The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

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Tēnā koe, Jacinta

**Agenda of the 66th Meeting of the Medicines Classification Committee (MCC)**

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on Agenda of the 66th Meeting of the Medicines Classification Committee (MCC).

The Royal New Zealand College of General Practitioners is the largest medical college in New Zealand. Our membership of 5,500 general practitioners comprises almost 40 percent of New Zealand's specialist medical workforce. Our kaupapa is to set and maintain education and quality standards for general practice, and to support our members to provide competent and equitable patient care.

**Submission**

The College wishes to comment on Agenda Item 6.1: Allopurinol – proposed change to the prescription classification statement.

The College has significant concerns regarding this proposal which will not necessarily reduce inequity related to gout management and may worsen existing inequity in the management of gout and other coexisting diagnosed and undiagnosed conditions.

The College recommends that the Medicines Classification Committee request that Dr Gauld discusses the proposal with the leaders of existing gout management programmes, the College, and other relevant stakeholders and resubmits a revised application to a future meeting if there is support for reclassification.

Classification sought

Allopurinol is currently classified as a prescription medicine.

The classification sought by the applicant, Dr Natalie Gauld, is:

> "Prescription medicine except when provided by a pharmacist who has completed gout training with the Pharmaceutical Society of New Zealand and is providing the medication to

a person who has previously been prescribed allopurinol tablets to prevent gout, and where the supply meets the approved criteria."[1]

## Gout and equity

Gout is estimated to affect around 6 percent of the New Zealand population aged 20 and over, however, it is much more common among Māori and Pacific peoples. Among those aged 20-44 years for example, the prevalence of identified gout for Māori is three, and for Pacific peoples, seven times that of non-Māori, non-Pacific populations.[2]

Māori and Pacific people with gout are slightly more likely than non-Māori, non-Pacific to receive urate lowering therapy such as allopurinol. However, Māori and Pacific with gout are less likely than non-Māori, non-Pacific to receive ***regular*** urate lowering therapy. Analysis of data from 2019 found only 39 percent of Māori and 36 percent of Pacific people with gout were ***regularly*** dispensed urate-lowering therapy, compared with 43 percent of the non-Māori, non-Pacific population with gout.[2]

For uric acid lowering treatment to be effective it must be taken continually, so these findings are concerning on two levels; the low percentage of gout patients on preventative therapy and the inequity that is demonstrated.

Maintaining regular allopurinol intake is challenging, particularly for patients who are not accustomed to taking daily medication. Once the pain from the gout flare has gone, the need to continue treatment is no longer front of mind. In addition, starting or restarting allopurinol can provoke a gout flare. Patients may then associate taking allopurinol with worsening symptoms, a further barrier to taking the medication.

## Gout Stop and Owning My Gout (OMG) programmes

These two gout management programmes have been established in areas with a high prevalence of gout, to improve the utilisation of urate lowering medication, in particular allopurinol.

Gout Stop began as a pilot in 2015. It now involves all general practices and 35 of the 36 pharmacies in Northland. Patients presenting to general practice who have experienced two or more gout flares within a year are referred to the programme. They are prescribed one of the four medication pack options, (*Fig 1*) which are preloaded in the practice management system. The community pharmacist and Kaiāwhina are involved in monitoring and educating the patient and blood test results are sent to the patient's GP.[3]

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[1] https://www.medsafe.govt.nz/profs/class/Agendas/Agen66/Allopurinol.pdf Accessed 12/4/21

[2] https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/gout/#[References] accessed 12/4/21

[3] https://www.arthritis.org.nz/wp-content/uploads/2020/07/Gout-Programmes-Evaluation-Report-April-2020.pdf Accessed 12/4/21

*Figure 1 : Gout Stop Pack prescription options based on renal function and diabetes status [3] (p18)*

