From: Timothy Cundy <Withheld under section 9(2)>
Sent: Wednesday, 9 September 2020 12:10 pm
To: PHARMAC Tender <tender@pharmac.govt.nz>
Subject: Proposal to fund two new medicines for type 2 diabetes

Thank you! Thank you!
Delighted to learn that Empagliflozin will be subsidised - I am fully supportive of your proposal
Tim Cundy
(Diabetes Physician)

From: Rob Walker <Withheld under section 9(2)>
Sent: Wednesday, 9 September 2020 12:22 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

Dear colleaagues,

I am writing in my capacity as HOD nephrology for the SDHB, as well as an academic nephrologist with a specific interest in cardiovascular risk factors associated with chronic kidney disease.

I fully support the proposal to fund access to empagafliglozin either alone or in combination with metformin. The SGLT2 inhibitors have been clearly demonstrated to have significant benefits in improving glycaemic control, weight reduction reducing the progression of chronic kidney disease and reducing the risk of cardiovascular disease in diabetics with or without established diabetic kidney disease. The benefits of introducing these medications early in the management of diabetics will have major benefits in risk reduction for diabetics. This will be especially the case for Māori and Pacific who have disproportionately higher rates of CKD and heart disease. They, in particular, need early fully subsided access to these medications in order to improve equity of health care. There also needs to be a very active education process for GPs to make sure that they are aware of the benefits and that these medications are prescribed early in the management of their Māori patients. Not only to reduce the impact of CKD and CVD on this high risk population, but also to ensure there is equity in health care. In the past Māori have not received the leading evidenced based care in managing their health problems Making the SGLT2 inhibitors available immediately to Māori at risk will be a major step forward in health care.

Do you support this proposal? Definitely.

What will help people with diabetes and their whānau access these medicines? See above. Good GP education and good community education to health support groups as to the benefits of these medications

What tools or approaches could be useful to support prescribers and people with diabetes? Good education community health care providers.

How could we specifically support Māori and Pacific people to access these medicines? As above.

Ngā mihi,

Professor Robert Walker
Department of Medicine
University of Otago

From: Mayanna Lund (CMDHB) <Withheld under section 9(2)(a)>
Sent: Wednesday, 9 September 2020 1:13 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC - consultation regarding medicines in type 2 diabetes

Kia ora Elena,

I'm always happy to have duplication of good news! Thank you so much for letting me know individually.

Ka nui te mihi
Mayanna

From: Elena Saunders [mailto:Withheld under section 9(2)(a)]
Sent: Wednesday, 09 September 2020 12:03 p.m.
To: Mayanna Lund (CMDHB)
Subject: PHARMAC - consultation regarding medicines in type 2 diabetes

Dear Mayanna,

I'm really pleased to share with you a consult that PHARMAC has released today regarding a proposal to fund an SGLT 2 inhibitor and a GLP-1 agonist. You can read the details here: https://smex12 5 en ctp.trendmicro.com:443/wis/clicktime/v1/query?url=www.pharmac.govt.nz%2fdiabetes&umid=508ac2fd-2d61-40cb-9366-532bafbb339a&auth=bb7c7bbf7acee6ae97e29073e34f3e8b1808c238-b61d1ab3c8b96e0374c3136ffda643837dfdd83f

My apologies – I suspect this is probably a duplication for you, but I wanted to be sure you were aware of this

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager
PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: +Withheld under | DDI: +Withheld under | P: +64 4 460 4990 | https://smex12-5-en-ctp.trendmicro com:443/wis/clicktime/v1/query?url=www pharmac govt nz&umid=508ac2fd 2d61 40cb-9366-532bafbb339a&auth=bb7c7bbf7acee6ae97e29073e34f3e8b1808c238 f19f76279059effa0b45caf4bc5967b7f37fef7c

From: Withheld under section 9(2)(a)
Sent: Wednesday, 9 September 2020 2:14 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

Fantastic. About time. Could we have continuous glucose sensing funded for type one diabetes too please?

Withheld under

Sent from my iPhone

From: Withheld under section 9(2)(a)
Sent: Wednesday, 9 September 2020 5:40 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Diabetes medication delivery

Hello,

I read with interest your call for consultation on new diabetes medications to be listed I support the proposal, and I think it will prove to be an important step forward for Aotearoa.

As PHARMAC's stated intentions and strategic goals have more and more strongly involved equity of access to medicines, I have become interested in that goal myself.

It's my belief that simply making medicines available on the Pharmaceutical Schedule isn't enough In order to provide equitable medicines access, particularly for chronic conditions which disproportionately impact Maori and Pacific peoples like diabetes, we need to work with patients more closely.

The link below is a paper from the Long-Term Conditions Conference 2019 which was held in Wellington.

https://www.healthnavigator.org.nz/media/7095/day-one-session-3a-2-janine-bycroft-digital-tools-for-long-term-condition-management.pdf

What caught my eye in that session was SMS4BG, a mobile text based motivational aid to support diabetes dietary and (potentially) medication adherence. Engaging with patients through text messages was proven to improve glycaemic control in a random controlled trial in Auckland. A long term follow up study earlier this year found the improvement was also lasting. Here is a link to the long term follow up journal article.

https://pubmed ncbi nlm.nih.gov/31722130/

Of course SMS4BG isn't a medicine itself in the chemical sense, so the supplier wouldn't ever submit it to PHARMAC in an application for funding. Yet it certainly is effective as part of "medicine" in the wider sense of the word, as proven by the outcomes of that study. Could funding for these diabetes medications be bundled with funding for related text message motivational support? It would help ensure that the government's significant investment in providing these medicines actually lands the desired outcomes.

I have no affiliation with Rosie Dobson or the National Institute for Health Innovation. But I certainly respect the scientifically sound work they've done to show how simply reaching out to people can make medicines more effective. More than just text messaging, I believe the delivery of medicine must evolve into a patient-centric collaboration among all the parties: government, suppliers, medical professionals,

pharmacists, community health workers, patient member organisations, and patients themselves.

Specifically for Maori and Pacific peoples: having a trusted health worker, a member of their own community, involved in their health decisions would make a huge difference in medicines uptake, persistence, and adherence. I think that the implementation of SMS4BG for diabetes patients could help to identify who those people are in patient's lives and help us work towards the desired collaborative outcome To achieve equitable medicines access, we need to involve ourselves in Maori and Pacific patients' culture, rather than insisting that they involve themselves in European culture.

When a health professional writes a prescription for one of these diabetes medications, is it possible that SMS4BG could be delivered as part of the complete medicine package?

--

Withheld under
Withheld under section 9(2)(a)
Withheld under section 9(2)(a)

From: Dr. Norma Nehren <Withheld under section 9(2)>
Sent: Wednesday, 9 September 2020 5:43 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: New DM meds

I fully support bringing in the two proposed DM medications - Wholly happy and relieved it is finally happening!
I work in a Maori Health Provider organisation with over 13600 patients. 70% of the patients in my clinic are Maori and our rates of Diabetes are quite high.

I need access to these medications to optimize their treatment and improve their life expectancy and quality of life

Norma

TE HIKU HAUORA

Dr. Norma Nehren · **Medical Director**
Te Whare Hauora
t Withheld under **m**
e Withheld under section 9(2)(a)
p 49 Redan Road, Kaitaia
w www.tehikuhauora.nz **f** Te Hiku Hauora

From: Peter Shepherd <Withheld under section 9(2)(a)>
Sent: Thursday, 10 September 2020 7:14 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC Consultation

Thanks Elena
This is a huge win for diabetes patients and step towards health equity in NZ.
Nga mihi
Peter Shepherd

On 9 Sep 2020, at 12:03, Elena Saunders <Withheld under section 9(2)(a)> wrote:

Dear colleagues,

I am writing to you as attendees at the Maurice Wilkins Centre combined diabetes, cardiology and renal specialist meeting held on 14th October 2019, where I had the opportunity to present on PHARMAC's work on diabetes medicines as well as medicines access equity.

I am delighted to share with you a consult that PHARMAC has released today regarding a proposal to fund two new medicines – a SGLT-2 inhibitor and a GLP-1 agonist. Details of the proposal, including instructions on how to provide feedback, are available here: www pharmac govt.nz/diabetes

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager
PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: +Withheld under | DDI: +Withheld under | P: +64 4 460 4990 | www pharmac govt nz

From: Elena Saunders
Sent: Thursday, 10 September 2020 9:16 am
To: Rinki Murphy <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Mark Weatherall <Withheld under section 9(2)(a)>; Peter Murray <Withheld under section 9(2)(a)>
Subject: RE: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Kia ora Rinki,

Thanks for this.

The maximal tolerated doses of oral antidiabetic agents and/or insulin has been left intentionally broad to allow clinician judgement here. We would not expect that a sulfonylurea/thiazolidinedione/acarbose would be required to qualify – dual therapy as you describe would be ok if that could reasonably be justified as the maximum tolerated oral diabetic therapy.

I will add this to the consultation feedback and ensure this is represented in the decision paper that goes to the PHARMAC board

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: +Withheld under | DDI: +Withheld under | P: +64 4 460 4990 | www pharmac govt nz

From: Rinki Murphy <Withheld under section 9(2)(a)>
Sent: Thursday, 10 September 2020 6:37 AM
To: Elena Saunders <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Mark Weatherall <Withheld under section 9(2)(a)>; Peter Murray <Withheld under section 9(2)(a)>
Subject: Re: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Kia ora Elena and all

I think it will be great to have the choice of empagliflozin (with and without metformin combination), or once weekly GLP1RA dulaglutide.

I would like to double-check that SA #2 and #5 which refers to "maximal tolerated doses of oral antidiabetic agents and/or insulin" can be taken as being dual therapy (eg: with metformin+vildagliptin), so such patients with HBA1c >53, in the presence of persistent microalbuminuria for example, would qualify for either SGLT2 or GLP1RA? This scenario is much closer to the international guidelines and I am happy with it.

I don't think it is appropriate to have had to use SU/pio/acarbose to qualify for empa or dulag, after failing triple or quadruple glucose lowering therapy, although in practice, those high risk renal and cardiac patients already on stable triple or quadruple therapy may have one of these two newer drugs added on (with a dose reduction of any that are producing undesirable side effects such as hypos or weight gain).

Clearly, those who can afford to self-fund one of the two will benefit from taking both a SGLT2i and GLP1RA as part of their therapy.

Very exciting to have these new medications for type 2 diabetes - a step change in management which I am sure will produce massive health benefits to many NZers!

Namaste

Rinki

From: Elena Saunders <Withheld under section 9(2)(a)>
Date: Tuesday, 8 September 2020 at 1:43 PM
To: Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Mark Weatherall <Withheld under section 9(2)(a)>, Peter Murray <Withheld under section 9(2)(a)>
Subject: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Tēnā koutou Diabetes Subcommittee,

I hope this finds you well.

I am very pleased to share with you (in confidence) that tomorrow we plan to release the attached consultation regarding the supply of diabetes medicines We wanted to give you some advanced notice of this to ensure you are prepared for any questions you might receive.

The proposal is to fund, under the proposed Special Authority criteria, an SGLT-2 inhibitor (empagliflozin) and a GLP-1 agonist (dulaglutide). It also includes a reduction in the price of the DPP-4 inhibitor vildagliptin. Further details are in the attached document.

I would like to take this opportunity to thank you for all your valuable contributions to the work on these medicines. In particular, your advice at the zoom meeting earlier this year was instrumental in allowing us to complete the necessary analyses of the proposals in order to progress

As you are aware, consultation is an important part of our process. All feedback will be considered by PHARMAC staff and the PHARMAC Board. The Board will then make a decision on this proposal at its meeting in late October, and we will notify of the decision as soon as possible after that.

If you have any questions at this point then please let me know. I would appreciate you keeping this confidential for now, and I will send you confirmation once the consultation has been made public (likely 12 noon tomorrow).

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: +Withheld under | DDI: +Withheld under | P: +64 4 460 4990 | www.pharmac govt nz

From: Elena Saunders
Sent: Thursday, 10 September 2020 2:18 pm
To: Diana McNeill (CMDHB) <Withheld under section 9(2)(a)>; Rinki Murphy <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Mark Weatherall <Withheld under section 9(2)(a)>; Peter Murray <Withheld under section 9(2)(a)>
Subject: RE: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Kia ora Diana,

We would support this transaction with an implementation plan, and we are engaging with Matui one of our responsible use of medicines providers on communication with primary care. You can read more about our general collaboration with Matui here: https://www.nzdoctor.co.nz/article/undoctored/matui-provide-resources-primary-health-care-professionals-behalf-pharmac. This would be in addition to any activities conducted by the relevant suppliers

As noted in the consultation, we would monitor uptake of these medicines to see whether the medicines are being accessed by those people with highest need (for example Māori and Pacific) We would seek clinical advice (including from the Diabetes Subcommittee) on whether the equity of access could be improved over time, and how PHARMAC could support this.

In terms of the need for ongoing special authority, we would review this periodically, but I think at this point it would be reasonable to assume that the existence of a special authority on these medicines would be unlikely to change in the first three years of funding.

We would welcome feedback on this proposal – ideally send this through to consult@pharmac.govt.nz. Consultation closes at 4pm on Friday 2 October 2020.

If you have specific feedback on the Special Authority criteria beyond what you provided when we sought your advice on this via email in November 2019 then we would welcome this. In providing feedback, what would be particularly useful is if you could provide options for changes in your order of preference, and evidence to support the options.

Consultation is a critical part of our process, and all consultation feedback will be considered by the PHARMAC Board prior to its decision.

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: +Withheld under | DDI: +Withheld under | P: +64 4 460 4990 | www.pharmac.govt.nz

From: Diana McNeill (CMDHB) <Withheld under section 9(2)(a)>
Sent: Thursday, 10 September 2020 9:31 AM
To: Elena Saunders <Withheld under section 9(2)(a)>; Rinki Murphy <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Mark Weatherall <Withheld under section 9(2)(a)>; Peter Murray <Withheld under section 9(2)(a)>
Subject: RE: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Hi Elena,

I'm very pleased with the decision to move forward with these medicines. Can I ask what will be in place to educate GPs about these medicines? Will the drug companies be doing sessions? I'm hoping this won't fall on secondary care (diabetes/cardiology/renal) only to prescribe as this will limit access/equity for patients who need these drugs. I'm also wondering when the need for ongoing special authority will be reviewed

Many thanks,

Diana

From: Elena Saunders <Withheld under section 9(2)(a)>
Date: 10 September 2020 at 9:16:36 AM NZST
To: Rinki Murphy <Withheld under section 9(2)(a)>, Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Mark Weatherall <Withheld under section 9(2)(a)>, Peter Murray <Withheld under section 9(2)(a)>
Subject: RE: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Kia ora Rinki,

Thanks for this.

The maximal tolerated doses of oral antidiabetic agents and/or insulin has been left intentionally broad to allow clinician judgement here. We would not expect that a sulfonylurea/thiazolidinedione/acarbose would be required to qualify – dual therapy as

you describe would be ok if that could reasonably be justified as the maximum tolerated oral diabetic therapy.

I will add this to the consultation feedback and ensure this is represented in the decision paper that goes to the PHARMAC board.

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

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Cell: +[Withheld under] | DDI: +[Withheld under] | P: +64 4 460 4990 | https://smex12-5-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=www.pharmac.govt.nz&umid=89cb991a-9f12-4377-b5de-4bc8676d87b7&auth=92832370a92c0cff5ff7e7d2be25089679458981-3ae691374fccd956cb22b4a8160853851c37add0

From: Rinki Murphy <[Withheld under section 9(2)(a)]>
Sent: Thursday, 10 September 2020 6:37 AM
To: Elena Saunders <[Withheld under section 9(2)(a)]>; Diabetes Subcommittee <[Withheld under section 9(2)(a)]>
Cc: Mark Weatherall <[Withheld under section 9(2)(a)]>; Peter Murray <[Withheld under section 9(2)(a)]>
Subject: Re: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Kia ora Elena and all

I think it will be great to have the choice of empagliflozin (with and without metformin combination), or once weekly GLP1RA dulaglutide.

I would like to double-check that SA #2 and #5 which refers to "maximal tolerated doses of oral antidiabetic agents and/or insulin" can be taken as being dual therapy (eg: with metformin+vildagliptin), so such patients with HBA1c >53, in the presence of persistent microalbuminuria for example, would qualify for either SGLT2 or GLP1RA? This scenario is much closer to the international guidelines and I am happy with it

I don't think it is appropriate to have had to use SU/pio/acarbose to qualify for empa or dulag, after failing triple or quadruple glucose lowering therapy, although in practice, those high risk renal and cardiac patients already on stable triple or quadruple therapy may have one of these two newer drugs added on (with a dose reduction of any that are producing undesirable side effects such as hypos or weight gain).

Clearly, those who can afford to self-fund one of the two will benefit from taking both a SGLT2i and GLP1RA as part of their therapy.

Very exciting to have these new medications for type 2 diabetes - a step change in management which I am sure will produce massive health benefits to many NZers!

Namaste

Rinki

From: Elena Saunders <Withheld under section 9(2)(a)>
Date: Tuesday, 8 September 2020 at 1:43 PM
To: Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Mark Weatherall <Withheld under section 9(2)(a)>, Peter Murray <Withheld under section 9(2)(a)>
Subject: CONFIDENTIAL - PHARMAC Diabetes medicines consultation

Tēnā koutou Diabetes Subcommittee,

I hope this finds you well.

