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Specialist Advisory Committees
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Record of the Nephrology Advisory Committee Meeting held on 29 April 2026

Nephrology Advisory Committee records are published in accordance with the Terms of Reference for the Specialist Advisory Committees 2021.

Note that this document is not necessarily a complete record of the Nephrology Advisory Committee meeting; only the relevant portions of the meeting record relating to Nephrology Advisory Committee discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

The Nephrology Advisory Committee may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

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1. Attendance

Present
Elizabeth Dennett (Chair)
Bruce King
Caroline Chembo
Colin Hutchison
Kannaiyan Rabindranath
Nick Cross

Apologies
Chanel Prestidge

2. Summary of recommendations

	Pharmaceutical and Indication	Provisional Recommendation
8.5	Potassium citrate tablets (a new formulation) for the treatment of recurrent calcium oxalate urolithiasis, subject to Special Authority Criteria	High Priority
9.4	Potassium citrate for the treatment of recurrent kidney stones – widening access to other stone types and amending criteria, subject to Special Authority Criteria	High Priority

10.4	Potassium citrate for the treatment of recurrent kidney stones – widening access for hypercalciuria, secondary to therapeutic ketogenic diet for epilepsy or other conditions, subject to Special Authority Criteria	High Priority

3. The role of Specialist Advisory Committees and records of meetings

3.1. This meeting record of the Nephrology Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021 and Specialist Advisory Committees 2021.Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

3.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference.

3.3. The Nephrology Advisory Committee is a Specialist Advisory Committee of Pharmac. The Nephrology Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Nephrology Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for renal conditions that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for renal conditions] that differ from the Nephrology Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Nephrology Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for treatments for renal conditions.

4. Welcome and introduction

4.1. The Chair welcomed the Committee with a karakia followed by whakawhanaungatanga.

5. Pharmac Update

5.1. The Committee noted the Pharmac update.

5.2. The Committee acknowledged the recent changes in Pharmac kaimahi and ongoing leadership and strategic changes, including the new Chief Executive who started at Pharmac in mid-September and the 2025/2026 Letter of Expectations.

5.3. The Committee noted an update about the organisation reset programme and acknowledged that more information can be found on the Pharmac Website.

5.4. The Committee noted the rapid advice pilot with this Committee from March 2025

5.4.1. Aim to right size advice approach and use of advisor's time, and maintain robust advice process

5.4.2. Progressed two of the planned tranches, the third was not progressed due to internal and external capacity at the time.

5.4.3. Strong support for the quality and style of the advice summaries for the pilot items progressed, easy to read and follow (see item 7).

5.5. The Committee noted the following updates to the record processes:

5.5.1. 30-day provisional recommendation trial update.

5.5.2. The Committee noted the removal of second committee reviews, with targeted reviews to be used as required, and supported the use of direct engagement with Discussion Leads to resolve outstanding issues.

7. Previous advice summary

7.1. The Committee noted and accepted the following advice summaries as reflecting the advice from members of the Nephrology Advisory Committee as part of a rapid advice pilot process for the following proposals:

- Empagliflozin for chronic kidney disease (CKD)
- Tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ADPKD)

7.2. Summary of email advice for empagliflozin for chronic kidney disease (CKD) – March 2025

7.2.1. Additional advice was sought from members of the Nephrology Advisory Committee on uncertainties as part of the assessment, specifically on:

- potential modification of the Special Authority criteria to better align with international guidelines.
- the presence of bias in eGFR formula.
- rates of diagnosis of CKD in New Zealand.
- usage of ACE-inhibitors or angiotensin receptor blockers (ARBs) in NZ, and whether these treatments or other treatments should be considered prerequisite treatment to empagliflozin.

7.2.2. Members considered the applicability of the EMPA-KIDNEY trial for empagliflozin compared to placebo [EMPA-KIDNEY Collaborative Group. NEJM 2-23;388:117-27] and noted the rate of hospitalisation and eGFR drop was reduced and significant and has been replicated using other medications in the same class.

7.2.3. Regarding the modification of Special Authority criteria, Members considered:

7.2.3.1. No renewal criteria are required for empagliflozin for CKD, as it is a lifelong treatment.

7.2.3.2. The participant inclusion criteria relating to eGFR, albuminuria, and uACR in the study would be appropriate to include in special authority criteria. I.e., eGFR of 20ml/min to <45ml/ minute regardless of albuminuria and eGFR of ≥45ml/min to < 90ml/min with uACR of ≥ 20mg/mmol.

7.2.3.3. An alternative criteria for risk could be based on the risk of progression to end stage kidney disease (ESKD), ie. a risk of progression to ESKD at > x% at 5 years (based on a validated estimating equation eg https://kidneyfailurerisk.com/).

