PBS Listing for Kalydeco and Soliris

Kalydeco and Soliris – new treatments for cystic fibrosis and aHUS respectively – will be listed on the Pharmaceutical Benefits Scheme (PBS) from December 1.

Health Minister Peter Dutton said the Government had approved the listings of the medicines which will have significant health benefits for patients suffering these diseases.

Ivacaftor (Kalydeco®) is a new treatment for cystic fibrosis in patients with a specific gene mutation and is the first medicine to treat the underlying cause of cystic fibrosis in these patients.

The PBS listing of ivacaftor will help more than 250 Australians affected by the cystic fibrosis G551D gene mutation.

“The PBS subsidy of this medicine, which would otherwise cost approximately $300,000 a year per patient, will bring great relief to the patients and the families of people affected by this life threatening condition,” Mr Dutton said.

The Government has approved $174.5 million over the next four years to provide ivacaftor on the PBS.

Cystic fibrosis is the most common life threatening recessive genetic condition affecting young people in Australia. It affects organs such as the lungs and pancreas causing irreversible damage and can cause death.

“With this new treatment many patients can experience an improved quality of life with reductions in respiratory and gastrointestinal complications, improved lung function and fewer hospitalisations,” Mr Dutton said.

“Consistent with the advice of the Pharmaceutical Benefits Advisory Committee (PBAC) that this medicine could be listed on the PBS based on a pay-for-performance basis, all cystic fibrosis patients six years and older who have a G551D mutation in the CFTR gene will be treated with ivacaftor for as long as needed.

“I’m pleased to announce that the sponsor of ivacaftor, Vertex Pharmaceuticals, has agreed to proceed with the PBS listing as recommended by the PBAC,” Mr Dutton said.

Soliris is a new treatment for atypical Haemolytic Uraemic Syndrome (aHUS) - an ultra-rare disease that severely damages vital organs like the heart, brain and kidneys. It affects both adults and children and is often fatal.
The PBS listing of Eculizumab (Soliris®) will help patients affected by aHUS control the symptoms and severity of attacks and can also help restore organ function.

“I'm pleased that patients will now have affordable access to this medication which will help improve their quality of life,” Mr Dutton said.

Before its listing on the PBS, the average cost of the treatment was $500,000 a year per patient, putting it out of the reach of most Australian families.

“The Government has been able to fund this medicine because of the incredible and tireless work of patients and clinicians to develop the criteria to manage its use in Australia,” Mr Dutton said.

The Government has approved $63 million over the next four years to provide eculizumab on the PBS.

Mr Dutton said the sponsor of eculizumab, Alexion, has agreed to proceed with the PBS listing. It will also continue to provide compassionate access for patients that meet the PBS listing criteria until the medicine is officially listed on 1 December 2014.

Nine other new and amended treatments also have been approved for a 1 December 2014 listing on the PBS including treatments for prostate cancer and hepatitis C.

All PBS listings are subject to final arrangements being met by the suppliers of the medicine.

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