I am very pleased to share with you (in confidence) that tomorrow we plan to release the attached consultation regarding the supply of diabetes medicines. We wanted to give you some advanced notice of this to ensure you are prepared for any questions you might receive.

The proposal is to fund, under the proposed Special Authority criteria, an SGLT-2 inhibitor (empagliflozin) and a GLP-1 agonist (dulaglutide). It also includes a reduction in the price of the DPP-4 inhibitor vildagliptin. Further details are in the attached document.

I would like to take this opportunity to thank you for all your valuable contributions to the work on these medicines. In particular, your advice at the zoom meeting earlier this year was instrumental in allowing us to complete the necessary analyses of the proposals in order to progress.

As you are aware, consultation is an important part of our process. All feedback will be considered by PHARMAC staff and the PHARMAC Board The Board will then make a decision on this proposal at its meeting in late October, and we will notify of the decision as soon as possible after that.

If you have any questions at this point then please let me know. I would appreciate you keeping this confidential for now, and I will send you confirmation once the consultation has been made public (likely 12 noon tomorrow).

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager

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From: Renate Koops (CMDHB) <Withheld under section 9(2)(a)>
Sent: Thursday, 10 September 2020 2:38 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: FW: Consultation: proposal to fund two new medicines for type 2 diabetes

Dear Sir, Madam

I fully support the proposal to fund these 2 new diabetes medications

New Zealand has been way behind in having access in life saving medications for diabetes.
To not be able to offer my diabetes patients the treatment they need, simply because they live in New Zealand, is heart breaking.
Coming from the Netherlands were these medications have been around for over 10 years, I feel to have gone backwards in diabetes care. Working in a diabetes trail centre I have experienced great outcomes with both these types of medications and seen improvement in HbA1c and reduction in cardio vascular event in front of my eyes.

These medications should NOT have Special Authority, so also primary care can prescribe this without restrictions
Therefore education should be extended to all levels of care, both primary and secondary, both doctors and nurses
We could specifically support Māori and Pacific people to access these medicines by providing flyers/brochure/information through the internet in their language

Happy to provide more information.

Regards, Renate Koops
Diabetes Specialist
Middlemore Hospital
Auckland
Withheld under

countiesmanukau.health.nz

Kind Manaakitanga | Excellent Rangatiratanga | Valuing everyone Whakawhanaungatanga | Together Kotahitanga

Please consider the environment before printing this email.

the New Zealand Blood Service (NZBS).
If you are looking for medical jobs in New Zealand, your career in health starts with us.

From: Consult
Sent: Friday, 11 September 2020 9:13 am
To: 'Helen Cant - work' <Withheld under section 9(2)(a)>
Subject: RE: Clarification of consultation Diabetes medications

Kia ora Helen,

Thanks for getting in touch This criterion has been left intentionally broad to allow for clinician judgement on what the appropriate maximal therapy would be.

We would welcome further feedback on this point (and the broader proposal). If you have suggestions on how the Special Authority criteria could be clarified then this would be considered as part of the final decision – in particular, if you have options in order of preference (including any rationale/evidence) then this would be particularly helpful in informing the deliberations.

Hope that is helpful, and thank you for engaging with this important step in our process.

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: +Withheld under | DDI: +Withheld under | P: +64 4 460 4990 | www.pharmac.govt.nz

From: Helen Cant - work <Withheld under section 9(2)(a)>
Sent: Thursday, 10 September 2020 6:53 PM
To: Consult <Consult@Pharmac.govt.nz>
Subject: Clarification of consultation Diabetes medications

Kia ora
Can I please request clarification on the consultation for new diabetes medications before make a submission.

I note the Special Authority requires that the person must have failed to achieve optimal HbA1c with maximal tolerated oral medications and / or insulin. Given that there are five different classes of oral medications that could potentially be used, could you please clarify your expectation of what "maximal tolerated oral medications" would be?

I recognise that insulin would be introduced for treatment intensification after two or three classes of oral medications have proved insufficient but I am thinking of those

cases where insulin is not practicable and an SGLT2 inhibitor would be potentially very helpful.

Nga mihi nui

Helen Cant
Pharmacist Prescriber

From: Withheld under section 9(2)(a)
Sent: Friday, 11 September 2020 12:30 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Proposal to Fund medicines for Type 2 Diabetes

Sir/Madam

I was diagnosed with Type 2 Diabetes in Withh In Withh I was taking Metformin and my fasting blood Glucose was in the range 8 to 10 mmo/L. Living in Withheld at the time I was prescribed Jardiance funded Withheld under section 9(2)(a). Jardiance made no noticeable difference to my fasting Glucose or Hb1c test results.

Today I take no medications and test between 5.0 and 6.8 mmo/L fasting. I achieve this simply by taking the processed carbohydrate out of my diet.

These medications may lower your blood glucose but it is a lot easier, cheaper and more effective simply to not put as much in. The money needs to be spent on education doctors and patents based on modern science not traditional practice.

Rather than buy ambulances for the bottom of the cliff, try putting up some signs at the top of the cliff.

If the current trend continues over half the people living in New Zealand today can expect to have type 2 diabetes in their lifetime so if we are to treat it with expensive medications, the cost will be crippling.

I would also like to point out that because I save the tax payer big dollars in not taking these medications, I have to fund my glucose testing strips myself Where is the justice in that?

Withheld under section

From: Linda Bryant <Withheld under section >
Sent: Sunday, 13 September 2020 6:46 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

Kia Ora,

Thank you for the opportunity to respond to this consultation The availability of a SGLT 2i and a GLP1 agonist will help optimise our management of the complications of type 2 diabetes and provide improved renal and cardiovascular outcomes and so these are a very positive inclusion on the Schedule

Do you support this proposal?
I support the proposal to provide access to these valuable medicines, although the Special Authority restrictions will severely limit the valuable that we derive from these medicines and especially penalise Māori and Pacific people

If I am reading criteria 2 *"Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months"* correctly, this would be out of line with the USA and European recommendations and would not address equity of outcomes as it would hinder the treatment of Māori and Pacific people by not addressing the high rate of renal and cardiovascular complications in a timely way.

Firstly, the statement should be 'either / or insulin' and not 'and / or', which could be read that the person needs to be on insulin as well. Due to the relatively small impact on Hba1c of SGLT 2i the use of insulin, or not, is not pertinent The primary benefit of the SGLT 2i and GLP1 agonists is the reduction in renal and cardiovascular outcomes outcomes that are particularly relevant in Māori and Pacific people.

The definition of "maximum tolerated doses of oral antidiabeteic agents" is also problematic. Which agents in particular? It would be detrimental for this to include a sulphonylurea and certainly not pioglitazone For a person with microalbuminuria or established CVD, even the use of a gliptin is not recommended before introducing a SGLT-2i or a GLP1 agonist

After the use of metformin, the algorithm, based on the USA and European should be:

Does the person have microalbuminuria or established CVD (secondary prevention)?

If **yes**, then a SGLT-2i (preferably) or a GLP1 agonist is initiated. This is before other blood glucose lowering medicine because the aim of therapy is reduction of renal and cardiovascular disease / events Blood glucose lowering is almost incidental

If **no**, then a non SGLT 2i or GLP1 agonist should be added

There could also be the inclusion of heart failure as criteria for using a SGLT 2i or GLP1 agonist

What will help people with diabetes and their whānau access these medicines?health outcomes

As above, without access to early and timely therapy that reduces the poor renal and cardiovascular outcomes, Māori and Pacific people in particular will be disadvantaged The focus of point two is on being unable to obtain HbA1c below target when it should be on preventing progression of renal disease and further cardiac events / heart failure. Microalbuminuria and CVD / secondary prevention are clearly defined and able to be audited as criteria and there is a pressing need to address these specifically for Māor and Pacific people [NB: it is appreciated that the HbA1c criteria is set as > 53 mmol/mol]

What tools or approaches could be useful to support prescribers and people with diabetes?
How could we specifically support Māori and Pacific people to access these medicines?
By removing the criteria in the Special Authority that targets blood glucose control initially through needing to have used "*maximum tolerated doses of oral antidiabetic agents"* when the primary use of the SGLT-2i and GLP1 agonists is renal and CVD. Having to maximise the antihyperglycaemics prolongs access to valuable treatment in a population that already has a higher rate of renal and cardiovascular disease.

Again, thank you for the opportunity to comment. I hope that the Special Authority criteria can be adjusted to reflect the evidence for benefit in renal and cardiovascular disease and more accurately follow the USA and Europe guidance by the first question after establishing the person on metformin being: "Does the person have microalbuminuria or established CVD?“, and if “yes’, then a special authority for an SGLT 2i is attainable. Due to cost, you may wish to add other criteria for a GLP1 agonist

Ngā mihi nui

Linda Bryant
MClinPharm, PhD, PGCert(prescribing)
FNZHPA, FNZCP, FPSNZ, (Gold Medal)PSNZ, NCAPA, RegPharmNZ
Clinical advisory and prescribing pharmacist
Porirua Union and Community Health Service and Newtown Union Health Service

From: Rick Cutfield (WDHB) <Withheld under section 9(2)(a)>
Sent: Monday, 14 September 2020 11:52 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: RE: Consultation feedback: Diabetes medications

Hi Elena,
I was thinking along the lines of "maximal tolerated drugs considered clinically appropriate" or "maximum tolerated drugs considering both side effects and relative contraindications "....this is to avoid overusing high dose sulphonylureas/pio. in those at risk.I do think unlike some that sulphonylureas like gliclazide have a place still albeit a smaller place
Rick

From: Consult [mailto:Consult@Pharmac govt nz]
Sent: Monday, 14 September 2020 10:29 a.m.
To: Rick Cutfield (WDHB)
Subject: RE: Consultation feedback: Diabetes medications

Dear Dr Cutfield,

Thanks for providing this feedback, which will be considered by PHARMAC's Board prior to it making a decision on this proposal. In relation to your point regarding the maximally tolerated criterion - what would be your suggested wording for this, on the basis of your points below? If you can provide some options, ideally in order of preference, this would be helpful in considering what changes could be made to the proposed criteria.

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager
PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: +Withheld under | DDI: +Withheld under | P: +64 4 460 4990 | https://ddec1 0 en ctp.trendmicro.com:443/wis/clicktime/v1/query?url=www.pharmac.govt.nz&umid=d822d7f1 0513-4c00-9803 b56680188cb6&auth=a3bd55c094d03421cab4e906146bf630b01a7779 96cffe0ce70cd3c56e1b7797ed8ed1474b462826

From: Rick Cutfield (WDHB) <Withheld under section 9(2)(a)>
Sent: Monday, 14 September 2020 6:38 AM
To: Consult <Consult@Pharmac govt nz>
Subject: Consultation feedback: Diabetes medications

Good work on getting these drugs for us to use As you are aware some of us on behalf of NZSSD are writing type 2 guidelines including tips on insulin use , complication screening and algorithms for oral agents . We will try to add notes on a personalized approach to drug use.

I feel we need to clarify a few points. Maximally tolerated must include the notion of relative contraindication. In other words a person likely to have significant consequences from or be at particular risk of hypos should ideally not be prescribed sulphonylurea agents.Pioglitazone is often rejected esp in women because those who benefit often gain weight and osteoporosis/ fracture risk warrants caution. So some with met and villa have reached their maximum tolerability when doctor and patient concerns are declared.

We need in NZ , a single cv risk calculator if possible? Predict Will those that need a GLP-1 and SGLT-2 I be able to purchase one of the agents at your negotiated reduced price?

GPs will need a lot of guidance regarding which of the new agents are best for their patients I do still believe more funded bariatric surgery should be looked at together with , like the NHS , more funded weight loss support(eg vlcl diets) as a separate step

Finally the evidence is clear for the use of sglt 2 s in non diabetic ht failure and probably chronic kidney disease. Including pts with heart failure and at least prediabetes as an indication might be quite cost effective.

Sincerely

Dr Rick Cutfield
Endocrinologist/ Diabetologist WaitemataDHB Patron Diabetes NZ (Auck)

Sent from my iPhone

From: Amanda de Hoop <[redacted]>
Sent: Monday, 14 September 2020 12:11 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

To whom it may concern,

Thank you for the opportunity to provide feedback on the "Proposal to fund two new medicines for type 2 diabetes". I strongly support the funding of these two medicines and have the following comments:

1) These medications are vital for Maori, Pasifika, and South East Asian people with type 2 diabetes that are significantly burdened by type 2 diabetes and its associated complications Funding these medications would be a step in the right direction to enable equitable diabetes care for these high risk populations.

2) I would strongly suggest including Registered Nurse Prescribers (along with medical or nurse practitioners) as a group of clinicians able to complete a special authority. Long Term Condition Nurses and Diabetes Specialist Nurses often have greater involvement in the care of the patients these medications are proposed for; therefore allowing Registered Nurse Prescribers to complete the special authority would reduce a barrier for the commencement of these drugs. I am optimistic that moving forward Nursing Council of New Zealand will update the Registered Nurse Prescribing medication list (feedback was sought on this in January 2020) and add SGLT-2 inhibitors and GLP-1 agonists to the list of medications able to be prescribed by Registered Nurse Prescribers.

   Given nurses would be the most likely profession to teach patients how to self-administer subcutaneous injections for GLP 1 agonists, it would seem appropriate that the nurse could also complete the special authority, to reduce the number of encounters the patient would need to commence on this drug (i.e. wouldn't need to see a doctor or nurse practitioner to have the special authority completed, and then need to book in separately to see a nurse to be taught how to administer the medication). Given the vulnerable patient population group, and current inequities that exist in these patients accessing and being able to afford primary care, consideration must be made to how barriers can be reduced.

3) Having an updated national type 2 diabetes treatment algorithm would be a useful resource for clinicians to provide guidance on when to utilise these medications. The current outdated treatment guidance is from the New Zealand Guidelines Group (2012) Primary Care Handbook, and would need to be replaced.

4) The criteria of "Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months" implies that the patient would need to be on more than one oral agent and/ or insulin to be eligible to go on an SGLT 2 inhibitor or GLP-1 agonist This goes against international guidance (ADA & EASD 2018 Management of Hyperglycemia in Type 2 Diabetes) that GLP 1 agonists and SGLT 2 inhibitors are recommended as second line medications in most instances (after Metformin) above other oral agents such as sulfonylureas, glitazones, DPP 4 inhibitors and also insulin Given this is best practice, we

should follow this, and not require our patients to commenced on inferior or less efficacious medications prior to being able to go on SGLT 2 inhibitors and GLP 1 agonists.

5) Special authority approvals not requiring further renewal is excellent, as this would reduce a barrier for long term use of these medications.

Kind regards
Amanda

Amanda de Hoop
Nurse Practitioner
Midcentral DHB Diabetes & Endocrinology Service
Ph: Withheld

From: Muhammad Arshad <[redacted]>
Sent: Monday, 14 September 2020 1:17 pm
To: PHARMAC Tender <tender@pharmac.govt.nz>
Subject: PHARMAC Diabetes Treatment Consultation

Excellent decision. It will bring NZ Practice closer to and in line with current evidence-based treatment of T2DM

Muhammad Arshad
Interventional cardiologist

From: John Wallace <Withheld under section 9(2)(a)>
Sent: Monday, 14 September 2020 2:58 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

I strongly support approving one or both of these medicines. As one of the diabetic doctors for South Canterbury DHB and Timaru Public Hospital, and a member of NZSSD, the addition of these medications will allow care of our patients with medications proven to add additional unique benefits, specifically for CHF.

John Wallace, MD
SMO Medicine
SCDHB

From: Suzanne Moorhouse <[redacted]>
Sent: Monday, 14 September 2020 5:10 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

Kia ora koutou katoa and thank you for the opportunity to provide feedback for the two medications that are being made available for whānau with Type 2 diabetes.

I work in a Māori health PHO, Te Puna Hauora Matua O Hauraki (Hauraki PHO) and although I welcome anything that supports whānau living with type 2 diabetes, I am afraid that this proposal is too little to change the outcome for Māori.

The situation currently:
I have a population of 2000 whānau with type 2 diabetes. 850 whānau live with an HbA1c over 80. 500 of this cohort are not prescribed insulin. 450 are not on optimal oral medications The reason for this is varied from whānau driven fear, engagement issues and knowledge; to practice driven – clinical inertia, engagement issues, acute demands overwhelming long term condition management.

Adding two more medications and attaching special authority prescribing does not address any of these issues – it makes life more complicated for the primary health care physicians and the medication only available for those who are in trouble already with their diabetes. We need to ensure these new meds get to the people who need them the most by removing the special authority [redacted].

The health benefits of these new medications are significant for whānau, and the health system in general We know that what we are doing in health right now is not working for Māori – in what way does this special authority going to reduce inequity in outcomes? How does this proposal make it easier for Māori to access medicine that will improve their renal and cardiovascular outcomes? If anything, the increased complexity involved in prescribing these meds is going to increase the inequity Take off the special authority requirement.

At the very least, a way of engaging the myriad of data based systems across the country to highlight when a patient is eligible for these meds would be useful Primary health care prescribers are focused on a huge variety of issues during one 15 minute consultation, an electronic prompt would be useful.

