen the PBAC provide a recommendation of Trikafta for 6-11's, and the expansion of the listing for Orkambi – and now we have today's news. Advocacy makes a difference!

The progress we have seen this year is immense and it is a good step in the right direction to ensure that everyone has access to the therapies they need. No one is forgotten and we are fighting to ensure that people with rare mutations also get the right outcomes.

However, we still have a lot of work to do and a long way to go to get the outcomes we need.

Imminently this includes the listing of Orkambi on the PBS. We received the great news of the PBAC recommendation for the expansion of Orkambi, for 1 and 2-year-olds, back in August, and now four months on, it is still yet to be available on the PBS.

I am diligently advocating and urging all relevant parties to expedite this process. No individual should endure unnecessary delays in receiving medication for which they are eligible.

Today's announcement is a great reminder that Consumer Comments do make a difference in helping transform people's lives. The PBAC is currently open for consumer comments for the extension of Trikafta to our 2-5-year-olds, where currently 286 little ones are awaiting the benefit from this listing.

I encourage you to share your comments with the PBAC today, you can do this HERE

Please note when providing your submission:
→Share what you know including lived experiences and be specific about symptoms, how you feel, and what your daily needs are.
→Explain the difficulties and realities of living with CF and why access is important to you.

Your input does make a difference. Together, let's keep fighting to get the right outcomes for all people living with CF.

Warm regards,

Jo Armstrong
CEO
Cystic Fibrosis Australia