| Renal function (eGFR) | Blister Pack 1 (14 days) | Blister Pack 2 (28 days) | Blister Pack 3 (28 days) | Blister Pack 4 (21 days) |
|---|---|---|---|---|
| Option 1<br>eGFR >60 | Prednisone<br>40 mg for 4 days,<br>20 mg for 4 days,<br>10 mg for 3 days,<br>5 mg for 3 days. | Allopurinol 100 mg daily<br>Colchicine 500 mcg<br>twice daily | Allopurinol 200 mg daily<br>Colchicine 500 mcg<br>twice daily | Allopurinol 300 mg daily<br>Colchicine 500 mcg<br>twice daily<br>*Laboratory form |
| Option 2<br>eGFR 31–60 | Prednisone<br>40 mg for 4 days,<br>20 mg for 4 days,<br>10 mg for 3 days,<br>5 mg for 3 days. | Allopurinol 50 mg daily<br>Colchicine 500 mcg<br>once daily | Allopurinol 100 mg daily<br>Colchicine 500 mcg<br>once daily | Allopurinol 200 mg daily<br>Colchicine 500 mcg<br>once daily<br>*Laboratory form |
| Option 3<br>eGFR 10–30 | Prednisone<br>40 mg for 4 days,<br>20 mg for 4 days,<br>10 mg for 3 days,<br>5 mg for 3 days. | Allopurinol 50 mg every<br>other day<br>Colchicine 500 mcg<br>every other day<br>*Laboratory form | Allopurinol 50 mg daily<br>Colchicine 500 mcg<br>every other day<br>*Laboratory form | Allopurinol 100 mg daily<br>Colchicine 500 mcg<br>every other day<br>*Laboratory form |
| Diabetes<br>alternative<br>eGFR >60 | Naproxen 500 mg twice<br>daily | Allopurinol 100 mg daily<br>Colchicine 500 mcg<br>twice daily | Allopurinol 200 mg daily<br>Colchicine 500 mcg<br>twice daily | Allopurinol 300 mg daily<br>Colchicine 500 mcg<br>twice daily<br>*Laboratory form |

Owning My Gout (OMG) is a smaller but expanding programme which began in 2017 in Counties Manukau DHB. Patients are referred from general practice to community pharmacists who dispense allopurinol under a standing order. Community pharmacists work with practice nurses to educate patients and titrate allopurinol doses with the aid of point of care uric acid testing using a BeneCheck© meter.[3]

The College supports both these programmes. The design of both programmes ensures integration with general practice and minimises fragmentation of care.

By contrast, the College is concerned about the model of care that will be created by the proposed reclassification. While the reclassification application states that the intention is that the "reclassification is intended to help ensure pharmacists can provide allopurinol to patients enrolled in a gout programme", there is nothing in the application that would ensure supply occurs within a well-designed and integrated gout management programme to ensure comprehensive continuity of care.

## College concerns

1. Assessment of renal function

Safe titration of allopurinol dose requires measurement of the patient's renal function. This cannot be obtained from the point of care testing device for uric acid but requires a blood test analysed at a laboratory. Gout is associated with worsening renal function. Patients who have previously taken allopurinol should have had an assessment of their renal function at some stage, and the pharmacist will be able to access this in many regions in New Zealand. However, an up-to-date assessment is necessary as renal function can deteriorate, especially in patients with gout. Community pharmacists are not able to order laboratory tests.

2. ‘Cover’ while initiating allopurinol

Initiating allopurinol can provoke a gout flare. Medications such as colchicine, and non-steroidal anti-inflammatory medications (NSAIDs) are used to provide ‘cover’ while allopurinol is being initiated to decrease the incidence of flares. ‘Cover’ medication is often required for an extended period, and the most appropriate medication should be selected based on medical assessment, past medical history, and assessment of renal function. This requires medical input. In addition, colchicine is only available on prescription. NSAIDs should be used with caution, particularly in the elderly and those with renal impairment, both conditions also associated with gout. Some NSAIDs are available without prescription however only in limited amounts. The need for ‘cover’ medications to be prescribed is a further reason for GP involvement.

3. Management of gout flares

If a flare does occur, medications such as prednisone, NSAIDs and colchicine are used to decrease the inflammation and pain. NSAIDs have been mentioned above.

Neither colchicine nor prednisone are available without prescription and they both carry a risk profile that would preclude this. There are obvious advantages for patients to be managed and monitored in general practice

4. Integration with general practice

As mentioned previously the Gout Stop and Owning My Gout programmes are both well integrated with general practice and community pharmacy. We have already noted above our concern that the proposal could allow prescription without this sort of integration in place.

5. Review period

The proposal would see pharmacists able to prescribe 3 months of allopurinol at a time (Part A section 5) with no limit on how long the patient can continue to receive allopurinol without medical review. The College is concerned that not only will the necessary review of symptoms, uric acid and renal function not occur but also that the management of the many other conditions that frequently coexist with hyperuricemia may be neglected. For example, in New Zealand 40% of people with gout have diabetes and/or cardiovascular disease.[4]

6. Multiple prescribers

The risk of potentially inappropriate drug combinations increases with the number of physicians involved in the medical management of an elderly patient.[5] Pharmacist supply will in effect be adding an additional prescriber. This risk must be mitigated by ensuring that care is integrated rather than fragmented. The current proposal will not guarantee this.