7.2.4. That the criteria outlined in EMPA-KIDNEY are appropriate for Māori and Pacific populations.

7.2.5. Prior ACE/ARB treatment should be included in special authority criteria.

7.2.6. Members highlighted the following studies which may report on the relationship between empagliflozin and management of chronic kidney disease:

- EMPA-KIDNEY Collaborative Group. Lancet Diabetes Endocrinol. 2024;12:39-50 Supplementary Appendix
- EMPA-KIDNEY Collaborative Group. Lancet Diabetes Endocrinol. 2024;12:39-50
- Ninomiya et al. J Am Soc Nephrol. 2009;20:1813-21
- Barzilay et al. JAHA 2024;13:e030131
- Borg & Persson. Ann Transl Med. 2017;5:478
- van der Velde et al. J Am Soc Nephrol. 2009;20:852-62

7.2.7. Regarding the estimation of the eligible population size for this proposal in New Zealand, Members considered:

7.2.7.1. NZ data in the context of diagnosed CKD cases would be more accurate than data from Szczech et al. PLoS One. 2014;9:e110535.

7.2.7.2. In the absence of appropriate NZ data on CKD diagnosis rates, it would be reasonable to use international estimates.

7.2.7.3. Access to empagliflozin treatment may stimulate a subsequent increase in screening and testing efforts, thereby increasing diagnosis rates.

7.2.7.4. The usage of ACEs and ARBs in people with CKD is likely similar to international estimates.

7.2.7.5. Access to empagliflozin would likely not alter the proportion of population trialling ACEs or ARBs, although this was considered uncertain.

7.2.8. Members considered that the below represented the most appropriate special authority criteria for the assessment:

Empagliflozin
Initial application – application from any relevant practitioner.
1. Patient has chronic kidney disease; and
2. Patient is receiving the maximum tolerated dose (unless contraindicated) of ACE inhibitor or angiotensin receptor blocker; and
3. Either:
   a. Patient has estimated glomerular filtration rate of 20-45 mL/min/1.73m2; or

b. Both
   i. Patient has estimated glomerular filtration rate of 45-90mL/min/1.73m2 and;
   ii. Patient has a urinary albumin-to-creatinine ratio of at least 20 mg/mmol.

7.3. Summary of email advice for tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ADPKD) – March 2025

7.3.1. Additional advice was sought from members of the Nephrology Advisory Committee on uncertainties as part of the assessment, specifically on:

- the strength, quality, and relevance of post-hoc evidence from the TEMPO 3:4 trial.
- Special Authority criteria and Mayo imaging classifications (MIC).

7.3.2. Members noted the post-hoc analysis TEMPO 3:4 trial for tolvaptan (Irazabal et al. Kidney Int Rep. 2016;1:213-220]. Members considered:

7.3.2.1. Participants were selected by total kidney volume, which is highly correlated to MIC, such that 89.5% of patients in TEMPO 3:4 were 1C-1E when reclassified.

7.3.2.2. The greatest effects of tolvaptan were on classifications 1C-1E, validating the use of MIC as a prognostic biomarker.

7.3.2.3. The analysis was exploratory, so the quality and strength are weak. However, the results are generally supportive of the relationship between renal volume and rate of enlargement as a marker of rapid renal function loss.

7.3.2.4. The analysis has reasonable relevance to the New Zealand setting and the base trial provided key evidence for informing the current Special Authority criteria.

7.3.3. Regarding the relationship between disease severity and the inclusion of Mayo classifications 1E, 1D and 1C in Special Authority criteria, Members considered:

7.3.3.1. Available information suggests that Mayo classifications 1E, 1D and 1C with risk factors have risks of renal decline similar to the current Special Authority criteria, noting that the criteria are aiming for the group at risk of disease progression.

7.3.3.2. Mayo imaging classification (MIC) is considered the best prognostic biomarker due to its basis on kidney volume and would allow a number of patients who do not currently meet Special Authority criteria (but ideally should) to access tolvaptan based on MIC.

7.3.3.3. The primary difference between criteria including MIC and current Special Authority criteria is the required observation period due to eGFR measurements.

7.3.3.4. The newly proposed Special Authority criteria would likely widen access to tolvaptan, however most MIC 1D/1E and more than half of 1C with risk factors would be expected to meet the current criteria over time.

7.3.3.5. It would be reasonable to allow patients assessed with ultrasound to start tolvaptan without waiting for a second scan. Members considered that if

kidney volume is large as assessed by ultrasound, there is little to be gained from classifying more precisely using MRI.

7.3.3.6. It would be necessary to test whether MIC can be reported reliably and accurately by general radiologists throughout New Zealand.

7.3.4. Members considered that anecdotally, tolvaptan can be hard for patients to tolerate given its significant impact on diuresis. This may contribute to the lower than predicted uptake thus far and could impact future uptake with any criteria change.

