Medical

MEDIA RELEASE

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SIMPLIFIED PBS LISTING FOR BRONCHITOL®

The Australian government has approved a new, simplified Pharmaceutical Benefits Scheme (PBS) status for Bronchitol in the treatment of cystic fibrosis (CF).

Following the successful Pharmaxis application to the Pharmaceutical Benefits Advisory Committee (PBAC) and discussions with the Department of Health and Ageing, the new Bronchitol PBS listing removes the restrictive requirement for patients to demonstrate a 10% increase in a spirometric measure of lung function at 4 weeks (known as the '10% Increase Rule').

This rule has been replaced with a family and physician based assessment allowing flexible decision-making, and this takes place at a more clinic-friendly 3 months, instead of at 4 weeks. There is also a requirement that patients' lung function does not decline during this first 3 month treatment period.

This extended 3-month period will be much better suited to a patient's normal clinic visits, and will allow enough time for the CF Care Team to adequately assess response to treatment.

Pharmaxis CEO Mr Gary Phillips said, "This is welcome news for cystic fibrosis patients in Australia. It simplifies the process for patients and allows clinicians more flexibility in managing people being treated with Bronchitol. The PBAC decision recognises the fact that Bronchitol patients in Australia are well managed by a team of CF specialists who provide close and ongoing assessment of their treatment."

Mr David Jack, CEO of Cystic Fibrosis Australia, the leading patient body representing CF patients in Australia said, "This is a positive step for CF patients in Australia, providing more appropriate access for many patients – especially people in rural areas and younger patients. CF is one of the world's commonest life-shortening genetic diseases, and this decision potentially improves access to much-needed CF treatments via the PBS for hundreds of CF patients, both children and adults."

The new Bronchitol PBS listing is expected to take effect from September, 2013. These new Continuation Rules rationalise the listing of CF treatments to better optimise good patient outcomes, and were prepared by Pharmaxis in consultation with the TSANZ CF SIG and peak CF clinical bodies, the CF Centre Directors and the CF Special Interest Group of the Thoracic Society TSANZ.

Associate Professor Hiran Selvadurai, a senior clinician working in cystic fibrosis said, "This is extremely positive news, allowing continuing treatment for patients to be determined using flexible judgement in line with current clinical best practice. I anticipate that many patients will want to discuss airway clearance therapy options with their doctors and their clinic in line with these progressive changes to PBS continuation criteria".

Bronchitol is a precision spray-dried form of mannitol, delivered to the lungs through a specially designed portable inhaler. Bronchitol is approved in Australia for the treatment of cystic fibrosis in adults and paediatric patients aged over six years, as either an add-on therapy to dornase alfa, or in patients intolerant of, or inadequately responsive to, dornase alfa.

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