Ngā mihi nui,
Suzanne

Suzanne Moorhouse
Diabetes Nurse Hauraki PHO

Withheld under

Withheld under section 9(2)(a)

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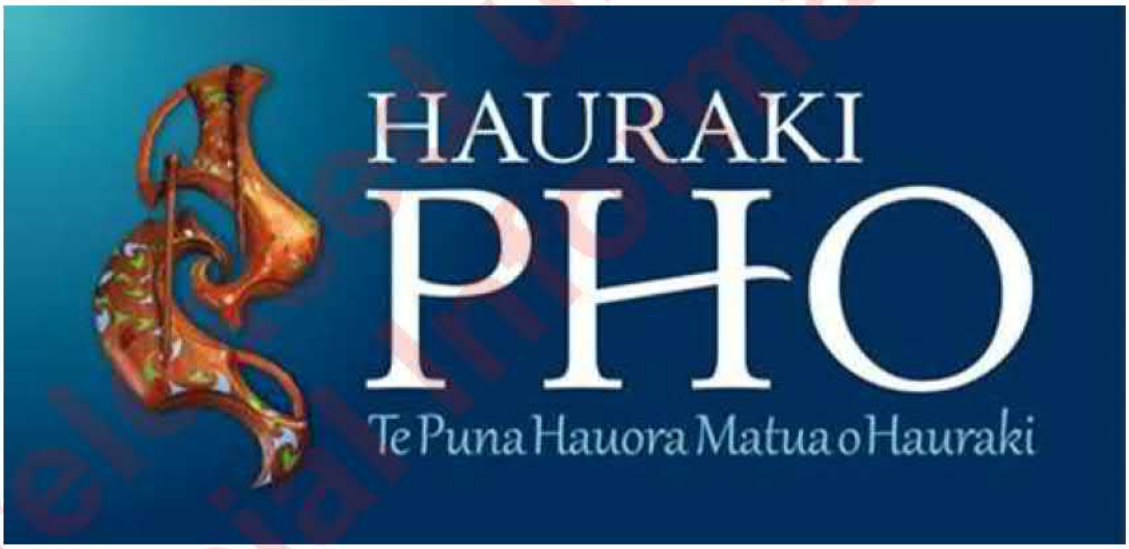

From: Catherine McNamara (WDHB) <[redacted]>
Sent: Tuesday, 15 September 2020 3:47 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

I strongly support the funding of both of these diabetes medications which is long overdue.
Rgds,
Catherine McNamara
Diabetes Consultant Waitemata DHB

Dr Catherine McNamara
MOB: [redacted]

From: Des Healy <Withheld under section 9(2)>
Sent: Wednesday, 16 September 2020 2:28 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

Morena, The focus of my submission is on removing the barriers to accessing the new diabetes medicines that Pharmac is funding, empagliflozin and dulaglutide.

I am a pharmacist who works for both a primary health organisation (WRHN) and as a locum community pharmacist . Part of my clinical pharmacist role involves seeing patients in the community, often in their homes.

Many have complex medicine regimens , polypharmacy , health literacy issues , are in lower socio-economic brackets as well as many Maori and Pasifika. The health barriers in health we talk about exist when these factors are present. Many of these people have type 2 diabetes

I also often work as a community pharmacist so I see from both sides of the "counter". The people I work with who have type 2 diabetes often have poor compliance and poor control over their diabetes despite the support they receive from general practice and pharmacy . Regular blood glucose testing often does not happen even with constant reminders to test, especially for those on insulin or a sulphonyl urea. It is when I do home visits for an MUR (Medicine Use Review) that the full picture is exposed. Excess , unused, expired test strips and medicines due to poor compliance My most common intervention is to reduce the number of dose times a day. Multiple dose times and multiple medicines often results in poor compliance . A good example of a medicine that has made a huge difference in this respect is Galvumet (Vildagliptin/Metformin) , which is why empagliflozin and dulaglutide are important additions to the Pharmac schedule.

As a community pharmacist much time is wasted following up on Special Authority Numbers. You could argue that this is the prescribers responsibility , however the reality is that it is often the pharmacist who has to contact the prescriber , request renewals etc. and then provide the patient with enough medicine until the S.A. number is issued or expiry date renewed. The pharmacist is placed in a difficult position of either charging "NSS" for a small quantity of an expensive drug- something many patients cannot afford or carrying the risk of loaning a quantity until the prescription can be filled– a practice that Medsafe auditors police against. It can at times seem a time wasting bureaucratic process.

The guidelines Pharmac has in place for prescribing are clear and defined , however the requirement to have to apply for a Special Authority Number will creatre more barriers than what exist already and I question whether that is necessary.

Kindest regards

Des Healy
Pharmacist
Whanganui Regional Health Network
100 Heads Road, P O Box 4260, Wanganui 4501
Phone (06) 348 0109 Withheld **Fax** (06) 348 8205 **Web** www.wrhn.org.nz

From: Withheld under section 9(2)(a)
Sent: Thursday, 17 September 2020 9:24 PM
To: Consult <Consult@Pharmac.govt.nz>
Cc: Web Enquiry <enquiry@Pharmac govt nz>
Subject: Consultation feedback: Diabetes medications and other priorities...

I would prefer money went towards funding effective medication for people experiencing problems with the poor substitutes of Lamictal and Efexor Perhaps if I came along to your office with a jackhammer to use throughout the day to give you an idea of what it is like to have a constant headache that happens every time the dose is increased. Perhaps I could pull your leg every so often or sharply pinch it, so you can appreciate how difficult it is to put up with leg cramps All the while try removing sentences from your presentations to other stakeholders, so you are stuck in the middle of one and not in a position to make the point clear as the train of thought left the station some time earlier. How about a strobe light in your eyes at the same time so you might have an idea of what the electric shock sensation is like?

I'm aware of the 'need to talk' line. What I would prefer that Pharmac actually listened, so that the experiences that are an everyday experience for many people affected by funding decisions I am lucky enough to be able to access well qualified professionals to talk to. Unfortunately a lot of people only have second rate pharmacological treatment which has left them unable to effectively function. Not being in a position to apply themselves to paid employment further reduces their chances to access health services that encourage long term wellbeing and remission of their illness

How much does that cost?

I am speaking from a professional perspective also

I'm not happy that we stick labels on medication for people who are not oblivious to the fact that funded medicines are the same as the ones they have previously been taking. 'Same, same but different, might apply to a copy Rolex watch', This however is not always the case with medicines.

Its disappointing that your response is lacking in empathy, acknowledgement of the situation and logic.

Robust is a term I tend to relate to coffee beans vs overseas studies of medicines comparasins. Besides these studies will not take into account genetic variation in populations outside of the countries they were tested in

If I downplayed a customer's experience in the same way, then it's likely I would be reported to my disciplinary body or the HDC.

I wish the same could be applied to your organisation.

Yours in disgust

Withheld

From: pamela campbell <Withheld under section 9(2)(a)>
Sent: Friday, 18 September 2020 11:32 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: Feedback re funding new Diabetes medications

To Whom it may concern

Prior to moving to NZ permanently in 2010, I was Prescribing Diabetes Specialist Nurse in NHS Highland covering a large rural geographical area providing care across the lifespan to people living with Type 1 and Type 2 DM and associated complications in both the hospital and community setting. Since living in NZ I have worked with Youth living with Diabetes and for the past 7 yrs in rural general practice as a PN and more recently as a NP.

Do you support this proposal?

- Absolutely Patients living with Type 2 Diabetes have had a disservice to them in the medications available to them. The proposed medications have been widley used globally for a number of years with demonstrable benefits other than glycaemic control. It is well documented the increasing incidence of diabetes amongst the NZ population and complications from poor control These medications add significantly to the armoury of the HP to reduce risk without associated weight gain from insulins and SU. Although it would be interesting to understand why dapagliflozin wasn't preferred especially with the positive impact it has on HF in patients with and without diabetes

What will help people with diabetes and their whānau access these medicines?
Informed health professionals

What tools or approaches could be useful to support prescribers and people with diabetes?
good resources and once HP begin to use these medications they will gain in confidence

How could we specifically support Māori and Pacific people to access these medicines?
Dulaglutide is ideally suited for Maori and Pacific populations as a weekly medication. Practice Diabetes funding could be utilised to fund appts for patients to attend for PN to administer medications. Healthcare providers for these groups should have access to funding to enable community based clinics to administer if need be until the patients build confidence in administration. It is ideal for rural areas.

Regards

Pamela Campbell

Nurse Practitioner
Rakaia Medical Centre

From: Withheld under section 9(2)(a)
Sent: Friday, 18 September 2020 6:03 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Feedback about 2 new meds

Hello

I am a type 2 Diabetic and fully agree with your plans to fund these two medications.

Thank you
Withheld under
Withheld under section 9(2)(a)
Sent from my iPhone

From: Vanessa <[redacted]>
Sent: Saturday, 19 September 2020 12:50 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: New diabetes meds

I totally support any new medications for diabetes . We are currently very restricted in NZ as to what we can prescribe and with frequent side effects to Metformin and poor renal function of patients , treatment options are often restrictive and from a medical practitioner view point " frustrating "

We desperately need more options I totally support new meds Guidance for usage is important but too much restriction by SA will be unhelpful

Regards Dr Vanessa Fardon MBBS FRNZCGP

Sent from my iPhone

From: Sally Talbot <Withheld under section 9(2)>
Sent: Sunday, 20 September 2020 8:22 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: New medication application

Re
empagliflozin (with and without metformin) and an injectable glucagon-like peptide 1 (GLP-1) receptor agonist, dulaglutide

I support the access of more drugs to treat diabetes in NZ. This disease is a huge problem in our country and to improve equity particularly for Māori & Pacific , we need more effective medications (many have been available in other western countries for some time)

Please make any special authority process simple of minimal , or abolish this barrier altogether

Yours sincerely
DR S E Talbot
GP Fellow

From: Ryan Paul <Withheld under section 9(2)(a)>
Sent: Sunday, 20 September 2020 5:07 pm
To: Peter Murray <Withheld under section 9(2)(a)>
Subject: RE: NZSSD/Matui/PHARMAC meeting yesterday

Hi Peter,

The meeting was very useful thanks and I look forward to working with Pharmac and Matui, and I have already met with Noni. I would not be surprised if you received a lot of feedback on the SA criteria. Personally, I believe that Pharmac have done a good job at basing the criteria on the evidence for those at highest risk. The only high risk group that misses out are our youth with T2D because their 5 year CVD risk will be < 15% because of the issues with CVD risk calculators in younger age groups, despite the fact that they may well have an MI at 40. It would be great if this could be addressed if possible, even by adding a caveat or the patient is < x years of age e.g. 25 or 30 years. As a heads up, as per international guidelines, we will be recommending that best practice is for a SGLT2i or GLP1RA after lifestyle management and metformin. Ideally the SA criteria would then be after 6 months of treatment with metformin and/or an alternative anti-diabetic agent (including insulin). I also believe that you will receive a lot of feedback that as the SA reads, that 6 months of alternative treatment will widen inequities of care because Maaori and Pasifika have reduced access to primary care. Although this is in any way not Pharmac's fault or problem, it is a reality and will affect successful uptake of the new agents. Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Many thanks

Ryan

From: Peter Murray <Withheld under section 9(2)(a)>
Sent: Tuesday, 15 September 2020 11:42
To: Helen.Snell Withheld under section 9(2)(a); Ryan Paul <Withheld under section 9(2)(a)>
Cc: Heather Milne <Withheld under section 9(2)(a)>
Subject: RE: NZSSD/Matui/PHARMAC meeting yesterday

This email is from an external source. Please be careful if opening any attachments or clicking on links within the email

Withheld under

Kia ora rā kōrua Helen and Ryan,

Just wanted to say thank you so much for your time yesterday and apologies that we went overtime.

PHARMAC and Matui got a lot out of the meeting and we really appreciated hearing how we can work together moving forward.

Please do not hesitate to get in contact with me if you have any further feedback or comments about yesterday's meeting or around the consultation
Thanks again and have a good rest of the week.

Ngā mihi

Peter Murray | Deputy Medical Director
_____
___
PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: +Withheld under | P: +64 4 460 4990 | www.pharmac.govt.nz

From: Consult
Sent: Monday, 21 September 2020 9:30 am
To: Withheld under section 9(2)(a)
Cc: Web Enquiry <enquiry@Pharmac govt nz>
Subject: RE: Consultation feedback: Diabetes medications

Kia ora With,

Thank you for your enquiry. At this point the proposal relates to empagliflozin and empagliflozin with metformin (as you note below).

Should the proposal be approved by the PHARMAC Board then both these medicines would be fully funded for eligible people in New Zealand from 1 December 2020.

The combination of empagliflozin and linagliptin was not within scope of the RFP, and would not fall into the category

We will add this to consultation feedback, noting that you would prefer it if empagliflozin in combination with linagliptin was also fully funded.

Ngā mihi nui.

From: Withheld under section 9(2)(a)
Sent: Saturday, 19 September 2020 6:31 PM
To: Consult <Consult@Pharmac govt nz>
Subject: Consultation feedback: Diabetes medications

> Hi, I am a diabetic Type 2 patient. I understand empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet) supplied by Boehringer Ingelheim will be funded starting from 1 December 2020.
> I am seeking clarification whether GLYXAMBI (Empagliflozin, Linagliptin) 25/5MG Tablets falls in the above category. I am dependent on this tablet and would like to know whether it will be available in NZ for me to purchase under Pharmac funding.
> Currently, I am purchasing this from overseas.
> Kind Regards
> Withheld under

Sent from Mail for Windows 10

From: Mary-Ann De La Haye <[redacted]>
Sent: Tuesday, 22 September 2020 8:53 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: Endorsement for funding of two new medicines for type 2 diabetes

Kia ora,

I am confirming my endorsement to the proposal that would result in the funding of two new medicines for type 2 diabetes:

- empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet) supplied by Boehringer Ingelheim, with funding to start from 1 December 2020;
- dulaglutide (Trulicity) supplied by Eli Lilly, with funding to start as soon as practicable following Medsafe approval.

I am a practice nurse/nurse prescriber in a large Hawkes Bay Hauora practice, I have a special interest in diabetes, and run clinics for patients with mainly type 2 diabetes. As many are already overweight, and often on low incomes making healthy kai an ongoing challenge, I believe these new medications will assist patients to manage their diabetes better and reduce their cardiovascular risk/renal damage.

Our practice experiences patients with a genuine equity disadvantage: low health literacy, poor education around their diabetes, left out of patient centred decision making, thus diabetes self-management is challenging. I believe there is also a paucity of health providers able to educate patients to better understand their condition, and to coach behaviour change. (medication adherence/diet/exercise)

Alongside, the provision of more medications, there also needs to be funding/claiming/reimbursement for more health coaches/nurses/psychologists to enable patients to fully embrace their condition to enable the best outcome and efficiency of these medications alongside lifestyle modifications/diet/exercise.

Nga mihi
Mary-Ann

Mary-Ann De La Haye, RGON, nurse prescriber teams and community

Withheld under section 9(2)(a)
wk
mob

From: Withheld under section 9(2)(a)
Sent: Tuesday, 22 September 2020 2:23 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Proposal

I support the new medicine proposal for type2 diabetes. I have been a diabetic type 2 for 10 years now and welcome any advanced medicines that will help my fight against coronary and kidney disease

What will help better access for this medicine is subsidy of these meds. More education with board notices in Pacific languages in GP rooms would assist Pacific patients to learn more of these medicines

Regards
Withheld under

New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

24 September 2020

PHARMAC

By email: consult@pharmac.govt.nz

Proposal to fund two new medicines for type 2 diabetes

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above proposal.

We note that under the proposal, empagliflozin (a SGLT-2 inhibitor) with and without metformin and dulaglutide (a GLP 1 agonist) would be funded for the treatment of people with type 2 diabetes at high risk of heart and kidney complications who meet the proposed Special Authority Criteria. This reflects clinical advice that these treatments provide benefits beyond glycaemic control. For empagliflozin, these include reduced rates of heart failure hospitalisation, all-cause death, progression to macroalbuminuria and initiation of renal replacement therapy For dulaglutide, benefits include a reduction in the rate of major cardiovascular events and progression to macroalbuminuria.

The NZMA strongly supports this proposal The proposed Special Authority criteria for the use of these medicines are broadly aligned with recent guidelines by the American Diabetes Association,[1] although left ventricular hypertrophy is omitted from the definitions of pre existing cardiovascular disease or risk equivalent in PHARMAC's proposed Special Authority criteria. Another point of difference is that the American Diabetes Association states that for patients without established cardiovascular disease, indicators of high risk of cardiovascular disease, chronic kidney disease or heart failure, the choice of a second agent to add to metformin is based on avoidance of side effects, particularly hypoglycaemia and weight gain. We contend that empagliflozin should also be made available for these reasons and ask PHARMAC to amend the proposed Special Authority criteria accordingly

[1] American Diabetes Association. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes. Diabetes Care 2020;43(Suppl. 1):S98 S110. https://care.diabetesjournals.org/content/diacare/suppl/2019/12/20/43.Supplement_1.DC1/Standards_of_Care_2020.pdf

We have been disappointed at the delay in the funding of new diabetes medicines such as empagliflozin. It should be noted that data on empagliflozin showing a reduction in cardiovascular death, as well as total death, and hospitalisation for heart failure was published in the NEJM in 2015,[2] and a second publication in the same journal the following year reported reduced incident or worsening nephropathy [3] In the United States, empagliflozin was approved for reduction in cardiovascular death in 2016 by the FDA.