[4] Winnard D, Wright C, Jackson G, et al. Gout, diabetes and cardiovascular disease in the Aotearoa New Zealand adult population: co-prevalence and implications for clinical practice. N Z Med J 2012;126:53–64.
[5] https://bpac.org.nz/BPJ/2006/October/docs/polypharmacy_pages_24-25.pdf Accessed 12/4/21

7. Will the risk mitigating strategies mentioned be implemented and effective?

We note that Section 10 of the application states that "Risk mitigating strategies will be agreed with a panel of experts". There have been previous instances where risk mitigating strategies have been put into place with similar reclassifications to 'prescription except". There has been little evaluation of these changes and what auditing that has occurred has revealed that risk mitigating strategies are not always followed.[6]

### Is reclassification of allopurinol needed?

The widespread use of patient portals and increasing use of virtual consultations have decreased the need for time off work and travel, which is cited as a barrier to gout management in general practice.

We were surprised to find that GPs involved in the existing gout programmes were unaware of the plan to make an application for reclassification of allopurinol. Certainly, there is no suggestion that the application has been made as the result of those involved in these programmes identifying a need for reclassification.

We note that while the recent evaluation of the Gout Stop and Owning My Gout management programmes includes a section on 'informing future roll out' it makes no mention of reclassification of allopurinol among its recommendations.

### Appreciation of the role of genetic predisposition to gout.

Gout used to be known as a disease of kings and associated with high living and rich food. More recently evidence has appeared that downplays diet as a risk factor for gout and establishes a genetic predisposition as being more significant. Neither patient understanding nor medical guidelines appear to have taken on board this new understanding.

This is unfortunate due to the whakamā (shame, feeling of disadvantage) associated with gout resulting from the assumption that the patient's diet is at fault, and this has been cited as one of the barriers to patient engagement with general practice.[7]

It is concerning to see that sources of GP guidance such as patient pathways[8] and the 2018 BPAC guidance on gout[9] perpetuate the misapprehension that gout is primarily the result of the patient eating the wrong foods. The College considers that there is an important opportunity here to improve both practitioner and population understanding.

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[6] https://www.nzdoctor.co.nz/article/news/audits-highlight-issues-around-correct-supply-sildenafil Accessed 12/4/21

[7] http://www.journal.mai.ac.nz/sites/default/files/MAI_Jrnl_2020_V9_2_TeKaru_FINAL.pdf Accessed 12/4/21

[8] https://3d.communityhealthpathways.org/ Accessed 12/4/21

[9] https://bpac.org.nz/2018/gout-part1.aspx Accessed 12/4/21

Kaimoana (seafood) is one of the food groups associated with gout. The gathering and eating of kaimoana has cultural significance for Māori and Pacific peoples, and the association of this cultural practice with the experienced whakamā of gout adds a further barrier to access to treatment for Māori and Pacific patients. Greater appreciation of the role of genetics, and a resulting decrease in the exclusive focus on diet, can potentially overcome this cultural barrier in addition to the shame felt by many gout sufferers.

## Support by professional bodies and other relevant organisations

Among the list of parameters that must be considered when changing the legal classification of a medicine is the support of professional bodies[10]. Therefore, we were surprised that this application has been made by Dr Gauld as an individual rather than by the Pharmaceutical Society, of which Dr Gauld is the Vice-President[11]. In addition, as mentioned earlier, we would have expected the application to mention support from the leaders of the Gout Stop and Owning My Gout management programmes, if indeed they are in favour of the submission.

## Conclusion

The College considers that many patients are missing out on the benefit of urate-lowering medication and further the burden of poorly controlled gout is inequitable and borne disproportionately by Māori and Pacific peoples, who already suffering from health inequity.

The College considers that the current proposal is not the best way forward but agrees that current management of gout is sub-optimal. The message that the urate lowering therapy should not be delayed while dietary improvements are pursued needs to be reflected in the clinical guidance available to health practitioners. There would also be benefit in more visible health promotions activity around the benefits of urate-lowering therapy.

We hope you find our submission helpful. If you have any questions, or would like more information, please email us at policy@rnzcgp.org.nz

Nāku noa, nā

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[10] https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf Accessed 12/4/21

[11] https://www.psnz.org.nz/Category?Action=View&Category_id=97 Accessed 12/4/21