

1<sup>st</sup> June 2024

## **Breaking News: PBS Listing for Kalydeco Extension**

We are thrilled to announce a significant advancement in the treatment of cystic fibrosis (CF) in Australia. Starting from 1 June 2024, Kalydeco (Ivacaftor) will be available on the Pharmaceutical Benefits Scheme (PBS). This expansion in PBS coverage marks a crucial step forward for the cystic fibrosis community.

### *Key Details of the PBS Listing:*

- **Eligibility:** Kalydeco will be available for patients aged 4 months or older who have a G551D or other gating (Class III) mutation on the CFTR gene. Additionally, patients aged 4 months or older with at least one non-gating mutation on the CFTR gene that is responsive to Ivacaftor potentiation based on clinical or in vitro data are also eligible.
- **Impact:** Approximately 95 people with cystic fibrosis in Australia will become eligible for a CFTR modulator for the first time under this new listing.

This development is a beacon of hope for the CF community, offering enhanced treatment options and improved quality of life for many individuals and families affected by cystic fibrosis.

*Mutations Covered Under the Listing:*

The listing includes patients with the following mutations:

- G551D
- Other gating (Class III) mutations

<b>Gating mutations (x 9)</b>	G178R	G1244E	S549R
	G551D	G1349D	S1251N
	G551S	S549N	S1255P
<b>IVA <i>in vitro</i>-responsive mutations (x 83)</b>	A120T	I175V	R170H
	A234D	H939R	R347L
	A349V	H1375P	R347H
	A455E	I148T	R352Q
	A1067T	I807M	R553Q
	D110E	I1027T	R668C
	D110H	I1139V	R792G
	D192G	K1060T	R933G
	D579G	L206W	R1070Q
	D924N	L320V	R1070W
	D1152H	L967S	R1162L
	D1270N	L997F	R1283M
	E56K	L1480P	S589N
	E193K	M152V	S737F
	E822K	M952I	S945L
	F311del	M952T	S977F
	F311L	P67L	S1159F
	F508C	Q237E	S1159P
	F508C; S1251N	Q237H	T338I
	F1052V	Q359R	T1053I
	F1074L	Q1291R	V232D
	G178E	R74W	V562I
	G194R	R75Q	V754M
	G314E	R117C	V1293G
	G576A	R117G	W1282R
	G970D	R117H	Y1014C
	G1069R	R117L	Y1032C
G1249R	R117P		

We encourage everyone to share this news and celebrate this milestone, which brings us closer to better health outcomes for people living with cystic fibrosis.

For more detailed information, please refer to the official PBS listing or contact your healthcare provider.

Thank you for your continued support and advocacy in the fight against cystic fibrosis.

[PBS Website Listing](#)

[TGA Product Information](#)

Warm regards

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