7.3.5. Members considered that the below represented the most up-to-date PICO (Population, Intervention, Comparator, Outcomes) for the assessment:

Population	People with confirmed diagnosis of ADPKD and an eGFR of greater than or equal to 25/min/1.73m^2 at treatment initiation and either of the following: - Patient has Mayo classification 1D or E disease based on ultrasound, CT or MRI assessment of Total Kidney Volume (TKV Calculator) or - Patient has Mayo classification 1C disease based on CT or MRI assessment of Total Kidney Volume (TKV Calculator) and has other risk factors* indicating a high risk of disease progression. - And has not met either of the pre-existing criteria below: o Patient's disease is rapidly progressing, with a decline in eGFR of greater than or equal to 5 mL/min/1.73 m 2 within one-year; or o Patient's disease is rapidly progressing, with an average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m2 per year over a five-year period. *Other risk factors- Family history of kidney failure in multiple individuals less than age 58, a truncating mutation of the PKD1 gene, below normal eGFR for age, early onset of urological complications or arterial hypertension prior to the age of 35	
Intervention	Tolvaptan, administered twice daily	
Comparator(s) (NZ context)	Group 1: People who do not fulfil the existing criteria for tolvaptan and receive best supportive care	Group 2: People who meet the existing criteria through substantiating they have a decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m2 per year over a five-year period
Outcome(s)	Slows decline in eGFR, thus delaying kidney failure. This is associated with: • Improved health-related quality of life • reduced health sector costs associated with renal replacement therapy • increased survival, through delayed progression to end-stage renal disease	
Table definitions: **P**opulation: The target population for the pharmaceutical, including any population defining characteristics (eg. Line of therapy, disease subgroup)		

Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).
Comparator: Details the therapy(s) that the target population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).
Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.

8. Potassium citrate tablets for the treatment of recurrent calcium oxalate urolithiasis

Application

8.1. The Committee reviewed the December 2023 clinician application for potassium citrate tablets for the treatment of recurrent calcium oxalate urolithiasis. The Committee noted the letter of support accompanying the application with endorsement by consultant nephrologists and urologists, renal physicians and advanced practitioner dietician.

8.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

8.3. The Committee **recommended** that potassium citrate tablets for the treatment of recurrent calcium oxalate urolithiasis (kidney stones) be listed with a **high priority**, within the context of treatment of renal disease, subject to the same Special Authority Criteria currently in place for the potassium citrate liquid formulation.

8.4. In making this recommendation, the Committee considered:

8.4.1. Potassium citrate tablet formulation would provide another treatment option to reduce the risk of recurrent kidney stones.

8.4.2. The tablet formulation has a suitability benefit over the liquid and this is likely to improve treatment adherence.

8.4.3. Amending the current Special Authority criteria is a separate consideration on the agenda.

Discussion

Māori impact

8.5. The Committee discussed the impact of funding potassium citrate tablets for the treatment of recurrent calcium oxalate urolithiasis (kidney stones) on Māori health areas of focus | Hauora Arotahi and Māori health outcomes. The Committee considered the exact impact unclear given there is uncertainty in the future uptake of different formulations, although noted that Māori experience a higher incidence of uric acid stones compared with non-Māori.

Populations with high health needs

8.6. The Committee discussed the health need(s) of people with kidney stones among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee considered that the impact of funding potassium citrate tablets relates to the types of kidney stones with greatest incidence in each of these population groups and noted that a request to consider widening access based on additional stone types was to be discussed subsequently on the current agenda.

Background

8.7. The Committee noted the history of advice and recommendations regarding potassium citrate tablets available on Pharmac's application tracker (link), including the following:

8.7.1. An initial recommendation in 2011 from the Hospital Pharmaceuticals Committee that potassium citrate not be included on the Hospital Medicines List (HML).

8.7.2. A recommendation from the Nephrology Subcommittee (now Advisory Committee) to fund a potassium citrate tablet formulation with a high priority in 2014, subject to a Medsafe approved product being available (at that time, no product was available).

8.7.3. Advice from the Nephrology Advisory Committee in March 2023, noting that there is an ongoing clinical need for potassium citrate in a tablet form, due to suitability issues in relation to the currently funded oral liquid formulation which impacts adherence to lifelong treatment.

8.8. The Committee noted that Pharmac first received a clinician application to fund a tablet formulation of potassium citrate in late 2023.

8.9. The Committee noted that Medsafe received a registration dossier for potassium citrate modified release (MR) tablets in January 2024 and the potassium citrate tablet formulation was approved by Medsafe in October 2025.

Health need

Recurrent kidney stones

8.10. The Committee noted that kidney stones are solids formed from compounds in urine and that the dominant stone types are calcium oxalate (70-80%), calcium phosphate (15%) and uric acid stones (8%), with only 1-2% being either struvite or cystine stones (Lieske et al. Clin J Am Soc Nephrol. 2014;9:2141–2146).

8.11. The Committee noted there is higher incidence of kidney stones in men (3 per 1,000 in the population) compare with women (1-2 per 1,000), and that this is increasing in New Zealand (Du et al. N Z Med J. 2009;122:13-20). The Committee considered that the prevalence of kidney stones is hard to determine and noted the applicant estimate of a prevalent group of about 5,000 people based on 2023 data.

