Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

18 December 2018

FRANCISCO T. DUQUE III, MD, MSc
Secretary
Department of Health

Dear **Secretary Duque:**

The Formulary Executive Council (FEC) respectfully recommends the **DISAPPROVAL** of the inclusion of **cinacalcet (as hydrochloride) 30 mg and 60 mg tablet** in the Philippine National Formulary (PNF) for use in the secondary hyperparathyroidism in patients with chronic kidney disease (CKD) on dialysis. Based on the results of the systematic review and meta-analysis (SR/MA) on the effectiveness and safety of cinacalcet, the use of the drug did not appear to reduce mortality among patients with chronic kidney disease (CKD) compared with other therapies for the management of secondary hyperparathyroidism. The said assessment showed, however, that cinacalcet lowered the incidence of parathyroidectomy. It was also found that cinacalcet use significantly decreased the level of intact parathyroid hormone (iPTH), while also lowering the calcium and phosphorus levels, but these additional biochemical changes might not necessarily be clinically significant. In terms of safety, cinacalcet use increased the rate of nausea/vomiting and hypocalcemia, which must be disclosed to patients for early detection of symptoms and appropriate management.

Further, the quality of evidence for all-cause mortality was rated as low due to the serious risk of bias and imprecision, while the evidence for parathyroidectomy was rated as moderate, with the only downgrade attributed to risk of bias. Because of the risk of bias and inconsistency, the evidence for intact PTH level, percent change in intact PTH, serum calcium level, and risk of nausea/vomiting, was rated as low, while proportion with ≥30% decrease in intact PTH was rated as very low, because of the additional downgrade due to potential for publication bias. Evidence for serum phosphorus level and risk of any adverse event were both rated as very low, while the evidence for risk of hypocalcemia was rated as moderate.

Given the above findings, the Council discussed that most trials reported biochemical measurements in their outcomes, while only a few studies reported patient-important outcomes, such as fractures, cardiovascular events, and quality of life indicators. There is a need to do more studies with longer follow-up time to analyze these outcomes and to adequately assess the long-term effectiveness and safety of cinacalcet use. Moreover, the cost-effectiveness data in other countries also did not seem to show that the drug was cost-effective. At the current discounted price offer of Php 142.80 per 30 mg tablet, the drug is deemed expensive considering that it has to be taken for the entire lifetime of the patient. Hence, the Council recommended to **DISAPPROVE** the inclusion of cinacalcet in the PNF.

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 local 1113, 1108, 1135
Direct Line: 711-9502; 711-9503 Fax: 743-1829 • URL: http://www.doh.gov.ph; e-mail: ftduque@doh.gov.ph

Please be informed that the above recommendation was posted on the website of the Pharmaceutical Division for 30 days to accommodate any comment or appeal from the stakeholders prior to final decision-making.

For your disposition, Sir.

Thank you and best regards.

Very truly yours,

For the Formulary Executive Council

ATTY. FROILAN BAGABALDO
Chair
Formulary Executive Council

Recommending approval of the FEC recommendation:

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Health Regulation Team

Approval of the FEC recommendation:

FRANCISCO T. DUQUE III, MD, MSc
Secretary