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Pharmaceutical Benefits Advisory Committee
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The Australian Kidney Foundation
Trading as Kidney Health Australia
ABN 37 008 464 426 I Charity No. CH 0614

Kidney Health Australia Submission to the Pharmaceutical Benefits Advisory Committee: To request a change in the listing of Soliris (eculizumab)

Kidney Health Australia is the peak national body representing the needs of those with kidney disease in Australia. As the lead organisation in the kidney sector, Kidney Health Australia advocates on matters relating to the welfare of kidney stakeholders and the delivery of services to people affected by kidney disease and those with kidney cancer. Furthermore, Kidney Health Australia has close ties with consumers, the medical community, renal units around the nation and is a member of the Australian Chronic Disease Prevention Alliance (ACDPA) and the National Vascular Disease Prevention Alliance (NVDPA).

Kidney Health Australia works to improve the awareness, support and information available to those affected by kidney disease. Kidney Health Australia works to bring together patients, their families and carers for support and information sharing and to advocate on behalf of the kidney disease community for equitable access to available treatments, clinical trials and innovative medical developments.

Kidney Health Australia has reviewed the application by Alexion to request an extension of the current Section 100 (Highly Specialised Drugs Programme) listing for Soliris (eculizumab 300 mg/30 mL) to include treatment for patients with atypical haemolytic uraemic syndrome (aHUS) in end stage renal disease (ESRD), and we are supportive of this application.

aHUS is a rare, life-threatening disease caused by chronic activation of the body's complement system (part of the immune system). This leads to the formation of tiny blood clots in small blood vessels throughout the body (known as thrombotic microangiopathy (TMA)), which in turn damages vital organs such as the kidneys, heart and brain. Most cases of aHUS are genetic, although some may be acquired due to the development of autoantibodies (such as during pregnancy) or occur for unknown reasons. aHUS may become chronic, and affected individuals may experience repeated episodes of the disease. The most common complication of aHUS is kidney disease, often resulting in ESRD and the need for long-term dialysis or a kidney transplant to stay alive.

The benefit of extending eculizumab to include treatment for patients with aHUS in ESRD is to facilitate equitable access to kidney transplantation for patients with aHUS, and to ensure post-transplant outcomes are optimised. The clinical experience summarised in the submission establishes, in our view, that eculizumab is highly clinically effective in improving kidney transplant outcomes in patients with aHUS when initiated prophylactically prior to transplant.

The clinical management algorithm proposed in Alexion's submission is an appropriate reflection of clinical risk stratification, with use restricted to patients with prior history of aHUS, eligible for a kidney transplant, and with a medium-high risk of subsequent TMA.

Conclusion
Kidney Health Australia is supportive of this request to extend the Section 100 listing for eculizumab to include treatment for patients with aHUS in ESRD. We would welcome the opportunity to further elaborate on these views either in person or in writing.

Yours Sincerely,

Mikaela Stafrace
Chief Executive Officer
Kidney Health Australia

Dr Marie Ludlow
General Manager Clinical Directorate
Kidney Health Australia