8.12. The Committee noted that people who present to hospital with kidney stones require admission for management and have a risk of future progression to end stage renal disease (Chen et al. Clin Kidney J. 2025;18:sfaf024). The Committee noted that

Australasian data indicates that 1.1% of people who start dialysis for ESRD have experienced kidney stones (Hassan et al. Nephrol Dial Transplant. 2025;40:320-8).

8.13. The Committee noted the lifetime risk of kidney stones is at least 6% to 12% in the general population, increases with age and is more common in Caucasians than non-Caucasian people (Li et al. Int J Surg. 2025;111:5843–51). The Committee noted that recurrence is more common in males and in people who do not receive treatment (Ferraro et al. J Nephrol. 2017;30:227-33). The Committee noted that kidney stones are associated with an increased risk of hypertension, diabetes mellitus and coronary artery disease or ischaemic heart disease (Ando et al. J Urol. 2013;189:1340-6; Borghi et al. Kidney Int. 1999;55:2397-406). Members considered there is likely to be increasing incidence of kidney stones with increasing cases of bariatric surgery in New Zealand, and a possible reduction in stone formation in patients who receive empagliflozin based on emerging evidence.

8.14. The Committee noted that recurrence is seen in about 10-30% from one to five years with calcium oxalate stones, and risk factors for recurrence include having low urine citrate, which is present in about 30% of those with calcium oxalate stones (Hiatt et al. Am J Epidemiol. 1996;144:25-33). The Committee considered that based on the applicant's estimate of 5,000 patients, about 3,500 to 4,000 would have calcium oxalate stones and 1,050-1,200 (30%) would have low urine citrate and therefore be expected to relapse in the coming years.

8.15. The Committee considered slight differences in clinical management may exist depending on whether a patient with kidney stones is under the care of a nephrologist or urologist, including terminology, prescribing, and both duration and frequency of clinical follow up.

Current formulation – potassium citrate liquid

8.16. The Committee noted that potassium citrate (funded as a liquid formulation) is prescribed for people who have had a kidney stone and have low urine citrate (hypocitraturia), with the aim of trying to make urine alkaline to reduce stone recurrence. The Committee noted there is established evidence that potassium citrate reduces the risk of stone recurrence, with a small study reporting a reduction of 19% (Phillips et al. Cochrane Database Syst Rev. 2015 Oct 6;2015(10):CD010057).

8.17. The Committee noted that the Australasian CARI Guideline for kidney stone management recommended potassium citrate for people with recurrent kidney stones with hypocitraturia and/or low urine pH that persists despite nutrition therapy (Tunicliffe et al. Kidney Int Rep. 2026;11:106346). The Committee noted the CARI guidelines states this is a strong recommendation, and that the overall certainty of the evidence was moderate.

8.18. The Committee noted that current funding of the potassium citrate liquid formulation includes Special Authority criteria targeting access to those with recurrent calcium oxalate urolithiasis and more than two renal calculi in the two years prior.

8.18.1. The Committee considered that this is relatively strict, requiring a patient to present clinically with symptoms of kidney stones rather than finding new stones on imaging. Members noted that this criteria would also not include asymptomatic recurrence or recurrence beyond two years.

8.19. The Committee noted that adherence with potassium citrate liquid is low and considered that many who are prescribed it cease to use it due to its taste, adverse effects, or other difficulty with adherence.

8.19.1. Members considered that the daily volume of liquid (10mL three times daily) was also a factor in poor adherence, noting that it is intended to be lifelong treatment. The Committee considered it reasonable to assume most eligible patients have tried the liquid and many have found it intolerable.

8.20. The Committee considered that poor adherence with the liquid formulation means that potential adverse events of treatment (eg gastrointestinal effects) are reported less than they would be if there was optimal treatment adherence.

Health benefit

8.21. The Committee noted that the application was for potassium citrate 1080mg tablets.

8.22. The Committee considered that the evidence for potassium citrate has increased over many years, however, that there are no trials directly comparing the liquid and tablet formulations. The Committee considered that the interpretation of benefits from potassium citrate tablets is based on physiological assumption and clinical experience, and therefore was considered to be supported by moderate quality evidence.

8.23. The Committee considered that there is a greater incidence of gastrointestinal adverse events reported with potassium citrate tablets compared with potassium citrate liquid.

8.23.1. The Committee considered this most likely reflected the regular and sustained use of tablets relative to the poor adherence with liquid, leading to less of the medicine reaching the gut, and therefore that these were same effects irrespective of formulation.

8.23.2. Members considered that, anecdotally, some patients in international settings tolerate the tablet formulation better while some tolerate the liquid better.

8.23.3. The Committee considered that effects were treatment-limiting with tablets and some discontinuation would be expected.

8.24. Overall, the Committee considered that while there was no direct comparative evidence comparing the liquid and tablet formulations, it is likely that the benefits and risks are similar.