As PHARMAC notes, the prevalence of diabetes in Māori and Pacific populations is estimated to be around three times higher than among other New Zealanders Furthermore, the occurrence and rate of progression of diabetes complications are notably higher in these populations. The unavailability in New Zealand of medicines such as empagliflozin that have been proven to reduce mortality in patients with type 2 diabetes is lamentable, particularly given the inequities experienced by Māori and Pacific populations. We are very pleased, therefore, that this hitherto unsatisfactory situation is finally being addressed

We hope our feedback is helpful.

Yours sincerely

Dr Kate Baddock
NZMA Chair

[2] Zinman B, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. N Engl J Med 2015 Nov 26;373(22):2117-28.
[3] Zinman B, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. N Engl J Med 2015 Nov 26;373(22):2117-28.

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES
SCHOOL OF MEDICINE

Rinki Murphy
MBChB, FRACP, PhD
Assoc Prof in Medicine

Consultant Physician,
Diabetes Specialist
Auckland District Health Board
Counties Manukau DHB

MAURICE WILKINS CENTRE
FOR MOLECULAR BIODISCOVERY

25 September 2020

Re: Feedback on proposal to fund two new medicines for type 2 diabetes

1. **Do we support this proposal?**

Our multidisciplinary group feedback is summarized as follows, although individuals named below may also be submitting additional feedback. Our preference would be for open access of both of these medicine (discussed under section 2 below)

We are happy with the choice of SGLT2i medication (empagliflozin) and GLP1RA medication (dulaglutide), because both have demonstrated efficacy for reducing CVD events and reducing progression of diabetic kidney disease.

However, the proposed restricted access criteria would benefit from the following key amendment:

Criteria #2: "Patient has not achieved target HbA1c (of less than or equal to 53mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months". Should be amended to " **despite maximum tolerated doses of at least one oral antidiabetic agent with or without insulin for at least 6 months.**"

This would provide more clarity that patients could be eligible for either SGLT2i or GLP1RA as second line medications after metformin in line with international guidelines, rather than necessarily as third line medications after any combination of dual glucose lowering therapies.

2. **What will help people with diabetes and their whanau access these medicines?**

Removing special authority criteria is important because it adds another barrier for receiving guideline care, particularly by Māori and Pacific people who have less access to medications due to multiple reasons. Special authority criteria medication prescribing may require additional primary care and pharmacy visits may further disadvantage vulnerable groups. Not being able to use funded empagliflozin and dulaglutide together in our highest risk patients is not ideal.

Open access to these medications would enable earlier glycaemic control among youth with type 2 diabetes, without the need to wait until microalbuminuria develops to prescribe either one of these medications in this vulnerable group. Pacific, Indian and Māori are over-represented in those who are diagnosed with type 2 diabetes in youth These young adults either have incalculable CVD risk or estimated low CVD risk, but develop complications at a much higher rate. Since other glucose lowering

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THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES
SCHOOL OF MEDICINE

Rinki Murphy
MBChB, FRACP, PhD
Assoc Prof in Medicine

Consultant Physician,
Diabetes Specialist
Auckland District Health Board
Counties Manukau DHB

MAURICE WILKINS CENTRE
FOR MOLECULAR BIODISCOVERY

therapies (beyond metformin and vildagliptin) cause weight gain and carry risk of hypoglycaemia, youth with type 2 diabetes will be particularly disadvantaged by restricted access to these medications contingent on microalbuminuria developing By the use of glucose lowering medications under "cost is a major issue" pathway, we find many youth with type 2 diabetes have already disengaged with type 2 diabetes management due to unacceptable side effects and quality of life and considerable effort will be required to re engage them once microalbuminuria has developed to introduce these additional newer medications

Under restricted access or otherwise, every patient who meets clinical criteria for SGLT2i and GLP1RA, should be systematically identified and receive counselling about these treatments within their first prescription renewal cycle, so these medications can be prescribed appropriately without undue delays

Patient facing resources (eg: posters, pamphlets, video clips), specifically designed for Māori, Pacific and Indian people with type 2 diabetes, describing the benefits of these new medications, correct use and encouraging broader adherence of medication management for type 2 diabetes. This would be a useful addition to standard pharmaceutical pamphlets which are not specifically designed with the needs of New Zealand people in mind.

3. What tools or approaches could be useful to support prescribers and people with diabetes?

Systematic detection of all those patients who are potentially eligible for these medications need to be flagged for appropriate counselling and prescribing. Practice level data queries, use of Testsafe repository, practice management support as well as workflow reorientation, automated texts, group/shared medical appointments, could assist with efficient, systematic and appropriate prescribing of these medications.

While prescribers would benefit from educational guidance on prescribing these medications, through content on accessible platforms such as HealthPathways, additional specialist support eg: through virtual case-study discussions, with various GPs to support prescribing in different patient settings on different background medications could be helpful.

Regular practice level monitoring of the proportion of patients who have been prescribed these medications out of the number who are broadly eligible with feedback to prescribers could help with uptake and systematic efforts to boost this number at a practice level

National monitoring of drug dispensing by ethnicity during the first year to evaluate any potential disparities is important.

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 ack for proposal to fund two new medicines for type 2 diabetes (empagliflozin and dulaglutide)

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FOR MOLECULAR BIODISCOVERY

4. How could we specifically support Māori and Pacific people to access these medicines?

Group visits, shared medical appointments, resources targeting Māori and Pacific people with type 2 diabetes at the practices they attend with a visiting specialist, may help patient and prescriber engagement with new medication starts, outside the time constraints of an individual appointment. Having the input of Māori and Pacific with type 2 diabetes in developing patient-facing resources highlighting the advantages of these new medications to treat type 2 diabetes alongside existing management strategies.

Electronically approved by:

Associate Professor RINKI MURPHY, Diabetologist, Auckland District Health Board, Counties Manukau District Health Board, Principal Investigator Maurice Wilkins Centre

Dr RYAN PAUL, Endocrinologist, Waikato DHB, Senior Lecturer university of Waikato, Executive member of the New Zealand Society for the Study of Diabetes (NZSSD), President of the New Zealand Society of Endocrinology (NZSE), Clinician Associate Maurice Wilkins Centre

Professor WARWICK BAGG, Endocrinologist, Diabetes Clinic Auckland District Health Board, Department of Medicine, University of Auckland

Dr RICK CUTFIELD, Endocrinologist, General Medicine Physician, Waitemata District Health Board, Diabetes NZ Auckland patron

Dr CHRIS HOOD, Nephrologist, Clinical Director Division of Medicine, Counties Manukau DHB

Dr MAYANNA LUND, Cardiologist, CMDHB, Clinical Lead, Northern Region Cardiac Clinical Network

Dr KERRY MACASKILL-SMITH, Mahoe Medical Centre, Te Awamutu, KMS Health, Clinician Associate Maurice Wilkins Centre

GINA BERGHAM (MN, DNS), Nurse Specialist-Diabetes/Designated Prescriber, Community Liaison, Auckland Diabetes Centre

Dr BRANDON ORR WALKER, Endocrinologist, Clinical Head of Endocrinology and Diabetes at Middlemore Hospital, Immediate past president of the New Zealand Society for the Study of Diabetes (NZSSD)

Professor ROB DOUGHTY, Cardiologist, Auckland District Health Board, Heart Foundation Chair of Heart Health, University of Auckland

Dr JANAK DE ZOYSA, Nephrologist and Clinical Director Renal services, Waitemata District Health Board, Clinician Associate at Maurice Wilkins Centre

Dr OLE SCHMIEDEL, Endocrinologist, Service clinical director of Auckland Diabetes Centre, ADHB

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C: ack for proposal to fund two new medicines for type 2 diabetes (empagliflozin and dulaglutide)

From: Withheld under section 9(2)(a)
Sent: Sunday, 27 September 2020 3:17 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

This medication showed a significant reduction in CV events in risk patient. I fall in this group and would benefit from this as would many other patients sharing this risk profile

I suggest a look at this just published in the Journal of the American Heart Association
Short-Term Changes in Albuminuria and Risk of Cardiovascular and Renal Outcomes in Type 2 Diabetes Mellitus: A Post Hoc Analysis of the EMPA-REG OUTCOME Trial

Withheld under

PASIFIKA MEDICAL ASSOCIATION GROUP

22 September 2020

Mr. Steve Maharey
Chairman
PHARMAC
Wellington

Tēnā koe Steve Maharey,

The Pasifika Medical Association strongly supports the proposal by PHARMAC to fund two new medicines for Type 2 Diabetes (T2DM);

- Empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet) supplied by Boehringer Ingelheim, with funding to start from 1 December 2020;
- dulaglutide (Trulicity) supplied by Eli Lilly, with funding to start as soon as practicable following Medsafe approval.

The proposal also includes amendments to the price and contractual arrangements with Novartis for vildagliptin (Galvus) and vildagliptin with metformin (Galvumet) from 1 December 2020. These treatments are already, and would continue to be, funded without restrictions.

Funding these additional medicines would significantly improve the options available to doctors treating people with T2DM. It will improve the quality of care for people with T2DM, especially Pacific and Māori New Zealanders who are disproportionately affected by T2DM with poor outcomes Improving patient care will reduce chronic inequities in health in Aotearoa/New Zealand.

Background

Type 2 Diabetes Mellitus (T2DM) is extremely common among Pacific (and Māori) people of Aotearoa/New Zealand. Population estimates suggest that the prevalence

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of T2DM is highest among Pacific people. Approximately, 10% of Pacific New Zealanders have T2DM and a further 10% have Impaired Glucose Tolerance. T2DM is approximately three times more common among Pacific people compared with non-Māori, non-Pacific (NMNP) New Zealanders.

The prevalence of T2DM among Pacific people in Aotearoa/New Zealand reflects similar rates of the disease in their home islands. In some cases, more than half the adult population in the Pacific Islands Countries and Territories (PICTs) have T2DM. It is generally accepted that the rising levels of T2DM and other Non-communicable Diseases (NCDs) among Pacific populations reflects changing diets and reduced physical activity levels.

It is essential for Aotearoa/New Zealand to invest in effective T2DM and other NCDs prevention programmes alongside improving access to medicines.

The NZ Health Quality and Safety Commission (NZHQSC) has produced the Atlas of Health Care Variation for common conditions in Aotearoa/New Zealand. The Atlas shows considerable variation in the prevalence and complications from T2DM between District Health Boards (DHBs) The Atlas also shows considerable variation in the quality of care provided to people with T2DM

The prevalence of T2DM increased significantly with age, from a mean of 0.3 percent in those aged 0–24 years to 17 percent in those aged 75 years and older In 2018, diabetes prevalence varied two-fold by District Health Board (DHB), from 9–25 percent of a DHB population aged 65–74 years and more than three-fold in those aged 45–64 years (4–15 percent)

T2DM remains under-diagnosed in Aotearoa/New Zealand. Studies suggest that there are other undiagnosed people with T2DM for every person diagnosed with the disease. Under-diagnosis is a particular concern among Pacific (and Māori) New Zealanders. A sample of over 4,700 people found higher rates of undiagnosed diabetes in Pacific peoples (6.4%), compared with Māori (2.2%) and New Zealand European and Others (1 5%) 1

The problem is complicated by the occurrence of impaired glucose tolerance (pre-diabetes) which often precede T2DM by several years People with prediabetes are also at increased risk of complications such as microvascular disorders.

Opportunistic screening for diabetes has often detected large numbers of people with undiagnosed diabetes. Opportunistic screening is not ideal because many people diagnosed with T2DM are not followed up.

A significant proportion of people with T2DM in Aotearoa/New Zealand are not receiving high quality care. Pacific people in particular with T2DM are more likely to be undertreated for their condition and as a result, they show high rates of complications such as renal failure, heart disease, blindness and microvascular diseases.

Māori and Pacific peoples have a higher rate of Angiotensin-Converting Enzyme Inhibitors (ACEI) or angiotensin receptor blockers (ARB) medicine use at a younger age, however some data also shows these populations have significantly higher rates of end-stage renal disease. A recent publication found Māori and Pacific peoples have a relative risk of 6 48 for developing end-stage renal disease due to type 2 diabetes compared with other New Zealanders (2)

Compared with New Zealand Europeans, Pacific peoples in New Zealand develop type 2 diabetes at a higher rate and a younger age, and have 3.8 times higher incidence of end-stage renal disease (ESRD) More than two thirds of Pacific ESRD is due to diabetes compared with just more than one third in New Zealand Europeans. Furthermore, diabetes and ESRD are increasingly being seen across multiple successive generations of Pacific families (3).

Figures 1 and 2 show the number of people on dialysis by prioritised ethnic group at Counties Manukau DHB as at the end of August 2020 More than half of all dialysis patients are Pacific people. The demand for dialysis at CMDHB continues to grow in an unsustainable manner.

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Figure 1. Total numbers of patients on dialysis by ethnic group at CMDHB, August 2020.

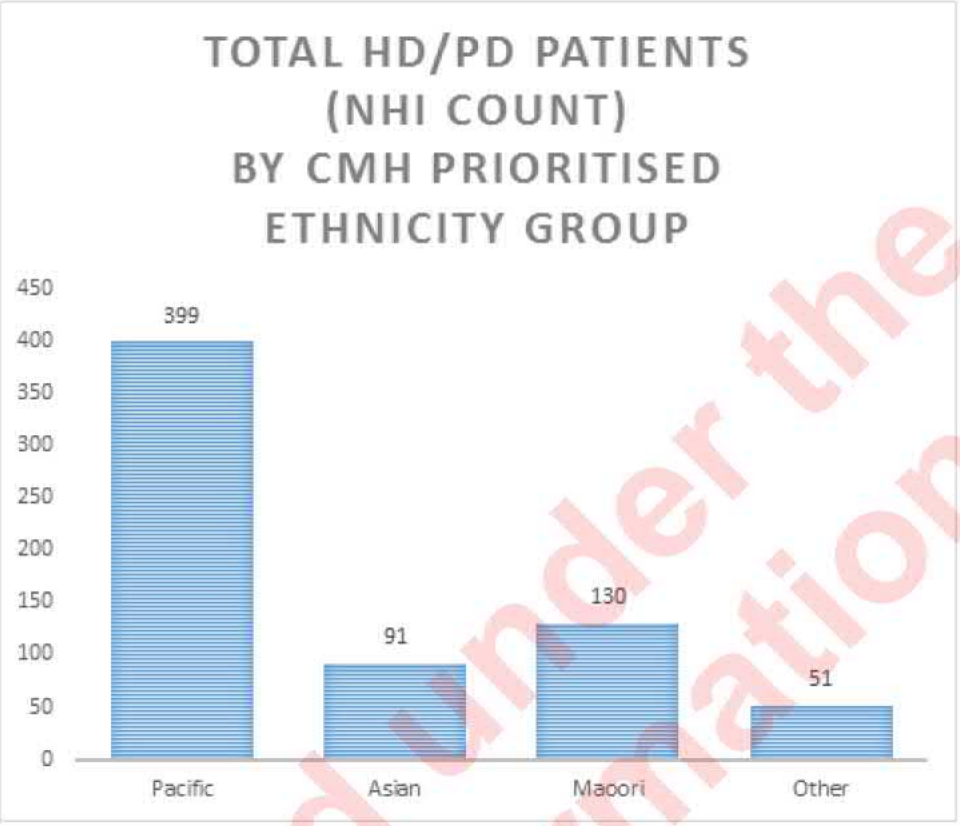
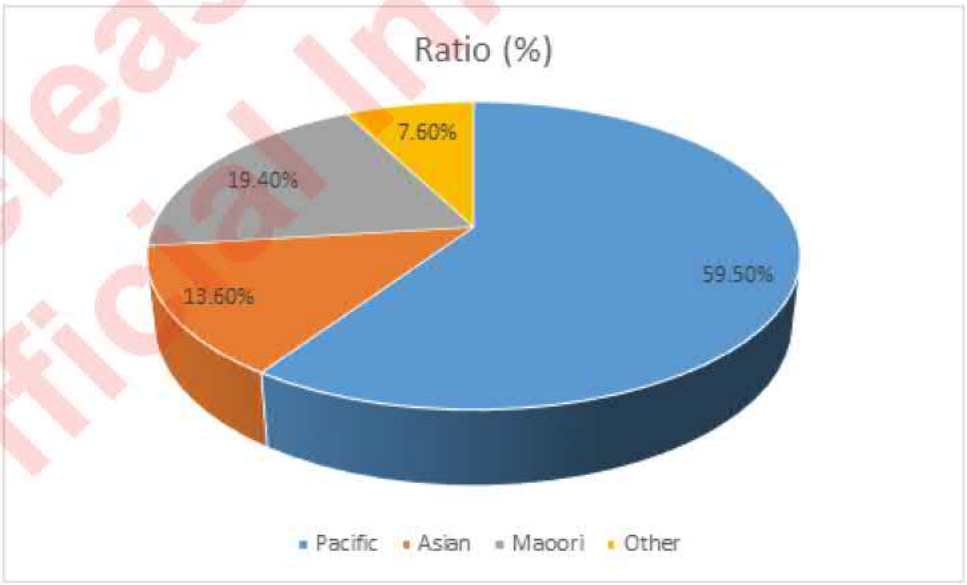


Figure 2 Patients on renal dialysis by ethnic group, AMDHB August 2020



People of Māori, Pacific and Asian ethnicities with diabetes occupied significantly more bed-days than those in the European/other ethnic group – 26 percent on average compared with 15 percent. The percentage of bed-days occupied by people with diabetes increased with age. There was a peak in the 65–74-year age group and the differences between ethnicities are highlighted; for example, 49 percent of bed-days were occupied by Pacific peoples compared with European/other at 20 percent.

