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

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Tēnā koe Paula

RNZCGP Submission: Pharmac - Proposed changes to Special Authority criteria for empagliflozin, liraglutide, and dulaglutide

1. About the College

The Royal New Zealand College of General Practitioners (the College) is the professional body and postgraduate specialist education college for general practitioners and rural hospital doctors in Aotearoa New Zealand. We represent more than 6,000 specialist GPs and rural hospital doctors, comprising approximately 40 percent of New Zealand's specialist medical workforce. Our motto is Cum Scientia Caritas — with knowledge, compassion.

This submission is made jointly with Te Akoranga a Māui, the College's Māori representative group, which has more than 300 members and was the first indigenous representative group established within any Australian and New Zealand medical college, and the College's Pacific Chapter, which has over 100 members and has provided clinical and cultural leadership on Pacific health over the past decade. Te Akoranga a Māui and the Pacific Chapter provide governance and clinical leadership on all matters relating to Māori and Pacific health equity respectively.

General practice is the front door of the health system. It is where type 2 diabetes is identified, managed, and monitored; where Special Authority applications are initiated; and where the consequences of funding criteria — both intended and unintended — are experienced directly by clinicians and their patients. The College therefore speaks to this consultation with direct clinical knowledge of how these criteria operate in practice.

2. Our position

The College, in partnership with Te Akoranga a Māui and the Pacific Chapter, strongly opposes the removal of the ethnicity-based access criterion for Māori and Pacific peoples from the Special Authority criteria for empagliflozin, liraglutide, and dulaglutide.

When Pharmac funded these medicines in 2021, the College welcomed the decision as a win for equity. That position reflected the College's long-standing clinical view that Māori and Pacific peoples carry a disproportionate burden of type 2 diabetes and its complications, face systemic barriers to accessing the standard care pathway, and were not receiving these medicines at rates commensurate with their need. Nothing in the evidence since 2021 has changed that assessment — if anything, the evidence has strengthened it. Removing the ethnicity criterion will delay or deny Māori and Pacific peoples with diabetes, early and timely access to the very medicines that prevent cardiovascular disease and renal failure. In practice, this shifts eligibility from a proactive, equity-focused model to one that requires documented end-organ damage in populations whose access to primary care has already been inequitable.

The College supports the proposal to lower the five-year cardiovascular risk threshold, which would appropriately extend access to additional patients. We support this as an additional pathway, not as a replacement for the

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ethnicity criterion. The two criteria address different patient populations and different barriers. Both are clinically warranted.

3. The clinical context: general practice and the diabetes burden

Type 2 diabetes and its cardiovascular and renal complications represent one of the most significant chronic disease burdens in Aotearoa New Zealand. Empagliflozin, liraglutide, and dulaglutide are not lifestyle medicines. They are organ-protective agents with demonstrated efficacy in reducing cardiovascular events, slowing progression of diabetic nephropathy, and reducing mortality in people with type 2 diabetes. The clinical evidence base is extensive and compelling.

General practitioners are the primary prescribers of these medicines. The Special Authority process is initiated in general practice in the vast majority of cases. This means the design of the SAC criteria directly shapes the prescribing decisions of GPs across Aotearoa — and where criteria are complex, risk-threshold-dependent, or administratively burdensome, the patients who are most likely to miss out are those whose GPs are already stretched, and those who have least continuity of care.

Māori and Pacific peoples with type 2 diabetes present with a clinical profile that makes access to these medicines more urgent, not less:

- Māori are affected by type 2 diabetes three times as often as Pākehā patients; Pacific peoples five times as often
- Māori and Pacific patients are seven to twelve times more likely to progress to end-stage renal failure compared with Europeans,
- Māori and Pacific peoples with diabetes are twice to three times as likely to die from cardiovascular disease and have mortality rates two to three times higher than, and die a decade earlier than non-Māori
- Māori and Pacific peoples develop type 2 diabetes 10 -15 years earlier than Europeans -and progress to serious complications faster, compressing the window in which organ-protective medicines can prevent irreversible harm
- Pacific peoples with type 2 diabetes have the highest rates of cardiovascular disease and renal failure, and diabetes related mortality in Aotearoa New Zealand.

These are not contested statistics. They are the reason the College advocated strongly for the ethnicity criterion in 2021, and the reason we oppose its removal in 2026.