8.25. Members considered that the greatest benefits from potassium citrate tablets would be achieved in younger patients with high rates of stone recurrence and high use of hospital services for management, potentially with a family history of kidney stones. Members considered individuals in this subgroup would be highly motivated to adhere to treatment.

Suitability

8.26. The Committee considered that the main suitability considerations relate to the formulation.

Cost and savings

8.27. The Committee noted that funding potassium citrate tablets would likely be an investment compared with the current spend on potassium citrate liquid, given a likely higher uptake.

8.28. The Committee considered that 30-50% of people with recurrent kidney stones could benefit from potassium citrate irrespective of formulation.

8.29. The Committee considered about 1,300 people would be eligible for potassium citrate under the current Special Authority criteria, noting there is a separate consideration on the current agenda regarding widening the current access. The Committee considered it reasonable to assume that many eligible patients would have trialled the liquid formulation of potassium citrate.

8.30. The Committee considered that the proportionate split between tablets and liquid was unknown but expected that the total usage of potassium citrate would be increased if the tablet formulation were funded.

8.31. The Committee considered that some patients may still develop kidney stones in future despite good adherence to potassium citrate, and that some waning of use and non-compliance should be expected with this lifelong treatment. Members considered that one assumption of a best-case for persistence after three years receiving potassium citrate tablets could be 50%, based on a study reporting that 42% of 199 patients prescribed alkali citrate in a tertiary stone-clinic cohort were adherent at long-term assessment (Golomb et al. J Endourol. 2019;33:469-74). The Committee considered that those that persist with treatment are likely the ones gaining the most benefit from treatment.

Funding criteria

8.32. The Committee considered that, while not optimal, this proposal was to consider funding potassium citrate tablets according to the existing Special Authority criteria for the liquid formulation and that consideration of amending the criteria (widening access) was a subsequent item on this agenda.

Summary for assessment

8.33. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for potassium citrate tablet formulation if it were to be funded in New Zealand for the currently eligible population with recurrent calcium oxalate urolithiasis. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	People with recurrent calcium oxalate stones (currently funded group) • About 5000 people in NZ with recurrent kidney stones (per the 2023 application) • Approximately 30% of people with recurrent stones would benefit from potassium citrate.

	• Approximately 70% of kidney stones are thought to be calcium oxalate • Approximately 1300 patients eligible overall.
Intervention	Potassium citrate extended-release tablets – 3 years to lifelong treatment.
Comparator(s)	Either: • Liquid formulation of potassium citrate (about 400 patients currently accessing) • No treatment (many patients are thought to not tolerate the liquid formulation) *Note that patients may also be treated with diet modifications eg lemon juice.
Outcome(s)	*For people currently on liquid formulation* • No difference in efficacy (assumption) • Potential adherence benefit (via improved palatability) for some patients, which may be associated with a small reduction in the number of kidney stones (as indicated in the 2023 application and supporting letter) • Slight increase in gastrointestinal side effects/ulceration with tablets due to more regular and sustained use of tablets. *For people currently not receiving treatment* • A reduction in kidney stones. This would lead to subsequent: - Reduction in hospital admissions, which may include surgery - Improved HRQoL from morbidity reduction
Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.	

9. Potassium citrate for the treatment of recurrent calcium oxalate urolithiasis –widening access to other stone types

Application

9.1. The Committee reviewed the clinician application which requested amendments to the existing Special Authority criteria for potassium citrate for recurrent calcium oxalate urolithiasis (kidney stones):

9.1.1. widening of access to other stone types

9.1.2. amending the requirement for two stones to have occurred in the past two years.

9.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

9.3. The Committee **recommended** that access to potassium citrate be widened for the treatment of other stone types and amendment to the criteria with a **high priority**, within the context of treatment of renal disease, subject to the following Special Authority Criteria (changes shown in **bold** and ~~strikethrough~~):

> Initial application from any relevant practitioner. Approvals valid ~~for 12 months~~ **without renewal** for applications meeting the following criteria:
> ~~Both~~ **All of the following**:
> 1. The patient has recurrent ~~calcium oxalate urolithiasis~~ **kidney stones and/or is at high risk of recurrence**; and
> 2. **Urinalysis has been completed and the patient has ongoing low urinary citrate and/or low urinary pH requiring treatment in addition to dietary advice for kidney stone prevention.**
> ~~3. The patient has had more than two renal calculi in the two years prior to the application.~~
> ~~Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefitting from the treatment.~~

9.4. In making this recommendation, the Committee considered:

9.4.1. targeting the eligible population based on urinalysis results (urine citrate and pH) rather than stone type would effectively describe the intended population for funding

9.4.2. that Māori and Pacific peoples are more likely than non-Māori, non-Pacific peoples to have uric acid stones which are sensitive to urine pH, and that potassium citrate is an effective treatment in this setting.