Summary

T2DM is a major public health problem in Aotearoa/New Zealand especially among vulnerable groups such as Pacific and Māori people. The burden of morbidity and mortality caused by T2DM among Pacific and Māori people continues to grow with considerable social and economic costs to affected individuals, their families, communities and the nation.

T2DM among Pacific and Māori New Zealanders is frequently under-diagnosed and under-treated. As a result, complications from T2DM such as kidney failure needing dialysis and blindness are common among Pacific and Māori people. Health care demand for T2DM continues to grow in an unsustainable manner

Funding for new medications proposed by Pharmac will improve the care of people with T2DM and reduce complications such as kidney failure needing dialysis and blindness needing expensive eye treatments Improvements in the quality of care for Pacific and Māori people will reduce the overall cost of health care to Aotearoa/New Zealand and reduce inequities in health between Pacific and Māori people, and other New Zealanders.

Sincerely,

Signed
Dr Colin Tukuitonga
PMA Life Member

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References

1. Coppell KJ, Mann JI, Williams SM, et al. Prevalence of diagnosed and undiagnosed diabetes and prediabetes in New Zealand: findings from the 2008/09 Adult Nutrition Survey. N Z Med J 2013; 126:23–42

2 Hill K, Ward P, Grace BS, et al 2017 Social disparities in the prevalence of diabetes in Australia and in the development of end stage renal disease due to diabetes for Aboriginal and Torres Strait Islanders in Australia and Māori and Pacific Islanders in New Zealand *BMC Public Health* 17(1): 802

3. Schmidt-Busby J, Wiles J, Exeter D et al. Understandings of disease among Pacific peoples with diabetes and end-stage renal disease in New Zealand. Health Expectations 2019 22 (5) 1122-1131.

TE OHU RATA O AOTEAROA
MĀORI MEDICAL PRACTITIONERS
TeORA

28 September, 2020
Pharmac Consultation Committee
PHARMAC
PO Box 10254
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consult@pharmac govt nz

Steve Maharey (PHARMAC Board Chair) Withheld under section 9(2)
Sarah Fitt (PHARMAC CE) - Withheld under section 9(2)(a)
Mr Bill Kaua (PHARMAC kaumatua) Withheld under section

Re: Proposal to fund two new medicines for type 2 diabetes - empagliflozin and dulaglutide

Thank you for the opportunity to provide feedback on the proposed funding of two new classes of type 2 diabetes medications. We support the availability of sodium glucose co-transporter 2 (SGLT-2) inhibitors and glucagon like peptide 1 receptor (GLP 1) agonists in Aotearoa (NZ) Te ORA fears however, that this will exacerbate inequity for Māori (and other marginalised groups) because, as we all know, privileged groups uptake new opportunities first and marginalised groups lag behind We should do everything possible to avoid this outcome.

We note that SGLT 2 inhibitors have been available globally since 2012 with the first receiving approval by Medsafe Aotearoa in June 2013. Similarly, GLP-1 agonists have been an option in diabetes management internationally for more than a decade, and in New Zealand to those who can afford to pay for it. We understand that applications to PHARMAC for these diabetes agents has occurred since at 2007 and we welcome this present move

But we understand that the proposal is to have these medications on Special Authority. This will exacerbate distancing of Māori patients to reasonable accessing of such medications It is like the BMI>35 excluding Māori from renal transplant, that is, it is a part of the structural bias that creates and perpetuates inequity by ethnicity We would therefore we recommend the proposal removes the Special Authority criteria that pertains these medications.

We also recommend PHARMAC to:

- Extend prescribing of empagliflozin and dulaglutide to nurse prescribers, pharmacy prescribers and nurse practitioners;
- Fund the dual prescribing of empagliflozin and dulaglutide;
- Develop a proactive plan to support prescribing in Māori and Pacific communities;
- Monitoring and reporting on the prescribing of these medications by ethnicity;
- the addition of equity member(s) on future PTAC clinical advisory group(s)

Our support for PHARMAC moving to making these medications available is unquestioned. But we very much urge a pro-equity approach be taken such that we do not inadvertently create new inequity by leaving those with highest prevalence of diabetes and worst clinical outcomes behind.

Heoi te kupu,

Prof David Tipene-Leach
Chair

Kidney Health NEW ZEALAND
Prevention • Support • Research

28 September 2020

To whom it may concern
Pharmac

Tēnā koe Sir/Madam

Support for funding of empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet) supplied by Boehringer Ingelheim, with funding to start from 1 December 2020; and dulaglutide (Trulicity) supplied by Eli Lilly, with funding to start as soon as practicable following Medsafe approval, from Kidney Health NZ

I am writing on behalf of Kidney Health New Zealand to provide the organisation's strong endorsement for proposal to fund empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet) supplied by Boehringer Ingelheim, with funding to start from 1 December 2020; and dulaglutide (Trulicity) supplied by Eli Lilly, with funding to start as soon as practicable following Medsafe approval

It is noted that clinicians have stated that these drugs separately and combined can have the effect to keep patients off dialysis for a further 15 years, http://www.voxy.co.nz/health/5/371792

For both diabetic/kidney patient this becomes a vital (group of) therapy(ies) for our patient communities.

KHNZ is the national organization that supports people with kidney disease We provide education for people with or at risk of kidney disease via a phone line, online education resources, written materials, talks to groups. We provide support and education for primary care health professionals about detection and management of kidney disease in their patients. We participate, as renal patient advocates, in national groups/forums for stakeholders to address issues around kidney diseases, NRAB, National Renal Transplantation service, DHBs, Ministry of Health.

For these reasons we strongly support the introduction of Jardiamet and Trulicity.

Nga mihi nui

Michael k Campbell

Michael Campbell
General Manager
Withheld under section 9(2)

Kidney Health New Zealand
Prevention • Support • Research
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29 September 2020

Re: Feedback on proposal to fund two new medicines for Type 2 diabetes

The New Zealand regional committee of the Cardiac Society of Australia and New Zealand, the Cardiac Network and the Heart Foundation of New Zealand welcome the funding of SGLT 2 inhibitor medication (empagliflozin) and GLP 1 agonist medication (dulaglutide) in New Zealand for Type 2 diabetes.

With the burden of Type 2 diabetes and cardiovascular disease falling unequally on Māori and Pacific people in New Zealand funding of these agents (in particular SGLT 2 inhibitor medication) provides a significant opportunity to improve equity in cardiovascular health in Aotearoa. We believe the benefit on reduction of cardiovascular events and the progression of renal disease will not be fully realised with the proposed restricted access criteria which we do not support.

The following proposed special authority criteria in particular is of concern to us given the benefit of SGLT 2 inhibitor medication with respect to patient characteristics as opposed to glycemic control.

Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months

This is inconsistent with international best practice guidelines and will deny many New Zealanders with type II diabetes, at high cardiovascular risk, access to these potentially lifechanging medications.

We are also concerned the use of restricted access criteria will increase, not decrease, inequity in cardiovascular health. The requirement for special authority approval adds another barrier for receiving care, particularly for high risk populations who frequently have less access to primary care and medications for multiple complex reasons.

In conclusion the New Zealand regional committee of the Cardiac Society of Australia and New Zealand, the Cardiac Network and the Heart Foundation of New Zealand welcome the funding of SGLT-2 inhibitor medication (empagliflozin) and GLP 1 agonist medication (dulaglutide) in New Zealand for Type 2 diabetes We do not support restricted access and recommend the following:

In line with international (EASD/ADA 2018, ESC/EASD 2019) evidence based guidelines, SGLT 2 inhibitors and GLP-1 agonists should be freely accessible to all New Zealand patients with Type 2 diabetes who meet the clinical indications for these drugs

Yours sincerely,

Gerry Devlin, Chair NZ Cardiac Network & Medical Director Heart Foundation
Michael Williams, Chair NZ Regional Committee, Cardiac Society Australia & NZ

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From: Withheld under section 9(2)(a)
Sent: Wednesday, 30 September 2020 10:14 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation feedback: Diabetes medications

I am a recently diagnosed Type 2 Diabetes patient who has been using metformin for the past 12 months. I am supportive of medicines being available which reduce the frequency of dosage, such as dulaglutide I am supportive as it creates fewer opportunities to miss dosages, thereby reducing stress and associated health concerns for patients.

I am aware of people who are ashamed to talk about diabetes in their family as the implication is that people are not looking after themselves properly- which is not true in many cases. As a healthy male Māori I have been able to improve my diabetic lifestyle through increased exercise and improved dietary habits, but this was not because of the information provided by the medical professionals I have seen- this information was too generic and vague to provide me with the direction and rational I needed to adjust my lifestyle. I was abe to find effective information through consultation with exercise specialists, and pharmacists upon receiving my medicines.

I think more specific focus needs to be placed on identifying and implementing solutions which reflect cultures and communities at risk in New Zealand. This should include seeing faces who represent these communities, presenting the information in a context and manner that is relatable.

Ngā mihi,

Withheld under section 9(2)(a)

Sent from Mail for Windows 10

Paediatric Society New Zealand

NZCYCN New Zealand Child & Youth Clinical Network

30 September 2020

PHARMAC

Re: Feedback for PHARMAC proposal on emagliflozin and dulaglutide.

We are writing in our capacity as the National Clinical Network on Diabetes, which is funded through the Ministry of Health and is managed via the Paediatric Society of New Zealand. The clinical network is represented by nurse specialists, dietitians, paediatric endocrinologists, general paediatricians, psychologists and community representation via Diabetes New Zealand Specifically, our national group represents the multidisciplinary team that look after young people with all types of diabetes, including type 2 diabetes.

We are providing feedback based on two themes:

1. Young people with type 2 diabetes that have sub-optimal glycaemic control have a very high lifetime risk of developing cardiovascular and kidney complications, and the current eligibility criteria do not address this issue
2. Youth with type 2 diabetes are disproportionally represented by Māori and Pacifica, and the eligibility criteria will drive inequity in this group by failing to aggressively treat type 2 diabetes and preventing cardiovascular and kidney complications

Do we support the proposal?

We do not support the proposal as it is currently written. In the opening statement, PHARMAC suggested that inclusion of these two medication should be "Restricted to people with T2 diabetes who are high risk of heart and kidney complications." However, due to the requirement of inclusion criteria 6.1 OR 6.2 OR 6.3, young people with type 2 diabetes are unlikely to be eligible. This is despite current literature that documents glycaemic control in type 2 diabetes during adolescence deteriorates faster than in adults with complication rates occurring earlier and higher mortality. Therefore, all young people diagnosed with type 2 diabetes are at the highest lifetime risk of developing heart and kidney complications because they have the longest duration of disease in front of them. Accordingly, international type 2 diabetes guidelines emphasize early and aggressive management of hyperglycaemia to prevent this eventuality The inclusion criteria currently would not allow access to these medications in order to prevent disease. We acknowledge that longitudinal data in paediatrics is limited, especially for the SGLT2 inhibitors; nevertheless, their use is advocated in guidelines, but with a low level of evidence at this stage due simply due to the lack of follow-up data that is yet to be published We propose that for any young people with type 2 diabetes who are not able to reach the HbA1c target of 53mmol/mol using current schedule medications, these pharmaceuticals should be accessible due to the very high long term cardiovascular and kidney complications A reasonable compromise would be to have a short period of time to document renewal of special authority requirements based on improvement on glycaemia

We argue that the life time benefit for the individuals and the benefit to the country is not captured in a 5 year risk model in the context of youth with T2 diabetes.

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What will help people with diabetes and their whanau access these medicines?

When we consider the paediatric population with type2 diabetes, the eligibility criteria as currently written would be near impossible to meet. Further, with evidence that our Māori and Pacific people have higher rates of kidney complications places, the eligibility criteria as currently written will promote health inequity, where those with higher socio-economic status (usually NZ European) may be able to fund the medications and prevent complications, where those with the most to gain remain unable to access them.

What tools or approaches could be useful to support prescribers and people with diabetes?

In youth we suggest accommodating eligibility criteria, with early review for renewal, to ensure that expected outcomes are being reached that will translate in to long-term clinical benefit. For example, eligibility criteria could be added as: OR 6 4 youth aged 16 years and under with an HbA1c >53mmol/mol

How could we specifically support Māori and Pacific people to access these medicines?

Similar to above, eligibility criteria should target youth who are Māori and Pacific due to the very high rate of cardiovascular and kidney complications they are likely to develop due to the long life course they have with type 2 diabetes Published New Zealand data shows that 80% of youth diagnosed with T2D are Māori or Pacifica. Data shows that Māori adults with T2 diabetes have unequal access to quality of diabetes care despite the higher rate of complications We need early intervention to address this inequity and therefore we argue that all youth with type 2 diabetes should be eligible. Currently, this does not represent a large amount of people – for example for 16 years and under, it is likely to be < 20 who would meet criteria (ignoring 6.1, 6.2, and 6.3).

In summary, managing youth with type 2 diabetes is challenging for a host of reasons and have the highest lifetime risk of developing complications. The current criteria promote health inequity and have missed a critical window of intervention. We encourage modification of the eligibility criteria to include young people due to that risk, but suggest early review to ensure the addition of these medications equates to a meaningful improvement in glycaemia that is associated with reduced risk.

Thank you for the opportunity to comment on this proposal. We look forward to receiving your response.

Kind regards

Dr Martin deBock
Chair, New Zealand Clinical Network for Children and Young People with Diabetes

From: Pauline Sanders <Withheld under section 9(2)(a)>
Sent: Wednesday, 30 September 2020 10:53 pm
To: Consult <Consult@Pharmac.govt.nz>
Cc: Hina Lutui <Withheld under section 9(2)(a)>; Charlotte Harris <Withheld under section 9(2)(a)>; Carol Ennis <Withheld under section 9(2)(a)>; Ajay Makal <Withheld under section 9(2)(a)>; Daniel Calder <Withheld under section 9(2)(a)>; Rawirimj Withheld under ; Allan Moffitt <Withheld under section 9(2)>; Gabrielle Lord <Withheld under section 9(2)(a)>; Kate <Withheld under section 9(2)(a)>; John Baker (MM Clinical Trials) <Withheld under section 9(2)(a)>
Subject: PHARMAC Proposal to fund two medicines for type 2 diabetes_FEEDBACK Metro Auckland Primary Healthcare Organisations
Importance: High

Kia Ora, Talofa lava, Malo e lelei, Kia Orana, Fakaalofa lahi atu, Bula Vinaka, Namaste, Ni hao,

Thank you for the opportunity to provide feedback on the PHARMAC proposal to fund first world diabetes medicines in NZ.
Please find attached the collective response from the seven Metro Auckland Primary Healthcare Organisations

Diabetes is a major health issue in NZ that has seen a significant increase in the incidence and complications over the last 10 years.
Significant health inequities from diabetes are experienced, particularly, by Maori, Pacific people and those living in high deprivation.
This is of particular importance in Auckland due to the high number of people with diabetes.

PHARMAC has the opportunity to provide a key element in the response to diabetes management which will significantly improve quality and length of life for many communities.

We look forward to working with PHARMAC to ensure we achieve equity of access to medicines for people with diabetes and also for prescribing clinicians.

Nga mihi nui, Ia Manuia

The Metro Auckland Primary Healthcare Organisations

Pauline Fuimaono Sanders ***RN, BN, MPP***
Nursing Director
ALLIANCE HEALTH+
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25 September, 2020

Pharmaceutical Management Agency (PHARMAC)
Te Pātaka Whaioranga
consult@pharmac.govt.nz

To whom it may concern,

Re: Proposal to fund two new medicines for type 2 diabetes.

The seven Primary Health Organisations in the Metro Auckland Region would like to thank you for the opportunity to provide feedback on the PHARMAC proposal to fund two new treatments for type 2 diabetes – empagliflozin, empagliflozin with metformin and dulaglutide. As stated, the funding of both treatments would be restricted to people with type 2 diabetes who are at high risk of heart and kidney complications. The proposal also includes amendments to the price and contractual arrangments for vildagliptin and vildagliptin with metformin which would continue to be funded without restrictions.

We support the availability of these medicines as they have been established as standard care to treat type 2 diabetes in first world countries These medicines improve life expectancy, slow progress of diabetes kidney disease and have minimal side effects that patients commonly experience presently which include weight gain, hypoglycaemia and gastrointestinal upset The new medicines remove the need for finger prick blood glucose monitoring as there is no risk of hypoglycaemia. Overall, this makes the treatment of type 2 diabetes easier to administer, easier to adhere to with long term health and life benefits for people with type 2 diabetes

This is significant for New Zealand as more than 250, 000 people have diabetes and for the most part type 2. Diabetes is not evenly distributed in the population, instead there are greater number of Māori, Pacific and South Asian people that are affected The number of people with diabetes is continuing to rise and has fast become one of the key drivers for health inequity.