4. The evidence for retaining the ethnicity criterion

4.1 The criterion achieved its intended purpose

The most direct evidence is the access to medicines data following the 2021 funding decision. Research published in the New Zealand Medical Journal (Paul et al., 2023), drawing on data from Auckland and Waikato covering more than 50,000 patients, found that the proportion of Māori and Pacific patients with cardiovascular and renal disease who were prescribed these medicines was significantly higher than for other groups — 42% compared with 30%. In the six months following funding, 47% of the 36,103 approved Special Authority applications used the ethnicity pathway.

These figures represent a genuine shift in a gap that had persisted for over two decades. They are evidence that the criterion worked as designed. A policy instrument that has demonstrably achieved its purpose should not be removed without an equivalent alternative that can demonstrate comparable outcomes.

4.2 The underprescribing gap is structural, persistent, and quantified

The context for the 2021 criterion was not abstract concern about equity. It was a documented, quantified prescribing gap. Research by Metcalfe et al. (New Zealand Medical Journal, 2018) found that after adjusting for population size and burden of disease, Māori received 41% fewer prescription items than non-Māori in 2012/13,

representing 1.26 million fewer prescriptions per year. This gap had widened from 37% in 2006/07. These figures are disease-burden-adjusted — they cannot be explained by Māori having lower need.

A similar pattern is seen for Pacific peoples. Metcalfe et al. found that Pacific peoples received 28% fewer prescription items than expected after adjusting for population size and disease burden, indicating a substantial and persistent under prescribing gap that cannot be explained by lower clinical need.

From a general practice perspective, this gap has a clear clinical explanation. Māori and Pacific patients are more likely to face cost barriers to GP attendance, less likely to have completed cardiovascular risk assessments on their clinical record, and more likely to present at later stages of disease progression. Standard criteria that require a completed risk score or an established cardiovascular diagnosis systematically and disproportionately disadvantage patients with high clinical need whose access to primary care, and therefore formal risk-assessment processes, has been constrained by structural inequities rather than lack of need.

4.3 A CVD risk threshold alone does not resolve the access barrier in general practice

The College wishes to be specific about why a lower cardiovascular risk threshold alone is an insufficient substitute for the ethnicity criterion, because this is a clinical point that may not be fully visible outside of general practice.

To access a risk-threshold-based criterion, a patient must have had their cardiovascular risk formally calculated and recorded — typically using the PREDICT or NZ CVD Risk Calculator tool. This requires a GP consultation, a laboratory request and a blood test, complete data entry of relevant risk factors, and a result that appears in the clinical record. Research has documented that Māori and Pacific peoples are significantly less likely to have a completed CVD risk assessment recorded, even when they have established risk factors, for the following reasons:

- Cost barriers: 22% of Māori and 18% of Pacific peoples (vs 13% of non-Māori) report a cost barrier to seeing a GP; 14% and 10% respectively (vs 5%) report a cost barrier to collecting a prescription
- Discontinuity of care: patients without a consistent enrolled GP are less likely to have had a cardiovascular risk assessment completed and updated
- Underfunding of Māori and Pacific health providers: many Māori and Pacific health practices have insufficient capacity to complete systematic risk assessment at the population level
- Cultural unsafety: Māori patients report poorer experiences in mainstream primary care settings, reducing engagement and follow-up; Pacific peoples similarly report lower satisfaction, reduced trust, and experiences of judgement or cultural mismatch in mainstream services, contributing to lower continuity of care and reduced likelihood of completing CVD risk assessments.

The practical consequence is this: a Māori or Pacific patient with type 2 diabetes who has not had their CVD risk formally assessed cannot access a risk-threshold criterion, even if their actual clinical risk is high. The ethnicity criterion bypasses this dependency. A CVD threshold criterion does not — it relocates the access barrier to an earlier point in the care pathway where inequity is already entrenched.

The College's members see this dynamic in practice. Replacing the ethnicity pathway with a lower threshold is not equivalent access. It is equivalent availability — which is not the same thing.

4.4 Consistency with the College's published positions

The College's position on this matter is consistent with its formal Te Tiriti o Waitangi and Māori Health Equity position statement (March 2025), which commits the College to:

- Unreservedly supporting initiatives and advocating for a health system that gives effect to Te Tiriti o Waitangi
- unequivocally acknowledging ethnicity as an evidence-based marker of need and health outcomes
- advocating for investment in hauora Māori solutions to addressing current health needs

The College also notes its 2024 submission on the Hauora Māori Strategy, which affirmed the need for Māori representation in health governance and policies that address the unique health challenges faced by Māori

communities. The proposed removal of the ethnicity criterion is inconsistent with those positions and with the direction of health policy that the College has consistently advocated for.