Discussion

Māori impact

9.5. The Committee discussed the impact of widening access to potassium citrate on Māori health areas of focus | Hauora Arotahi and Māori health outcomes. The Committee considered that Māori more likely than non-Māori to have uric acid stones which are sensitive to urine pH, and that potassium citrate is an effective treatment in this setting.

Populations with high health needs

9.6. The Committee discussed the health need(s) of people with kidney stones among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee discussed the impact of widening access to potassium citrate and considered that, like Māori, Pacific peoples more likely than non-Pacific and non-Māori peoples to have uric acid stones which are sensitive to urine pH, and that potassium citrate is an effective treatment in this setting.

Background

9.7. The Committee noted the discussion on the agenda regarding kidney stones, the access and suitability barriers presented by the liquid formulation of potassium citrate, and consideration of potassium citrate tablets. The Committee noted that discussion also described the history of the applications for potassium citrate including the tablet formulation.

Health need

9.8. The Committee considered that the current Special Authority criteria for potassium citrate narrowly target an eligible subgroup of the population who would benefit from funded access. The Committee considered it unclear why funded access was originally targeted to calcium oxalate stones only, but that this likely relates to the evidence available at the time. The Committee considered that specific issues causing barriers to appropriate funded access for the intended, clinically appropriate population are as follows:

9.8.1. the terminology for 'recurrent stones' is not well aligned with evidence and clinical guidelines for management of kidney stones. Members considered that current framing of the stone events and timeframe are arbitrary.

9.8.2. the criteria are silent on dietary advice, which is a highly valuable strategy and clinical guidelines indicate it should be considered ahead of potassium citrate in the management of kidney stones.

9.8.3. the criteria do not mention urinalysis which is an important step in identifying patients who could benefit from treatment with potassium citrate (eg based on hypocitraturia).

9.8.4. the criteria specify calcium oxalate stones only, excluding other common stone types (eg uric acid stones) which would be expected to respond well to potassium citrate. The Committee considered this resulted in quite narrow eligibility based on stone type and that there was no clear evidence to support targeting in this way.

9.9. The Committee noted it had already considered the relative proportions of each stone type in its discussion on potassium citrate tablets, with the most common stones being calcium oxalate (about two-thirds), then calcium phosphate, and then uric acid (8%). The Committee noted that uric acid stones are highly sensitive to urinary alkalisation, which potassium citrate achieves, therefore it is considered a very appropriate and useful treatment for uric acid stones.

9.10. The Committee noted the 2026 CARI guidelines (Tunicliffe et al. Kidney Int Rep. 2026;11:106346) recommends only a basic medical evaluation for people who have experienced formation of a kidney stone for the first time, but for those with recurrent stones or a high risk of recurrence, then a more detailed assessment should be undertaken by a urologist or nephrologist. The Committee considered that 'high risk' may include having had a kidney stone at a young age, multiple stones at once, frequent stone occurrence or a strong family history of stones at a young age.

9.11. The Committee considered that dietary adjustments are essential to reduce the risk of stone recurrence and are an important first line consideration for management.

9.12. The Committee noted the CARI recommendation to investigate the compounds in urine which form the stone, specifically urine calcium concentration, pH and citrate. Members noted this was not focussing on the confirmation of the kidney stone itself, or type of stone. Members considered that if urinalysis has been completed, this indicates that the kidney stone is problematic enough to require investigation and therefore it is reasonable to assume that the patient will be likely to require lifelong treatment.

9.13. The Committee noted that, for adults with recurrent non-infection related kidney stones, nutritional advice would be given as a first effective management approach. The Committee considered that those who cannot achieve urine metric targets would progress to receive medicines to reduce urine calcium levels.

9.13.1. The Committee considered that treatment for uric acid stones aims to ensure pH is elevated, if it remained low previously, and/or reduce excessive uric acid in the urine by using xanthine oxidase inhibitors (eg allopurinol) if required.

9.13.2. The Committee considered that management of cystinuria, which is rarer, aims to elevate pH as high as possible.

Health benefit

9.14. The Committee again noted the Australasian CARI Guideline recommends potassium citrate for people with recurrent kidney stones with hypocitraturia and/or low urine pH that persists despite nutrition therapy (Tunicliffe et al. Kidney Int Rep. 2026;11:106346); a strong recommendation based on moderate certainty of the evidence.

9.15. The Committee was made aware of the systematic review by Phillips et al. (Cochrane Database Syst Rev. 2015 Oct 6;2015(10):CD010057) containing three trials with a total of 144 individuals included. The Committee noted it was investigating new stone formation, and trial participants were randomised to receive citrate or placebo. The Committee considered that although this included a small number of people, there was a consistent effect in reduction of recurrence stones, and this was strong when taking the point estimate. The Committee considered this supported the conclusion that potassium citrate is an effective treatment for preventing recurrence in a variety of stone types.

9.16. The Committee considered that, while there is a limited evidence base, it is reasonable to assume the same magnitude of treatment effect from potassium citrate irrespective of stone type (including extrapolating the evidence of benefit to include uric acid stones), noting that urine citrate and pH are more relevant than stone type for targeting the population who require potassium citrate.

