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Removal of Cinacalcet (Sensipar) from the Pharmaceutical Benefits Scheme A Position Statement

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The Honourable Sir Peter Cosgrove AK MC
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Kidney Health Australia is aware that from 1 August 2015, the treatment cinacalcet (Sensipar) is no longer available on the Pharmaceutical Benefits Scheme (PBS). Amgen has voluntarily removed Sensipar from the PBS for financial reasons. The safety and efficacy profile of Sensipar is unchanged. Sensipar will remain available in Australia on private (non-PBS) prescription and a special access program has been implemented by Amgen to facilitate access for those patients whose medical condition may be significantly impacted by cinacalcet withdrawal. The criteria for patients to use this special access scheme have been developed in consultation with the nephrological community and widely promulgated to all nephrologists.

Cinacalcet has unique properties and is of proven benefit (in particular to dialysis patients with secondary hyperparathyroidism) in reducing parathyroid hormone and calcium levels, controlling severe hyperparathyroidism, and reducing the need for parathyroidectomy (surgical removal of the parathyroid gland). However, the definitive trial assessing the effect of cinacalcet on cardiovascular events, patient survival and risk of fracture was unable to demonstrate a benefit (despite its proven ability to favourably change body chemistry)¹. This trial was not completed until some years after the initial approval by the Pharmaceutical Benefits Advisory Committee (PBAC) for cinacalcet to be subsidised. Despite an independent consensus meeting organised by Kidney Health Australia in October 2013 strongly recommending that the PBAC continue to subsidise cinacalcet, the negative trial results led to the PBAC reassessing the clinical role of cinacalcet and renegotiating the pricing arrangements. This eventually led to Amgen's decision to withdraw its application for PBS subsidy.

Kidney Health Australia notes that no other country has altered the subsidy arrangements in regard to availability of cinacalcet. Kidney Health Australia regrets that the PBAC and Amgen have been unable to find agreement on this issue. As a result of the Government renegotiated price arrangements which led to Amgen's decision to voluntarily withdraw its application for PBS subsidy, any change to the PBS status of cinacalcet is at the moment a decision for Amgen to consider.

Anyone who would like to have their eligibility for the special access program assessed should consult their Nephrologist.

Anne Wilson

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¹ Chertow GM et al. *N Eng J Med* 2012;367:2482-94