4.5 Genomic evidence: IL-1 variants in metabolic syndrome

Emerging genomic studies associate variants in the interleukin-1 (IL□1) gene family (IL1B and IL1RN) with greater systemic inflammation, higher metabolic syndrome risk, increased insulin resistance, and faster progression to type 2 diabetes and complications. These inflammatory pathways interact with environmental and social factors to amplify cardiometabolic risk.

Certain IL-1 variants are more prevalent in Polynesian-ancestry populations. In New Zealand, this includes Māori and around 90% of Pacific peoples. Here, ethnicity serves as a practical marker of integrated biological (genetic), environmental, and structural risks rather than a crude proxy. The ethnicity criterion therefore reflects genuine clinical need, supported by emerging genomic and established epidemiological evidence.

5. Responding to the 'needs-based' framing

The proposed change has been framed publicly around the principle that clinical need, not ethnicity, should determine access to funded medicines. The College does not disagree with the principle. It disagrees that the proposed changes give effect to it.

The ethnicity criterion is a needs-based criterion. It exists because Māori and Pacific peoples have documented, measurably higher clinical need for organ-protective diabetes medicines, and face documented barriers to accessing them through the standard risk-threshold pathway. It is a clinical correction for a structural failure in the care pathway, not a departure from clinical reasoning.

Moreover, the framing that a risk-threshold criterion is more 'needs-based' than an ethnicity criterion misunderstands how need is distributed. A patient's CVD risk score is not a neutral measure of need — it is a measure of need that has been successfully assessed and recorded. For patients who cannot access the system in which that assessment occurs, the score does not exist. The ethnicity criterion reaches those patients. A risk threshold does not.

6. Te Tiriti o Waitangi obligations

The College's March 2025 position statement commits it to recognising and upholding Waitangi Tribunal-identified Te Tiriti o Waitangi principles, including equity, active protection, and partnership. These are not aspirational commitments — they are embedded in the College's rules and strategic documents.

The Waitangi Tribunal's WAI 2575 Health Services and Outcomes Kaupapa Inquiry found systemic Crown failures in Māori health access and identified active protection as a core Crown obligation. Active protection requires more than avoiding deliberate discrimination — it requires the Crown to take positive steps to address inequity where it is identified and documented.

The ethnicity criterion in this Special Authority is a concrete act of active protection. Its removal, at a time when the access gains it has enabled are still fragile and relatively recent, would be inconsistent with the Crown's active protection obligations. The College calls on Pharmac to apply a Te Tiriti analysis to this decision and to publish that analysis alongside its final determination.

7. Recommendations

The College makes the following recommendations to Pharmac:

1. **Retain the ethnicity criterion for Māori and Pacific peoples in the Special Authority criteria** for empagliflozin, liraglutide, and dulaglutide in its current form. The criterion is working, it is clinically warranted, and its removal risks reversing demonstrated access gains.

2. **Implement the proposed lower five-year cardiovascular risk threshold as an additional access pathway**, not a replacement for the ethnicity criterion. The two criteria address distinct clinical populations and distinct barriers.

3. **Commission ongoing, publicly reported monitoring of ethnicity-disaggregated prescribing rates for these medicines**. Any future criteria change should be accompanied by a commitment to act if Māori and Pacific access rates decline from current levels.

4. **Conduct and publish a formal Te Tiriti o Waitangi analysis of the proposed criteria changes prior to making a final determination**, in accordance with Pharmac's obligations under the Pae Ora (Healthy Futures) Act 2022.

5. **Engage with the College and Te Akoranga a Māui, and with Māori and Pacific health providers**, on the development of complementary strategies to address the upstream primary care barriers to CVD risk assessment that undermine the effectiveness of any risk-threshold-based criterion for Māori and Pacific patients.

8. In summary

In 2021, the College called Pharmac's decision to fund these medicines with an ethnicity criterion a win for equity. It was. The evidence since then has confirmed it. GPs across Aotearoa have used the ethnicity pathway to prescribe medicines that protect the hearts and kidneys of their Māori and Pacific patients — patients who, without that pathway, would have missed critical opportuties to access organ-protective therapies early in the disease course, while facing additional barriers in a system that has already failed them too often.

The College's motto — Cum Scientia Caritas, with knowledge, compassion — describes the obligations we hold as clinicians and as an institution. The knowledge says: this criterion works. The compassion says: keep it.

We urge Pharmac to make the decision that both the evidence and the Treaty require.

Nāku noa, nā

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