We *do not* support the narrow restrictions that are being proposed to access these medicines. The proposed restrictions support inequitable access to medicines, particularly for Maori, Pacific and people living in high deprivation and inequitable access for prescribing clinicians in Aotearoa. These reasons are outlined below.

1. Equitable access to medicines for populations most affected by diabetes in Aotearoa

PHARMAC [1] refers to achieving equitable access to medicines in relation to the health need/burden of disease PHARMAC highlights there are significant barriers in accessing and utilising medicines for certain groups, particularly, Maori, Pacific people, those living in high socioeconomic deprivation and rural/isolated areas and people from former refugee backgrounds. This is reflected in the incidence of diabetes as Maori and Pacific populations are disproportionately affected in Aotearoa, are less likely to be prescribed and dispensed insulin and are more likely to be affected by complications of diabetes including end stage renal disease, lower limb amputation.

A summation of data for Maori, Pacific people and those living in areas of high deprivation, in particular, are outlined below:

- Diabetes disproportionately affects Pacific, Indian and Maaori, with 15% of Pacific peoples 15 years and over affected compared with 12% of Indian, 9% of Maaori and 5% of NZ European or other[2].
- High socioeconomic deprivation increases risk substantially, with 12% prevalence of diabetes in the most deprived quintile versus 3% in the least deprived quintile[2]
- When standardised for age, ethnic disparity also exists for diabetes control, with Pacific and Maaori considerably more likely to have an HbA1c ≥75 mmol/mol than NZ European/other (41%, 37% and 23%, respectively)[2].For many people this poor control lasts for years.
- Maaori and Pacific peoples with poorer control are less likely to be dispensed with insulin than European/other For example 44% of Pacific patients and 48% of Maaori with an HbA1c of ≥75 mmol/mol receive insulin, versus 60% of European/other. A similar pattern is seen at a lower HbA1c with Pacific people with diabetes typically 30-40% less likely to receive insulin than European/other in most HbA1c bands from 50 54 upwards[2].
- Maaori and Pacific patients with type 2 diabetes are disproportionately affected by complications, such as end stage renal disease[3] and lower limb amputations[4]
- It could be argued that metformin extended release should also be funded in NZ, on the basis of equity. Maaori and Pacific patients in NZ have lower adherence to metformin than Asian, and European and other ethnicities[5] While the reasons for this need to be explored, the extended release metformin can modestly increase adherence[6], and is better tolerated.
- Further evidence can be found in 'A New approach to the management of type 2 diabetes' by the Diabetes Foundation of Aotearoa, Dr John Baker – PHARMAC submission [8]

There is a clear correlation between poorly controlled diabetes and complication rates Individuals with poorly controlled diabetes risk developing blindness, heart disease, stroke, renal impairment and in some cases limb amputations. These complications have a negative impact on the individual, their whanau and our society as a whole As an example, diabetes is the most common cause for patients requiring dialysis in New Zealand. The direct cost associated with dialysis for one person is approximately $55,000 per year. The indirect costs add to this, when considering reduced ability to work and reduced life expectancy Further support by Dr Rick Cutfield, Endocrinologist and General Physician, can be found in the NZ Doctor 19 June 2019 article [7].

The PHARMAC consultation paper states 'We estimate that around 50,000 people per year would be eligible for treatment under the proposed Special Authority criteria for these

agents'. Therefore, the proposed restrictions would result in only one out of every five patients being eligible for the new medicines This means that the current old regime (metformin IR, sulphonylurea, & insulin) would remain as standard treatment for 80% of patients. These medicines are not expensive. This treatment regimen cannot be found in any other first world country, and is now only recommended for developing countries This is not acceptable and is contributing to the health inequities that we currently experience, in particular, for Maori, Pacific and South East Asian people

Overall, in Auckland there has been little improvement of HbA1c control over the last 10 years therefore, a whole new approach is required. PHARMAC [1] recognises that standardising the approach may worsen equity if it does not allow adaption to groups to achieve the same outcome. The proposed restrictions do not align with the priority groups PHARMAC has outlined or the application of equity to achieve the same outcomes A strong, action-focused commitment to providing effective pharmaceutical tools is one way that PHARMAC can significantly contribute to this important health issue.

2. Equitable access to medicines for prescribing clinicians in Aotearoa

Type 2 diabetes can largely be managed entirely in primary care and in doing so will result in every patient experiencing substantial improvement in quality of life and lifespan from these medicines Currently, the majority of diabetes care does take place in the community and this is where our NZ diabetes strategy will either succeed or fail. However, this relies on appropriate investment in the treatments that allow us to do so.

At present, GPs and practice nurses are trying to manage diabetes with patients using a very limited array of sub-optimal medications. Other countries with healthcare systems comparable to ours have successfully introduced these additional pharmaceutical options Clinicians in Aotearoa are restricted to fewer options, unless the patient is able to self-fund.

Also, imposing restrictions through the proposed special authority process would mean potentially increasing the workload for our secondary care colleagues. This supports the status quo of secondary care only being able to start medications and for a select sub-group of people with diabetes and established renal and cardiac complications As stated before, we need to *change the approach to change the outcome*.

Enabling primary care to prescribe modern, first world diabetes treatments is a cost-effective way of reducing the burden on other parts of the healthcare system. The proposed restrictions, using the current criteria, would require an application for a special authority for each individual patient to access the new medicines The current criteria places prescribing primary care clinicians in a challenging ethical dilemma. Four out of five patients

will be told they are not eligible for gold standard diabetes care in New Zealand. This is inequity at a system level.

Primary healthcare is well positioned to support the care and management of people with diabetes. However, this can only be as effective the tools that are available. We support New Zealand coming into line with the diabetes medications available in other first world countries. We also request the criteria with which to use these pharmaceutical tools are aligned with the needs of the population. Specifically, the populations that experience significant health inequities related to diabetes

We recommend a review of how these medicines are accessed to achieve equitable access for prescribing clinicians and the populations they serve

We look forward to continued engagement with PHARMAC to ensure the communities that are most affected by diabetes receive treatments that will improve quality and length of life for themselves and their whanau.

Yours sincerely,

The Metro Auckland Primary Healthcare Organisations

Pauline Fuimaono Sanders *Nursing Director, Alliance Health Plus Trust*	Dr Hinamaha Lutui *Clinical Director, Alliance Health Plus Trust*
Dr Charlotte Harris *Clinical Director, Auckland PHO*	Carol Ennis *Clinical Quality Manager, Auckland PHO*
Dr Ajay Makal *Clinical Director, Comprehensive Care*	Dr Daniel Calder *Clinical Director, East Health Trust*
Dr Allan Moffitt *Clinical Director, ProCare*	Gabrielle Lord *Nursing Director, ProCare*
Dr Rawiri Jensen *Clinical Director, National Hauora Coalition*	Kate Moodabe *General Manager, Total Healthcare PHO*

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Diabetes Foundation Aotearc

Aotearoa College of Diabetes Nurses
NZNO

30 September 2020

To whom it may concern
PHARMAC

On behalf of the Aotearoa College of Diabetes Nurses the committee would like to provide feedback on the Pharmac Proposal to fund two new medicines for type 2 diabetes.

We whole heartedly agree with the funding of these two medications which have shown in landmark clinical trials to make a difference to health outcomes by reducing death from cardiovascular disease, reduced worsening kidney disease, reduced hospitalisations from heart failure and reduced all cause mortality in people with type 2 diabetes. They have been second line treatment for several years for people with type 2 diabetes in Europe and the United States

We would like to make some comments around the ability to prescribe these new glucose lowering agents

- Equitable diabetes care - we recommend that all people with type 2 diabetes have access to these drugs and that this does not have special authority criteria attached. The high risk population groups including Maori, Pasifika and South East Asian people will be disadvantaged if these cannot be used with open access. Due to barriers in accessing diabetes care both in primary and secondary settings many of these high risk patients do not reach maximum oral treatment/insulin titration effectively. Open access would make it easier for these patients to start treatment early with these proposed medications
- The criteria of "Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months" implies that the patient would need to be on more than one oral agent and/ or insulin to be eligible to go on an SGLT 2 inhibitor or GLP 1 agonist. International guidance (ADA & EASD 2018 Management of Hyperglycaemia in Type 2 Diabetes) states that GLP-1 agonists and SGLT-2 inhibitors are recommended as second line medications in most instances (after Metformin) above other oral agents such as sulfonylureas, glitazones, DPP-4 inhibitors and also insulin Given this is best practice, we should follow this guideline, and not expect patients to commence medications that are considered to be less effective than the use of SGLT 2 inhibitors and GLP 1 agonists

- We would also recommend that Registered Nurse Prescribers and Nurse Practitioners be able to use special authority if this criteria remains These nurses regularly see patients for diabetes assessment and on going diabetes education and are in a prime position to prescribe these medications. If special authority is granted to these nurse clinicians a barrier would be

removed so improving patient care for this long term condition The Nursing Council of New Zealand would have to approve and update the Registered Nurse Prescribing medication list for these two new agents but we are hopeful this will happen as feedback for prescribing new agents is currently being assessed by Nursing council.

- Education about the use of the new diabetes medications is required both for primary care and nurse prescribers to overcome the clinicial inertia in prescribing medications to improve diabetes control, reduce poor health outcomes and reduce and improve complications from diabetes. Utilising the diabetes nurse workforce will enable prescribing of these medications to occur more quickly to the right patients Often patients seeing a diabetes nurse who is able to prescribe, do not have to pay for this privilege which reduces the barriers for patients being seen by them This would enable Maori and Pacific people to access these medications more readily. Education should be free to nurse prescribers, and done face to face or via webinar
- For Maori and Pacific people to be able to access health professionals able to prescribe these medications for free would benefit these patients.

Thank you for giving consideration to our comments. We feel strongly that open access would remove patient barriers to treatment, improve adherence and increase equity for these high risk patients.

Regards

Roberta Milne
Chairperson
ACDN committee

From: John Baker <[redacted]>
Sent: Thursday, 1 October 2020 7:38 am
To: Consult <Consult@Pharmac.govt.nz>; [redacted]
[redacted]
Subject: Feedback on proposal to fund new drugs for diabetes

Dear Pharmac

Thank you for the opportunity to provide feedback on the Pharmac proposal to fund empagliflozin and dulaglutide diabetes medications subject to Special Authority. Our feedback is attached.

To restate our position summarised in a submission to Pharmac dated 4th May 2020, we do not believe it is enough simply to fund new drugs on an *ad hoc* basis. What is required is a whole new approach to treating type 2 diabetes based on open access to SGLT-2 inhibitors and GLP-1 receptor agonists, the only drugs shown to reduce death and progress to end stage kidney disease. This is consistent with standard-of-care in most other counties in the western world. New Zealand cannot afford to be left with a "**third world**" approach to treatment.

We remain concerned that **patient satisfaction** & **tolerability** have not been considered for the 80% of patients with Type 2 diabetes in Aotearoa who will not have access to new medications. Our current approach to treatment is simply too complex; it requires too many doses of medicine each day; there is too much dependence on regular dose adjustment; and there is an excessive reliance on insulin as default therapy when tablet treatment fails. Rates of unacceptable side-effects are high particularly with immediate-release metformin tablets (nausea, vomiting, diarrhoea) and insulin (hypoglycaemia and weight gain) These factors have a large impact on quality of life for many patients and do not appear to have been considered.

Kind regards
John Baker
Chairman, Diabetes Foundation Aotearoa
[redacted]
Mobile [redacted]

www.diabetesfoundationaotearoa.nz

Diabetes
Foundation Aotearoa

Re: Feedback on proposal to fund two new medicines for type 2 diabetes

Do we support this proposal?
No, although Pharmac has made an excellent choice of SGLT2 inhibitor and GLP1 receptor agonist for patients with T2DM in Aotearoa. However, Diabetes Foundation Aotearoa cannot support the business proposal because it does not go far enough to provide universal access to these new drugs.

The DCSS audit showed that blood glucose control (HbA1c) in predominantly Maori, Pacifika and South Asian patients with Type 2 diabetes in South Auckland was very poor with no improvement over the past 10 years. Only a whole new approach to management is going to make any difference

We have previously set out the case for open access to metformin XR, SGLT2 inhibitor, and GLP-1 receptor agonist medications for the treatment of Type 2 diabetes in a detailed submission to Pharmac dated 4 May 2020. We believe metformin XR, SGLT2 inhibitor, and GLP-1 receptor agonist medications that are standard-of-care in the rest of the Western World including Australia should be fully funded for all patients with Type 2 Diabetes in Aotearoa.

We see the proposed restricted access criteria as a crude attempt to regulate spending on pharmaceuticals by limiting care to just 50,000 patients with Type 2 diabetes. Crude because it's only notional that these are the patients with the most need; this is not an ideal world of perfectly treated patients; and the Special Authority selection criteria are a very blunt instrument.

The remaining 200,000 patients with Type 2 diabetes are left to struggle with an outmoded treatment regimen that is excessively complicated to administer, hampered by high rate of side effects and non-adherence, and depending on insulin as default therapy for far too many patients. Inevitably, many Type 2 diabetic patients who would benefit from this treatment approach will miss out and poor health outcomes and health inequities will not improve as rapidly as we would wish.

After twenty years of an increasingly outmoded treatment regime that does not improve patients health outcomes, we think it is unethical to deny full open access to these 'new' drugs that actually improve life quality and span, particularly at their low price point.

Patients who are at most risk or who may be in lower socio-economic groups and will have many barriers to getting these drugs. We know that many of these patients are Māori and Pacifika and access to care is already less than ideal for them It's likely that they're currently on sub-standard treatment or not following it well. It's likely that other patients, more active in their treatment choice and with stronger advocacy from their doctors, will get the Special Authority ahead of these equally needy patients

A more cost-effective business plan is for Pharmac to fund open access to metformin XR, SGLT2 inhibitor, and GLP-1 receptor agonist medications. Savings can be made by reducing funding for less effective medications (sulphonylureas, acarbose, pioglitazone, vildagliptin), substantially limiting insulin use to that small proportion of patients with type 2 diabetes who fail metformin XR, SGLT2 inhibitor, and GLP-1 receptor agonist medications, and stopping funding of home blood glucose monitoring for patients not prescribed insulin or sulphonylureas. Additional investment by the government may be required, but this is only appropriate for a health indication (Type 2 diabetes) that generates preventable high health costs in other areas (kidney dialysis & hospitalizations)

What will help people with diabetes and their whanau access these medicines?
It's fair to say, you don't know what you don't know We need patients, and their GPs, to be aware of the difference these drugs will make to their lives. Direct-to-consumer marketing will play an important part to provide equity of empowerment by informing the community of the benefits of the new treatment options and how to access care Direct-to-consumer marketing needs to be administered in conjunction with a concerted drive to reduce barriers to care

What additional support does Primary Care require to make this an effective roll out?
This is a better question because Primary Care is the bastion of health care delivery in Aotearoa and currently provides care for more than 85% of patients with Type 2 diabetes. At the very least, this proposal should include funded GP and diabetes practice nurse visits to initiate changes in management. We should also consider cancelling prescription fees for new drugs, so cost is not a barrier to care. This in conjunction with the usual devices such as patient-facing resources (eg: posters, pamphlets, video clips), specifically designed for Māori, Pacific and Indian people with type 2 diabetes, describing the benefits of these new medications, correct use and encouraging broader adherence of medication management for type 2 diabetes. This must be in addition to standard pharmaceutical pamphlets which are not specifically designed with the needs of New Zealand people in mind

What tools or approaches could be useful to support prescribers and people with diabetes?
A prominent finding of the DCSS audit in South Auckland over two decades was that Primary Care was perfectly capable of managing hypercholesterolaemia and hypertension and meeting OECD standards of care but failed to meet treatment targets for Type 2 diabetes. Professor Simmons attributed this to lack of modern tools to treat Type 2 diabetes. It's no coincidence that most patients with hypercholesterolaemia and hypertension are managed with a one-tablet-a-day treatment regimen (i.e. statin ± ezetimide or ACEi ± thiazide). In contrast, management of Type 2 diabetes is complex and difficult requiring a multi-drug, multi-tablet regimen that is hampered by high rates of treatment failure (suplhonylureas & pioglitazone) and need for insulin as default therapy at an early stage.

We need to make the right thing the easiest thing to do.

Modern therapies for Type 2 diabetes in stark contrast comprises one tablet once or twice a day (metformin XR ± empagliflozin) that would meet the treatment needs of >70% of patients with Type 2 diabetes with the addition of one injection per week of dulaglutide a further 20% of patients who fail to meet treatment goals. This leaves basal insulin as treatment of last resort for <10% of patients. These are safe, effective, well tolerable treatments that are easy to administer with minimal dose titration and no risk of hypoglycemia so no need for home blood glucose monitoring. However, GPs must be permitted to co-administer dulaglutide with empagliflozin for those patients who require dual therapy if the full benefit of this treatment regimen is to be realized.