Suitability

9.17. The Committee considered that the suitability considerations relate to formulation, as discussed previously at this meeting.

Cost and savings

9.18. The Committee considered that widening access to potassium citrate would provide an additional treatment option for those among the clinically appropriate population who are not currently eligible and would not displace any funded medicines.

9.19. The Committee considered it likely that a reduction in the rate of recurrence in the population targeted by amended criteria would lead to a reduced requirement for future surgical interventions. Members noted that the target population are selected based on a higher risk of recurrence and that this increased the likelihood of avoiding future surgery.

9.20. The Committee considered that removing the requirement that patients must have had more than two renal calculi in the two years prior to the application would not change the number of patients eligible for treatment.

Funding criteria

9.21. The Committee considered that recommendations for management from clinical guidelines are based on urinalysis results, target urine citrate and pH rather than stone type and considered that the funding criteria should be in alignment with this.

9.22. The Committee considered it reasonable to include comment that the patient requires dietary advice in addition to treatment with potassium citrate in the Special Authority criteria, noting that both would be required for the target population at high risk of recurrence and this may help to target access to potassium citrate to this group who would benefit most. The Committee considered that such advice might be provided by a dietician, urologist, nephrologist, or General Practitioner.

9.23. The Committee considered that the following amendments to the Special Authority criteria would be reasonable:

9.23.1. Retain the concept of recurrent kidney stones, simplified to remove the timeframe or number of stones. Members considered that the two-year timeframe is poorly defined and impractical for various clinical situations where stones may be detected.

9.23.2. Add a requirement for urinalysis to have been completed.

9.23.3. Include the need for dietary advice on reducing stone forming potential alongside the need for potassium citrate, to target the narrower high-risk population that require treatment with potassium citrate in addition to dietary changes. Members considered that in clinical practice, it would be practical for this to be “advice given” rather than requiring confirmation of adherence to dietary advice (likely assessed at a subsequent appointment) before being able to access potassium citrate.

9.23.4. Incorporate the CARI wording (ie requires treatment for ongoing hypocitraturia and/or low urinary pH).

9.24. The Committee considered that specialists and dieticians would be able to reasonably identify patients who would be suitable for treatment based on the suggested criteria.

9.25. The Committee considered that renewal criteria were unnecessary in this context given the lifelong nature of this treatment.

Summary for assessment

9.26. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information if

access to potassium citrate were widened for the treatment of other stone types and amendment to the criteria. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	People with recurrent kidney stones and/or at high risk of recurrence (e.g. based on family history) who: • Have had urinalysis performed • Have ongoing low urinary citrate and/or low urinary pH • Require treatment in addition to dietary advice for kidney stone prevention
Intervention	Potassium citrate liquid (3mmol per mL), 10mL three times daily in addition to dietary intervention (as below) *In the case that a tablet formulation is funded, the intervention could also be a tablet*
Comparator(s) (NZ context)	Dietary intervention, increase fluid, decrease sodium intake, increase calcium intake etc
Outcome(s)	A reduction in kidney stones. This would lead to subsequent: • Reduction in hospital admissions, which may include surgery (or laser lithotripsy). • Improved HRQoL.
Table definitions: **P**opulation: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup) **I**ntervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation). **C**omparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation). **O**utcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.	

10. Potassium citrate - widening access for hypercalciuria, secondary to therapeutic ketogenic diet for epilepsy

Application

10.1. The Committee reviewed the clinician application requesting widened access to potassium citrate for people who are using therapeutic ketogenic diets for epilepsy control.

10.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

10.3. The Committee **recommended** that access to potassium citrate be widened for the treatment of hypercalciuria, secondary to therapeutic ketogenic diet for epilepsy or other conditions, with a **high priority**, within the context of treatment of renal disease, subject to the following Special Authority Criteria (proposed changes in **bold** and ~~strikethrough~~):

> Initial application from any relevant practitioner. Approvals valid for ~~12 months~~ **without renewal** for applications meeting the following criteria:
> Either:
> 1. Both:
> 1.1. The patient has recurrent calcium oxalate urolithiasis; and
> 1.2. The patient has had more than two renal calculi in the two years prior to the application; or
> **2. Both:**
> **2.1. Patient is on a therapeutic ketogenic diet recommended by a paediatrician, neurologist or metabolic disease specialist; and**
> **2.2. Patient is at risk of renal stones with continued elevated urinary calcium:creatinine ratios.**
> ~~Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefitting from the treatment.~~

10.4. In making this recommendation, the Committee considered:

10.4.1. The small group of paediatric patients on therapeutic ketogenic diets have a distinct, high health need due to their underlying disease and its management (ie intractable epilepsy or a rare disorder) and would be substantially impacted by the development of a kidney stone.

10.4.2. Prevention of kidney stones in those among this group with an elevated calcium:creatinine ratio is more appropriate than treating after a first stone occurrence to reduce recurrence.

