Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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DEPARTMENT CIRCULAR
No. 2022 - 0291

FOR: **ALL CENTERS FOR HEALTH DEVELOPMENT, NATIONAL DRUG POLICY COMPLIANCE OFFICES, LEAGUES OF CITIES, PROVINCES AND MUNICIPALITIES, PROFESSIONAL HEALTH SOCIETIES, DIRECTORS OF BUREAUS AND REGIONAL OFFICES, BARMM MINISTER OF HEALTH, CHIEFS OF MEDICAL CENTERS AND SANITARIA, AND OTHER CONCERNED**

SUBJECT: **Health Technology Assessment Council (HTAC) Recommendation to include Potassium Citrate 15 mEq Extended Release (ER) Tablet in the Philippine National Formulary**

By virtue of Republic Act 11223, otherwise known as the Universal Health Care (UHC) Act, health technology assessment (HTA) shall be institutionalized as a fair and transparent priority-setting mechanism to provide financing and coverage recommendations on health technologies to be funded by the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth).

Since 2020, the Health Technology Assessment Division (HTAD) has been accepting applications for minor inclusion in the Philippine National Formulary (PNF). Minor inclusions are applicable for drugs that are currently listed in the PNF, but are being applied for additional strength, immediate packaging, and net content.

As such, please be informed that the Secretary of Health has approved the HTAC recommendation **minor inclusion of Potassium Citrate 1620 mg (15mEq) Tablet in the Philippine National Formulary (PNF)** to wit:

Current PNF Listing	Updated PNF Listing following the Approved Minor Inclusion
Potassium (as citrate), 10 mEq tablet	Potassium (as citrate), 1080mg (10 mEq) tablet Potassium (as citrate), 1620mg (15 mEq) tablet

The current indication of *Potassium (as citrate), 10 mEq tablet* in the PNF as shown in *Appendix A* is for the management of renal lithiasis, hypocitraturia, chronic formers of calcium oxalate, phosphate calculi, uric acid lithiasis and renal tubular acidosis with calcium nephrolithiasis. This proposed minor application presents the use of Citrate (in its salt formulation as Potassium citrate), *1620mg (15 mEq)* for (1) severe hypocitraturia and (2) recurrent stone formers.

The PNF listing of *Potassium (as citrate), 10 mEq* **tablet** already encompasses several types of tablets allowable for government financing as clarified in the Department Memorandum 2016-0258 or the *"Further clarification and guidance on the bidding specifications of solid oral dosage forms (tablets) in the Philippine National Formulary."*
This includes modified release tablets, specifically **'extended release' tablets**. In addition, the locally available *potassium citrate* 10 mEq tablet approved by the Philippine FDA is also in the form of an

'extended-release tablet'. Therefore, there is no need to include the Potassium (as citrate) 1080 mg (10 mEq) ER tablet as this is included in the PNF.

Further, the HTAC thoroughly reviewed the application and recommends the minor inclusion of **Potassium Citrate 1620 mg (15mEq) Tablet** in the PNF on the basis of the following:

- The Philippine FDA issued a Certificate of Product Registration (CPR) for Potassium Citrate valid until 08 June 2025. The issuance of a CPR established the efficacy and safety of the product.
- Potassium Citrate is a standard of care for the management of renal lithiasis, hypocitraturia, chronic/recurrent stone formers of calcium oxalate, phosphate calculi, uric acid lithiasis and renal tubular acidosis with calcium nephrolithiasis.
- While the total treatment cost of shifting from 10mEq tablet to 15 mEq tablet will incur the following minimal additional costs:
    - For severe hypocitraturia :
        i. Php 14.20 for a 6 month duration of treatment
        ii. Php 146.00 for a 5 year duration of treatment
    - For recurrent stone formers:
        i. Php 29.20 for a one-year duration of treatment
        ii. Php 146.00 for a 5-year duration of treatment

  the HTAC puts premium on the advantage of the 15 mEq tablet in terms of **improved patient compliance due to the reduced number of tablets needed to be taken** (*4 tablets per day of the 15 mEq formulation versus 6 tablets per day of the 10 mEq formulation*) as noted by the proponent and the Philippine Urological Association (PUA) in a consultation.

For more details, you may refer to the HTA Philippines website:
https://hta.doh.gov.ph/2022/04/22/secretary-of-health-approval-of-the-htac-recommendation-on-fourth-dose-for-immunocompromised-populations-icps/

For your information and guidance.

By Authority of the Secretary of Health:

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