Educational guidance on these new medications will be available through established accessible platforms such as HealthPathways, Secondary Care specialist support (eg clinic letters, virtual case-study discussions), and GP peer group meeting to support prescribing in different patient settings on different background medications. Regular practice level monitoring of the proportion of patients who have been prescribed these medications out of the number who are broadly eligible could help with uptake and systematic efforts to boost this number at a practice level

How could we specifically support Māori and Pacific people to access these medicines?
The most effective way to support Maori and Pacifika people to access these medicines is by removing the need for Special Authority. It is a complicated barrier that will make access challenging for GPs and their patients.

People with diabetes and their whanau are already very well informed about Type 2 diabetes and its devastating health sequelae. It is very difficult to find a Maori and Pacifika family in Aotearoa that do not have a close family member with diabetes who has suffered premature death or progress to end-stage kidney disease or amputation of the lower limb. It's also fair to say there is a high level of disillusionment at the failure of Western Medicine to make any difference Insulin treatment for Type 2 diabetes is deeply unpopular because of weight gain and hypoglycaemia side effects, need for home blood glucose monitoring and prior whanau memories associating starting insulin and terminal events. Nonadherence with insulin (not taking as prescribed) and non-persistence (not continuing with prescribed medication) is very high.

That means many Maori and Pacifika patients do not have a medical record which will pass an application for Special Authority; the continuity of care and adherence is poor; and thus their condition is poor

We believe the answer that will be attractive to Maori and Pacifika is a whole new approach to treatment of Type 2 diabetes with full access to these new medications This is an approach that is simple, requires minimal tablets per day, has low rate of side effects, does not require blood glucose monitoring and frequent dose adjustments and does not depend on insulin therapy at an early stage This should be applied in conjunction with standard compliance measures (regular recall, regular scripts, and intensive education by Maori and Pacifika health coaches).

From: Helen Cant - work <Withheld under section 9(2)(a)>
Sent: Thursday, 1 October 2020 4:42 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Proposal to fund two new medicines for type 2 diabetes

Thank you for the opportunity to comment on this proposal. This is a very important proposal for the treatment of the many people in NZ with Type 2 Diabetes. I would like to comment specifically on the access to the SGLT2 inhibitor class. I am a pharmacist prescriber working primarily in the area of Type 2 diabetes and cardiovascular risk management, in a population that has a high proportion of Maori and Pacific people, and low health literacy and a low socioeconomic demographic.

Do you support this proposal?
I totally support funded access to SGLT2i medications for people with Type 2 Diabetes in NZ. I am concerned that the Special Authority Restrictions as outlined will preclude funded access for many people who would benefit long-term, until CVD and renal disease is already well established

I am concerned that the current wording of the Special Authority requirements will lead to delay in initiating SGLT2 inhibitors until such time as **all** other classes of antidiabetic medications including insulin have been trialled and failed to reduce HbA1c I think that refining the working of the SA would improve targeting access to those who will benefit most.

Please consider altering the requirement
Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months; to
Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of metformin
The remainder of the SA requirements will ensure that the person has CVD or renal disease.

In addition
Please also consider funding for people where weight loss or avoidance of further weight gain is a significant consideration, irrespective of CV or renal disease.

Rationale
It is fair to say that the cost of pharmaceutical intervention should be compared to the cost of not providing the intervention In this case, the likely results of non-intervention are increased heart failure and renal failure, with consequent increased demands on both primary and secondary health services. The likely consequences of poorly controlled diabetes are increased demand for expensive secondary services such as renal dialysis units and cardiovascular interventions such as stenting and cardiovascular bypass, not to mention vascular services resulting all too often in amputations In

addition, reduced disability and consequent inability to work or to enjoy a good quality of life are also costs to both the country and the person and their whanau.

As it stands, this proposal is out of line with the European and US recommendations, where SGLT2i are second line after metformin for almost all situations (apart from where cost is the driving factor) While I accept that cost must be taken into account, as stated above, the whole costs to the health system and to the person must be considered in making this decision

I disagree that the primary target should be HbA1c reduction using all possible other medications before introduction of SGLT2i. In particular, I have concerns about the pressure to use sulphonylureas, pioglitazone and insulin first

Weight gain is a major concern for most of the population with Type 2 Diabetes; apart from the direct consequences in quality of life, it increases insulin resistance, thus producing a spiral of increased medications leading to increased weight leading to increased medications etc etc.

Sulphonylureas and insulin have the potential to both cause hypoglycaemia, and encourage weight gain; neither of which are desirable outcomes. They also require regular blood glucose testing, which has a significant impact on quality of life.

Insulin is difficult for most people to manage, and while undoubtedly when used appropriately it will bring HbA1c down, for most of the people I work with, it is just too difficult, and they give up treatment. All too often, this results in major CV disease, renal disease and early disability and death.

Pioglitazone, while helpful for a subset of the population with Type 2 diabetes, has significant contraindications or cautions, so should not be considered for many people.

The access to another oral medication which not only helps with diabetes control but also with reduction in heart failure, renal disease and hypertension would be of immense benefit to not only the people able to be treated, but the health system in years to come.

What will help people with diabetes and their whānau access these medicines?
Focus on the wider benefits of these medications in prevention / delay of cardiac and renal disease will benefit Maori and Pacific populations where these diseases are significantly more common. Streamlining access and removing barriers are key approaches The more barriers, the longer the delay in introducing treatment, and the more irreversible damage done

Sadly, in many families, Type 2 diabetes is so common that people accept it as inevitable. There is also a strong belief that insulin is the "end of the line" and that death

is inevitable soon after starting insulin. Having access to medications that are not insulin will allow treatment that is easy to take early in the disease.

What tools or approaches could be useful to support prescribers and people with diabetes?

In the population where I work (and I know in other similar populations), there is a very significant delay in introducing and uptitrating treatment This is a combination of people not presenting to the GP (often because they know their diabetes is not well controlled and don't want to hear that or be told to start insulin), and of limited access to appropriate services in different areas of the country.

Ensuring equitable access across the country to specialist diabetes expertise provided by appropriate people in accessible settings is also essential. Leaving primary care to manage the most complex of patients without access to specialist support is a recipe for disaster

In the population where I work (and I know in other similar populations), there is a very significant delay in introducing and uptitrating treatment. This is a combination of people not presenting to the GP (often because they know their diabetes is not well controlled and don't want to hear that or be told to start insulin), and of limited access to appropriate services in different areas of the country.

Type 2 Diabetes is a Public Health problem

Food choices and costs: highly processed sugar and carbohydrates are cheap and readily available. While fresh vegetables, meat and fish are prohibitively expensive and highly processed carbohydrates like white bread, 2 minute noodles, and sugary fizz are on special in all our supermarkets, making appropriate food choices for most people with type 2 diabetes is doomed to failure.

How could we specifically support Māori and Pacific people to access these medicines?

I am not Maori; my experience is that Maori or Pacific health workers and health coaches with specific expertise in supporting people with Type 2 diabetes are very effective in enabling maximal benefit from health services for their whanau.

References

https://care.diabetesjournals.org/content/diacare/41/12/2669.full.pdf
https://www.hri.org.nz/health/learn/cardiovascular-disease/heart-disease-in-the-m%C4%81ori-community

Thank you for the opportunity to comment on this proposal

Helen Cant
Pharmacist Prescriber
Tokoroa

Proposal to fund two new medicines for type 2 diabetes

Submission from Diabetes Christchurch Inc and Canterbury Diabetes Consumer Group in response to PHARMAC consultation of September 9th, 2020

Introduction

Diabetes Christchurch is an independent Incorporated Society and not a branch of Diabetes New Zealand. Diabetes Christchurch's financial membership sits at around 800 although there are 23,700 people with diagnosed diabetes in Canterbury Many of these people benefit from the services of Diabetes Christchurch without becoming financial members.

The Canterbury Diabetes Consumer Group takes representation from across the diabetes consumer spectrum and from many different communities, including Māori and Pacific peoples, and migrant communities. The group reports 6 monthly to CDHB Planning and Funding.

We understand the enormous cost that diabetes places on the PHARMAC budget, and the unexpected impact that Covid 19 has had on that budget We also believe that limited availability of a range of treatments that match individuals needs can result in repercussions in terms of poorer control and quality of life in the short term, and could lead to poorer health, complications and a greater burden on the health system in the long term

Not reaching an HbA1c target over a period of years can lead to a range of complications, including cardiovascular disease and renal damage. Not all patients are able to make the necessary changes to HbA1c with just weight loss and exercise alone. Not all patients can tolerate metformin and other agents that may cause gastrointestinal upsets. Some patients are reluctant to tell their physician they have stopped taking these agents as they fear that injecting insulin may be the next step. We welcomed the recent funding of vildagliptin in 2018, however this have been used routinely overseas for several years.

Do we support this proposal?

Most certainly yes and we applaud PHARMAC for considering more options to individualise treatment options for patients with Type 2 diabetes – however we are concerned at the lengthy timeline to get to this point and also with the current restrictions to high risk patients only. We hope in time, that all patients with Type 2 diabetes might have the option of using these medications BEFORE they become high risk.

What will help people with diabetes and their whānau access these medicines?

Being a funded option with Special Authority requirements removed

What tools or approaches could be useful to support prescribers and people with diabetes?

Educating prescribers to apply for Special Authority for these drugs rather than the standard outdated treatments, and Consumer knowledge that they do have other funded options that would improve their quality of life, and life expectancy

How could we specifically support Maori and Pacific people to access these medicines?

By using groups such as the Canterbury Diabetes Consumer group, Diabetes Christchurch and other communities that these at-risk groups access to dissipate information. Diabetes, and its co-morbidities of kidney disease and cardiovascular disease are areas of high morbidity and mortality for Māori and Pacific people who often suffer from complications younger and sooner than other groups.

Hopefully moving forward, the restrictions that you plan to impose initially will be reduced to allow far broader accessibility. The long term positive outcomes of these well tolerated drugs have already

been widely documented. We therefore feel Jardiance and Jardiamet should be funded for ALL people with diabetes before they become at risk.
We hope that Trulicity will be Medsafe approved as soon as possible and funding commenced without delay.

Summary
Some of the medications being proposed have been standard in developed countries for a number of years, as has the Libre device that has been having a significant impact on Type 1 management, yet this also remains unfunded. (The Libre 3 is now available in Europe.) We would also like PHARMAC to seriously look at the considerable improvements being made to control and overall wellbeing by people who are self funding continuous glucose monitoring (using either Freestyle Libre or Dexcom) thus saving PHARMAC considerable expense on funded test strips that are no longer required These devices mean levels are monitored far more often giving better understanding of the impact of food choices Out of range levels, especially dangerous lows, are treated far sooner and proactively meaning far better quality of life and, like the proposed new Type 2 treatments, reducing risk of complications and cost to the health system in the long term.
All people with both Type 1 and Type 2 diabetes should have access to more modern management tools and medications to ensure healthy futures - not just available to the wealthy or those predisposed to complications

We thank PHARMAC for the opportunity to comment on this proposal

Lynne Taylor
Chair, Canterbury Diabetes Consumer Group
Manager, Diabetes Christchurch

Chris Murray
Secretary, Canterbury Diabetes Consumer Group
Community Liaison, Diabetes Christchurch

RACP
Specialists. Together
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The Royal Australasian College of Physicians' submission to PHARMAC

Funding of Type 2 Diabetes Medicines

Mahuru 2020

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to submit feedback to the PHARMAC.

The RACP works across more than 40 medical specialties to educate, innovate and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society By working together, our members advance the interest of our profession, our patients and the broader community.

Position on Funding Proposed Medicines

The Royal Australasian College of Physicians (RACP) welcomes PHARMAC's decision to fund two new medicines to manage type 2 diabetes: empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet); and dulaglutide (Trulicity) We support the availability of sodium glucose co transporter 2 (SGLT-2) inhibitors and glucagon-like peptide 1 receptor (GLP 1) agonists in Aotearoa NZ, for improved health and wellbeing outcomes for people with type 2 diabetes and their whānau The evidence supporting the efficacy of these therapies is substantial, and the availability of additional funded treatments is long overdue, given the morbidity and mortality attributed to type 2 diabetes in Aotearoa NZ

Framework for Introduction, and Criteria for Access

Key points

The RACP believes that PHARMAC's proposed criteria for access may have significant equity implications for Māori, Pasifika and other groups who experience marginalisation from the health system.

Any policy which does not properly consider equity pushes the tide of change in the healthcare sector, and the findings of the Wai 2575 *Hauora* report We need to ensure that unnecessary barriers to the access and delivery of healthcare are removed, and that Māori have access to equitable care

The RACP strongly supports the availability of sodium glucose co transporter 2 (SGLT 2) inhibitors and glucagon like peptide 1 receptor (GLP 1) agonists in Aotearoa SGLT 2 inhibitors have been available globally since 2012 with the first receiving approval by Medsafe in June 2013. Similarly, GLP 1 agonists have been an option in diabetes management internationally for more than a decade, and in Aotearoa to those who can afford to self fund A lack of availability, and funding from PHARMAC has contributed to inequity since at least 2007, when the first application was put to PHARMAC for new diabetes agents The proposal to fund these medicines is essential, and long overdue

We believe that the current PHARMAC proposal for the funding of these medicines, fails to acknowledge:

- the impacts of the social determinants of health
- inequitable access to health care
- the disproportionate burden of disease of type 2 diabetes and secondary complications which fall on Māori and Pasifika and their whānau

By placing Special Authority criteria on both medicines, PHARMAC will create additional barriers to prescription and treatment The proposed Special Authority pathway will entrench inequity because:

- funded prescription of both medicines is prohibited
- of reliance upon testing which is inequitably delivered

The RACP is committed to equitable outcomes through action on the social determinants of health Our #MakeItTheNorm campaign recognises that health is dependent on many factors beyond the health system[1]. The RACP calls for

1. Healthy Housing: It must be the norm for all whānau to have warm, dry and safe housing
2. Good Work: It must be the norm for all incomes to be liveable, and for work to contribute positively to health and wellbeing
3. Whānau Wellbeing: it must be the norm for people and whānau to enjoy the highest possible standards of physical and mental health
4. Health Equity: the system must be just and fair.

Issues found in the Proposal

1. The current proposal fails to acknowledge persisting inequities in healthcare access, delivery and outcomes throughout Aotearoa.

Health inequities experienced by tangata whenua and entrenched within our healthcare system as a result of colonisation, are facts established through decades of research and reports

Equitable outcomes are not possible if the system continues to treat everyone the same Our healthcare system continues to fail to provide the level of care guaranteed to Māori under Te Tiriti o Waitangi This has been conclusively established in both the Waitangi Tribunal's *Hauora* report, and the wider analysis provided by the Welfare Expert Advisory Group's *Whakamana Tangata*, and the Health and Disability System Review's final report[2] [3] [4] [5]

[1] The Royal Australasian College of Physicians Make It The Norm [Internet] Sydney: The Royal Australasian College of Physicians; 2020. Available from https://www.racp.edu.au/advocacy/make-it-the-norm. Accessed 29 September 2020.

[2] Government Inquiry into Mental Health and Addiction. He Ara Oranga: Final Report of the Government Panel on Mental Health and Addiction [Internet] Wellington: Government Inquiry into Mental Health and Addiction; 2018. Available from: https://mentalhealth.inquiry.govt.nz/inquiry-report/he-ara-oranga/ Accessed 1 October 2020

[3] Welfare Expert Advisory Group. Whakamana Tangata - Restoring Dignity to Social Security in New Zealand. [Internet] Wellington: Welfare Expert Advisory Group; 2019. Available from: http://www.weag.govt.nz/weag-report/whakamana-tangata/. Accessed 1 October 2020.

[4] Health and Disability System Review Pūrongo Whakamutunga | Final Report of the Health and Disability System Review. [Internet]. Wellington: Health and Disability System Review; 2020. Available from https://systemreview.health.govt.nz/assets/Uploads/hdsr/health_disability-system_review-final-report.pdf.

[5] Waitangi Tribunal. Hauora: Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry. [Internet] Wellington: Waitangi Tribunal; 2019. Available from https://forms.justice.govt.nz/search/Documents/WT/wt_DOC_152801817/Hauora%20W.pdf Accessed 28 September 2020.

We must recognise that our healthcare system must change, or it will continue to reproduce inequity PHARMAC must take an active, pro equity approach to its work to reflect this[6]

Type 2 diabetes in Aotearoa

Pronounced inequities exist in type 2 diabetes in Aotearoa[7], and Māori living with type 2 diabetes have reduced access to appropriate preventative healthcare, leading to increased rates of complications[8]

The 2018/19 New Zealand Health Survey found 41 per cent of Māori and 36 per cent of Pacific individuals reported unmet need in primary healthcare in the past 12 months, with increasing unmet need seen over the past 10 years[9]. Fewer Māori are diagnosed, or screened for diabetes, and in the cases when they are, are less likely overall to be prescribed oral hypoglycaemic therapy or be started on insulin therapy. During treatment, Māori are less likely to have an annual diabetes review or regular retinal screening[10].

During monitoring, Māori are also likely to have higher HbA1c measurements[11]. Māori living with type 2 diabetes have less frequent HbA1c measurement, annual albumin creatinine ratio measurement, or a cardiovascular risk assessment, all of which are criteria in the proposed special authority[12]. This is another barrier in care which perpetuates equity.

PHARMAC's proposal does not address this, and while this may not be intention, is an example of systemic racism - creating criteria for access that Māori will be less likely to meet.