Discussion

Māori impact

10.5. The Committee discussed the impact of funding potassium citrate for the treatment of treatment of hypercalciuria, secondary to therapeutic ketogenic diet for epilepsy or other conditions, on Māori health areas of focus | Hauora Arotahi and Māori health outcomes. The Committee noted relevant considerations were already discussed on the same meeting agenda during the previous potassium citrate items.

Populations with high health needs

10.6. The Committee discussed the health need(s) of people with hypercalciuria, secondary to therapeutic ketogenic diet for epilepsy or other conditions, among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee noted relevant considerations were already discussed on the same meeting agenda during the previous potassium citrate items.

Health need

10.7. The Committee considered that while children with intractable epilepsy experience good responses to a therapeutic ketogenic diet, the diet increases hypercalciuria,

hypocitraturia, and urinary calcium excretion. The Committee noted there is good evidence of elevated calcium: creatine ratios in this population (McNally et al. Pediatrics. 2009;124:e300–4). The Committee noted the application indicates that renal calculi occur in 3% to 7% of children who are on ketogenic diets long-term.

10.8. The Committee noted that the application highlights the health need of paediatric patients who are using therapeutic ketogenic diets for intractable epilepsy control and are at risk of renal stones with continued elevated urinary calcium:creatinine ratios.

10.8.1. The Committee considered this need might also apply to paediatric patients with rare disorders (eg pyruvate dehydrogenase deficiency, glucose transported type-1 deficiency, and other conditions) requiring a ketogenic diet, who are also at risk of developing renal calculi (kidney stones) where they have continuously elevated urinary calcium:creatinine ratios.

10.9. The Committee considered that the small group of paediatric patients on therapeutic ketogenic diets have a distinct, high health need due to their underlying disease and its management (ie intractable epilepsy or rare disorder) and would be substantially impacted by the development of a kidney stone. The Committee considered it is not feasible to predict which of these patients will develop kidney stones other than using an elevated urinary calcium:creatinine ratio as a marker of risk.

10.10. The Committee considered the estimated population size of 25 paediatric patients per year nationally was reasonable, noting this was based on KetoCal dispensing data from the past five years.

10.11. The Committee considered that other groups, such as adults on a ketogenic diet for any reason, would have a different health need to this population group.

Health benefit

10.12. The Committee noted a study investigating the incidence of kidney stones in children on ketogenic diets treated with potassium citrate (Sampath et al. J Child Neurol. 2007;22:375-8). The Committee noted that the children on ketogenic diets were treated with potassium citrate if their urinary calcium to creatinine ratio was elevated, and the authors reported that the prevalence of kidney stones was 3.2% for those treated with potassium citrate (and had an elevated calcium to creatinine ratio) compared with 10% in those who were not (as they did not have an elevated calcium to creatinine ratio).

10.13. The Committee noted the applicant data reporting that 25% of patients on ketogenic diets for control of epilepsy are at risk of developing kidney stones and may require potassium citrate for management of hypercalciuria at any one time. However, the Committee considered that prevention of kidney stones in all of those among this group with an elevated calcium:creatinine ratio is more appropriate than treating after a first stone occurrence, given their existing high health need and the inability to predict which individuals will otherwise develop kidney stones.

Cost and savings

10.14. The Committee considered that it was reasonable to assume a maximum duration of treatment of two years, given that the ketogenic diet is followed for up to two years in this context.

Funding criteria

10.15. The Committee considered that the criteria should specify that a therapeutic ketogenic diet would need to have been recommended by a paediatrician, neurologist or metabolic disease specialist as this would target those paediatric patients with intractable epilepsy or rare disorders whilst enabling applications from a range of relevant practitioners.

10.16. The Committee considered that, based on the high health needs of this group, prevention of any kidney stones for those with an elevated calcium:creatinine ratio is more appropriate than having funded access to potassium citrate only available after a stone occurrence and therefore this criterion should differ from the currently funded population.

10.17. The Committee considered that no renewal criteria would be needed for this population and that potassium citrate would be used for a maximum of two years, alongside the ketogenic diet.

Summary for assessment

10.18. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for potassium citrate if it were to be funded in New Zealand for paediatric patients on therapeutic ketogenic diets. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	Paediatric patients who are on therapeutic ketogenic diets for intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet, and at risk of developing renal calculi (kidney stones), with continued elevated urinary calcium:creatinine ratios. Estimated population size of 25 paediatric patients per year.
Intervention	Potassium citrate liquid (3mmol per mL), weight-based dosing/ 5-10mL, three times daily. Treatment until urinary calcium:creatinine ratios are back within normal range, or when the patient discontinues the diet.
Comparator(s)	Possible treatments include: • Ural sachets. • Thiazide diuretics
Outcome(s)	A reduction in kidney stones. This would lead to subsequent: • Reduction in hospital admissions, which may include inpatient surgery. • Improved HRQoL
Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.	