

7 August 2015

Proposal to fund a multivitamin for renal patients

PHARMAC is seeking feedback on a proposal to fund renal multivitamin capsules (Clinicians Renal Vit capsules) resulting from a provisional agreement with Natural Health Laboratories Limited (a subsidiary of Douglas Pharmaceuticals) and PHARMAC.

In summary, this proposal would result in the listing of renal multivitamin capsules (Clinicians Renal Vit) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 October 2015. Funding would be restricted to patients with chronic kidney disease (CKD) who are on dialysis or with CKD Grade 5.

The proposal would also result in pricing being added to the existing listing in Part II of Section H for a multivitamin and mineral supplement which is restricted to patients with burns and other criteria.

Details of the proposal are set out on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 21 August 2015** to:

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Senior Therapeutic Group Manager/Team Leader	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

Details of the proposal

From 1 October 2015:

In relation to Clinicians Renal Vit:

- Clinicians Renal Vit capsules would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following price and subsidy (ex-manufacturer, exclusive of GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Multivitamin renal	capsule	Clinicians Renal Vit	30 caps	\$8.39

- Prior to 31 September 2017, the price of Clinicians Renal Vit would reduce if a volume based sale cap is exceeded.
- From 1 October 2017 the price of Clinicians Renal Vit would reduce to \$6.49 per 30 capsules.
- Note: Clinicians Renal Vit capsule composition includes folic acid 400 mcg, pyridoxine HCl 10 mg (8.2 mg pyridoxine), cyanocobalamin 2.4 mcg, ferrous fumarate 24.3 mg (elemental iron 8.0 mg), ascorbic acid 60 mg, cholecalciferol 25 mcg, thiamine nitrate 1.5 mg, riboflavin 2 mg, biotin 30 mcg, calcium pantothenate 5 mg, nicotinamide 20 mg, zinc oxide 8 mg (zinc 6.43 mg), copper gluconate 0.9 mg (copper 0.12 mg), sodium selenite 55 mcg (22.99 mcg selenium).
- Clinicians Renal Vit capsules would be listed with all-at-once (STAT) dispensing.
- Clinicians Renal Vit capsules would be protected from subsidy reduction or delisting until 1 October 2018.
- Clinicians Renal Vit capsules would be listed subject to the following Special Authority criteria in the community and restrictions in the Hospital Medicines List.

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1. The patient has chronic kidney disease and is receiving either peritoneal or haemodialysis; or
2. The patient has chronic kidney disease grade 5, defined as patient with an estimated Glomerular Filtration Rate of <15 ml/min/1.73m² BSA (body surface area).

In relation to Multivitamin and Mineral Boost capsules

- The existing listing for multivitamin and mineral supplement capsules in Part II of Section H of the Pharmaceutical Schedule would be amended to list Clinicians Multivitamin and Mineral Boost capsules at the following price (ex-manufacturer, exclusive of GST):

Chemical	Presentation	Brand	Pack size	Price
Multivitamin and mineral supplement	capsule	Clinicians Multivitamin and Mineral Boost	180 cap	\$23.35

- The hospital restrictions for multivitamin and mineral supplement capsules would remain the same (as outlined below):

Restricted

Limited to 3 months treatment

Both:

1. Patient was admitted to hospital with burns; and
 2. Any of the following:
 - 2.1 Burn size is greater than 15% of total body surface area (BSA) for all types of burns; or
 - 2.2 Burn size is greater than 10% of BSA for mid-dermal or deep dermal burns; or
 - 2.3 Nutritional status prior to admission or dietary intake is poor.
- Note: Multivitamin and mineral supplement capsule composition includes vitamin A 250 IU, thiamine 2.5 mg, riboflavin 2.5 mg, nicotinamide 12.5 mg, vitamin B5 10 mg, pyridoxine 5 mg, vitamin B12 6.25 mcg, vitamin C 125 mg, cholecalciferol 2.5 mcg, vitamin E 25 mg, betaine 12.5 mg, biotin 12.5 mcg, boron 250 mcg, calcium 25 mg, choline 6.25 mg, chromium 25 mcg, citric acid 50 mg, citrus bioflavonoid complex 50 mg, coenzyme Q10 1.25 mg, copper 125 mcg, folic acid 37.5 mg, inositol 6.25 mg, iodine 25 mcg, iron 250 mcg, L-Glutamine 6.25 mg, magnesium 12.5 mg, molybdenum 12.5 mg, manganese 0.5 mg, potassium 5 mg, selenium 18.75 mcg, zinc 1.875 mg.

Background

Clinicians Renal Vit

Clinicians Renal Vit capsules are a multivitamin supplement developed specifically to meet the clinical needs of New Zealand patients with chronic kidney disease. Clinicians Renal Vit is a once daily capsule containing 12 ingredients, and there is no such product currently available in the New Zealand market. Natural Health Laboratories has developed this product in conjunction with local renal physicians and dietitians.

PHARMAC estimates there would be up to 4800 patients in New Zealand who would meet the proposed criteria.

The Pharmacology and Therapeutics Advisory Committee (PTAC) reviewed the funding application in February 2013 and recommended that the renal multivitamin be listed on the Pharmaceutical Schedule for patients with CKD with a medium priority subject to the proposed Special Authority criteria. The Committee noted that maintaining good nutritional status in patients with CKD is challenging, due to inadequate nutritional intake as a result of

uraemic anorexia, nutritional restrictions and the unpalatability of the prescribed diet, co-morbidities such as diabetes requiring dietary restrictions and seasonal variation in access to fruit/vegetables. In addition, vitamins and minerals may be poorly absorbed or lost in patients with CKD due to increased clearance in blood, excretion of protein bound vitamins in patients with proteinuria, and losses of water-soluble vitamins may occur in the dialysate during dialysis. The Committee considered that avoiding supplements containing vitamin A and E seemed reasonable in CKD patients.

Further details, including the PTAC minutes, can be found via the Application Tracker on PHARMAC's website:

<http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=747>

Multivitamin and Mineral Boost capsules

From 1 May 2015, PHARMAC listed this product in the Hospital Medicines List to be used for patients with severe burns who require additional vitamin and mineral support. The proposal would secure supply at the agreed price for hospital pharmacies.

Refer to PHARMAC's Application Tracker for more information:

<http://pharmac.govt.nz/patients/ApplicationTracker?SearchTerm=mineral>