[6] Hobbs M, Ahuriri-Driscoll A, Marek L, Campbell M, Tomintz M, Kingham S. Reducing health inequity for Māori people in New Zealand Correspondence. [Internet] Lancet 2019; 394(10209):1613 14 Available from https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(19)30044-3.pdf. Accessed 28 September 2020

[7] Ministry of Health. Diabetes. Tatau Kahukura: Māori health statistics [Internet]. Updated 2 August 2018 Available from https://www.health govt nz/our-work/populations/maori health/tatau kahukura maori-health-statistics/nga-mana-hauora-tutohu-health-status-indicators/diabetes. Accessed 28 September 2020

[8] Ministry of Health. Wai 2575 Māori Health Trends Report. [Internet] Wellington: Ministry of Health; 2019. Available from: https://www.health.govt.nz/publication/wai 2575-maori health trends report. Accessed 1 October 2020.

[9] Ministry of Health. Unmet need New Zealand Health Survey: Annual Update of Key Results 2018/19. [Internet]. Updated 4 December 2019. Available from https://www.health.govt nz/publication/annual update key results 2018 19 new-zealand health survey. Accessed 28 September 2020

[10] Health Quality and Safety Commission. Diabetes. Atlas of Healthcare Variation [Internet]. Updated 19 March 2020. Available from https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas of healthcare variation/diabetes Accessed 28 September 2020

[11] Elley CR, Kenealy T, Robinson E, Bramley D, Selak V, Drury PL et al. Cardiovascular risk management of different ethnic groups with type 2 diabetes in primary care in New Zealand. [Internet]. Diabetes Res Clin Pract 2008;79:468–73. http://dx.doi.org/10.1016/j.diabres.2007.09.018. Accessed 28 September 2020.

[12] Lawrenson R, Gibbons V, Joshy G, Choi P. Are there disparities in care in people with diabetes? A review of care provided in general practice. [Internet] J Prim Health Care. 2009;1(3):177 83. Available from https://pubmed.ncbi.nlm.nih.gov/20690380/. Accessed 28 September 2020

2. The current proposal does not recognise the increased risk of secondary complications for Māori individuals living with type 2 diabetes

Medications of these classes have demonstrated a benefit in cardiovascular disease, renal disease, and heart failure, over and above glycaemic control[13] [14] The American Diabetes Association (ADA), the European Association for the Study of Diabetes (EASD), and the Royal Australian College of General Practitioners (RACGP) all recommend first line availability of both SGLT 2 inhibitors and GLP 1 agonists in their management guidelines of type 2 diabetes[15] [16].

The RACP acknowledges PHARMAC's review processes, including the consideration of evidence through the Pharmacology and Therapeutics Advisory Committee (PTAC).

PHARMAC's funding decision statement, while intending to take action based on risk, in fact does the opposite. Where the proposal intends for high risk patients to have greater access to medicine, in reality, Māori and Pasifika those at higher risk of kidney and heart complications associated with type 2 diabetes are faced with reduced access to this therapy due to the application of Special Authority criteria.

The RACP believes Māori and Pasifika living with diabetes must be recognised as having a high risk of heart and kidney complications and provided with a direct pathway to access medications.

Māori and Pasifika have higher rates of renal and cardiac complications due to diabetes, even when compared to the higher rates of type 2 diabetes in these communities[7] [17]. Cardiovascular disease (CVD) is a major cause of avoidable death for Māori, alongside diabetes[18] [19]. These

[13] Yandrapalli S, Aronow WS. Cardiovascular benefits of the newer medications for treating type 2 diabetes mellitus [Internet] J Thorac Dis 2017; 9(7):2124 2134 Available from https://pubmed.ncbi.nlm.nih.gov/28840014/. Accessed 28 September 2020.

[14] Neuen BL, Young T, Heerspink HJL, Neal B, Perkovic V, Billot L et al SGLT2 inhibitors for the prevention of kidney failure in patients with type 2 diabetes: a systematic review and meta-analysis. [Internet] Lancet Diabetes Endocrinol 2019; 7(11):845 54 Available from https://pubmed.ncbi.nlm.nih.gov/31495651/. Accessed 28 September 2020.

[15] Buse JB, Wexler DJ, Tsapas A, Rossing P, Mingrone G et al 2019 update to: Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) [Internet] Diabetologia 2020; 63: 221–228. Available from: https://link.springer.com/article/10.1007/s00125-019-05039-w. Accessed 1 October 2020

[16] The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. [Internet] Updated 17 September 2020. Melbourne: The Royal Australasian College of General Practitioners. Available from: https://www.racgp.org.au/clinical-resources/clinical guidelines/key-racgp guidelines/view-all racgp guidelines/diabetes/introduction Accessed 1 October 2020.

[17] Schmidt-Busby J, Wiles J, Exeter D, Kenealy T Understandings of disease among Pacific peoples with diabetes and end-stage renal disease in New Zealand. [Internet] Health Expect. 2019; 22(5): 1122-31. Available from https://pubmed.ncbi.nlm.nih.gov/31368649/. Accessed 29 September 2020.

[18] Ministry of Health. Major causes of death. [Internet] Wellington: Ministry of Health. Available from: https://www health govt nz/our-work/populations/maori health/tatau kahukura maori health statistics/nga-mana-hauora-tutohu-health-status-indicators/major-causes-death. Accessed 1 October 2020

[19] Walsh M, Grey C. The contribution of avoidable mortality to the life expectancy gap in Māori and Pacific populations in New Zealand a decomposition analysis. [Internet] NZ Med J March 2019, Vol 132 No 1492. Available from: https://www.nzma.org.nz/journal-articles/the-contribution-of-avoidable-mortality to-the-life expectancy gap in maori and pacific populations in new-zealand a decomposition-analysis. Accessed 1 October 2020.

trends continue with end stage renal disease, with high rates of progression for Māori in Aotearoa remaining even after factoring in higher rates of poverty, increased prevalence of diabetes, hypertension, and CVD[20]

Māori are inequitably affected by renal decline and CVD, but this has not been considered in the mechanisms for the funding of these medicines Due to clear evidence of the benefits of these medicines in combating cardiovascular renal disease, leading to improved outcomes, we believe that Māori and Pasifika must be prioritised for access

Proposed funding of these medicines also does not recognise pharmacotherapy benefits with respect to heart failure, which like CVD and renal decline, disproportionately affects Māori [13]. Comorbid diabetes and heart failure increase the likelihood of admission to hospital, all cause death and CV death[21]. Māori are at a 40 per cent higher risk of heart failure with diabetes, which in and of itself may be inaccurate, due to inequitable access to echocardiograms and specialist expertise[22]. The use of SGLT2 inhibitors for people living with diabetes complicated by heart failure or at risk of heart failure, is best practice. GLP 1 agonists and SGLT 2 inhibitors also have the added benefit of promoting weight loss.

The RACP is disappointed that proposed Special Authority criteria limit funded access to only one of the classes of medications. PHARMAC needs to make an active commitment to ensuring whānau living with diabetes have access to both medications without self-funding, due to their individual benefits.

3. The current proposal will increase ethnic inequity in access to medications, contravening the PHARMAC goal 'to eliminate inequities in access to medicines by 2025'

Inequity in the Aotearoa NZ healthcare system is based on a litany of historical and contemporarypolicy deicisions, which have perpetuated disadvantage for Māori. These proposals fail to account for this, and will lead to PHARMAC continuing to fail to achieve medicines equity for Māori.

Medicine equity, as defined by PHARMAC, is based on availability, affordability, accessibility, acceptability and appropriateness[23]. Continuing to approach these through PHARMAC's historical world view cannot achieve equity Equity itself must become a primary lens through which these domains are viewed Historically, affordability favours those with the ability to buy medicines, which in turn impacts on the domains of accessibility; acceptability and appropriateness Limitations on 'availability' through the application of a Special Authority process has the potential to exponentially increase inequity

[20] Lloyd H, Li G, Tomlin A, et al Prevalence and risk factors for chronic kidney disease in primary health care in the southern region of New Zealand. [Internet] Nephrology 2019;24:308–15. Available from: https://pubmed ncbi nlm nih gov/29717528/ Accessed 1 October 2020

[21] Seferovic PM, Petrie MC, Filippatos GS, Anker SD, Rosano G, Bauersachs J et al. Type 2 diabetes mellitus and heart failure: a position statement from the Heart Failure Association of the European Society of Cardiology. [Internet] European Heart Agency: Brussels; 2018. Available from: https://pubmed ncbi nlm nih gov/29520964/ Accessed 1 October 2020

[22] Kenealy T, Elley CR, Robinson E, Bramley D, Drury PL, Kerse NM et al. An association between ethnicity and cardiovascular outcomes for people with Type 2 diabetes in New Zealand. [Internet] Diabet Med 2008; 25(11):1302-8. Available from: https://pubmed.ncbi.nlm.nih.gov/19046220/. Accessed 1 October 2020.

[23] PHARMAC. Achieving medicine access equity in Aotearoa New Zealand: towards a theory of change. [Internet] Wellington: PHARMAC; 2020. Available from: https://www.pharmac.govt.nz/medicines/equity/medicine-access/. Accessed 1 October 2020.

As outlined, the Special Authority criteria will mean that only an estimated 20 per cent of people with diabetes will be eligible for subsidised supply 80 per cent of patients will be required to self fund, with obvious implications for those with lower levels of economic resources Those who are poorly served in the current system are also less likely to be screened and therefore less eligible to access these medicines under the proposed Special Authority criteria. That vildagliptin (an agent without proven cardiac outcome benefit) is funded without restriction sets an additional path of differential care for Māori[24]

That these implications have not been considered in the development of this proposal, especially from an organisation with a role as important as PHARMAC is disappointing, and does not bode well for future action addressing the greater inequities experienced by Māori and Pasifika individuals and their whānau.

However, this could be addressed through the introduction of an equity criteria, within the proposed Special Authority.

Medicines such as these need a plan which outlines how prescribing will reach Māori, Pasifika and other traditionally under-prescribed populations. If such a plan is not developed and implemented, priority populations may not see the considerable possible benefits. This will mean publicising, educating and supporting primary care to prescribe these two classes of medications. Without this, prescribing may not entirely reach primary care, which will increase inequity. In this vein, PHARMAC must implement a monitoring programme that focuses on equity and reports uptake of prescribing based on region, and by ethnicity. This will provide a metric by which PHARMAC's performance can be measured in this way.

PHARMAC must also ensure that each clinical subcommittee of PTAC has access to expertise in ethnic health equity, to ensure that all future proposals properly consider methods of achieving equity. In-depth consideration of systemic racism, and time periods for feedback commensurate with this, must be provided. A mere eight weeks between the closing of this feedback and the proposed start date of delivering the medications (i.e. early December), is not sufficient for such rigorous work to be undertaken. This calls into question the validity of the feedback process, and whether meaningful review will be undertaken by PHARMAC based on the feedback received.

Recommendations

The RACP calls on PHARMAC to take the following actions to improve equitable outcomes for Māori and Pasifika in the treatment and management of type 2 diabetes.

1. The **removal of the special authority criteria** for either or both of these medications

The proposed special authority needs to be removed or changed to avoid additional inequity through the mechansims stated above.

[24] Williams R, Vries F de, Kothny W, et al. Cardiovascular safety of vildagliptin in patients with type 2 diabetes: A European multi database, non interventional post authorization safety study. [Internet] Diabetes Obes Metab 2017;19:1473–8. Available from: https://pubmed.ncbi.nlm.nih.gov/28338281/. Accessed 1 October 2020.

2 If PHARMAC persists with the decision to put in place a Special Authority, then we recommend the **addition of an equity criteria**

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

Patient is of Māori or Pacific ethnicity and has an HbA1c above 49mmol/mol.

3 That messaging is provided which makes it clear that pharmacist prescribers and nurse practitioners are covered under the Special Authority, and that consideration is given to including nurse prescribers

Nurse prescribers, pharmacist prescribers and nurse practitioners improve access in the community. For many in the population, particularly those already experiencing inequities in access to healthcare, these professionals will be a person's primary prescriber We support the decision PHARMAC has made to include a broader prescribing group in the Special Authority application i.e. any relevant practitioner.

We encourage PHARMAC to make this very clear in the release of these medications, and to consider including nurse prescribers Including all prescribers who currently managing diabetes is fundamental for access to these important medications also. This is particularly relevant currently due to the COVID 19 pandemic, where we see health disparities increase and access to care decrease

4. That PHARMAC commits to an **active plan to ensure equitable prescribing** of these medications

Equitable prescribing requires a plan of action. This plan must include, but is not limited to, partnering with Māori experts and expert groups to publicise, educate and support primary care to deliver these new classes of medications to Māori and Pacific communities. In addition to this, PHARMAC requires an active monitoring and reporting programme that regularly reports prescribing data by ethnicity and region.

Given that dulaglutide will require regulatory approval before it can be prescribed, PHARMAC should commit to regular updates on this medication's approval progress, so that delays in access can be monitored. A plan towards funding the prescribing of empagliflozin and dulaglutide is needed to truly impact on secondary outcomes of diabetes for Māori and Pacific individuals.

5. That PHARMAC reviews their processes for equity in funding decisions

Underpinning our objection to this proposal is that the fact that known equity data in this area does not appear to have been considered in the funding of these medications PHARMAC has a stated goal to "eliminate inequities in access to medicines by 2025", which outlines the control PHARMAC wields, by managing equity through decision making processes in investment, funding restrictions or schedule rules[23] [25]

[25] PHARMAC. 2020. Medicine access equity driver diagram. [Internet] Wellington: PHARMAC; 2020. Available from: https://www.pharmac.govt.nz/assets/medicine-access-equity-driver-diagram.pdf. Accessed 1 October 2020.

If PHARMAC had approached the funding of new diabetes therapies through an equity lens, this situation would not have arisen We strongly advocate that PHARMAC reflect on their processes and responsibility under Te Tiriti o Waitangi We would remind PHARMAC of the definition of institutional racism in the Waitangi Tribunal's most recent findings, including recommendations for partnership and advocacy, which should underpin the work of PHARMAC**Error! Bookmark not defined**

Lastly, the feedback process should include PHARMAC actively seeking opinion from equity partners, to ensure robust critique of funding proposals. We encourage PHARMAC to facilitate the development of equity reviews for all future funding proposals, but particularly with those proposals with consequences for equity. We also recommend that PHARMAC ensure sufficient time following feedback to review, consider and act upon the feedback received.

Conclusion

The RACP thanks PHARMAC for the opportunity to provide feedback on this consultation. To discuss this submission further, please contact the NZ Policy and Advocacy Unit at policy@racp.org.nz.

Nā māua noa, nā

Dr Sandra Hotu
Chair, Māori Health Committee
The Royal Australasian College of Physicians

Dr George Laking
Aotearoa NZ President
The Royal Australasian College of Physicians

Te Rōpū Whakakaupapa Urutā
NATIONAL MĀORI PANDEMIC GROUP

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Cc:
Steve Maharey (PHARMAC Board Chair) Withheld under section 9(2)
Sarah Fitt (PHARMAC CE) - Withheld under section 9(2)(a)
Mr Bill Kaua (PHARMAC kaumatua) Withheld under section

Re: Proposal to fund two new medicines for type 2 diabetes - empagliflozin and dulaglutide

He kawau ka tuku ki roto i te aro maunga

Kei ngā pātaka iringa kai, tēnā koutou katoa.

E aku manawa kakapa nei. He auhi, he pūkatokato e mākatikati mai nei. Renarena te taura here o mahara mō koutou I takahia te ara otinga ki te poho o Hine-nui te-Pō Haere atu rā koutou, whakangaro atu.

Rātou ki a rātou, tātou ki a tātou ngā mangainga e tohe ana mō ēnei take o te hunga ora kia tae atu tātou ki ngā whenua haumako o māramatanga me whakaaro nui. Kia whakatinana hoki tātou i te mana ora, i te mana tangata, me te mana taurite.

Thank you for the opportunity to provide feedback on the proposed funding of two new classes of type 2 diabetes medications. Te Rōpū Whakakaupapa Urutā (The National Māori Pandemic Group) and the named signatories below (also members) strongly and unreservedly support the availability of sodium glucose co-transporter 2 (SGLT-2) inhibitors and glucagon like peptide 1 receptor (GLP 1) agonists in Aotearoa (NZ). However, we firmly believe the presented proposal will lead to **unnecessary and unacceptable increases in inequity for Māori** (and other marginalised groups) This includes inequities in medication access and initiation, resulting in avoidable morbidity from type 2 diabetes complications and premature death

The current proposal **fails to acknowledge the persisting inequities in the Aotearoa health system** and the **unfair distribution of the determinants of health** This proposal will increase inequity through a Special Authority that **creates a further barrier to health care delivery** and is an example of **structural racism** The proposed Special Authority criteria makes prescribing of these medications to Māori and Pacific less likely because it:

- **limits access to community level prescribing**;
- prohibits funded prescribing of **both medications**;
- relies on testing that **is inequitably delivered**;
- does not recognise the **increased risk of secondary complications in Māori and Pacific** individuals living with type 2 diabetes

As such, we recommend **prior** to subsidised funding in early December that:

- if PHARMAC persists with the decision to put in place a Special Authority then an **equity criteria** is added (see below); or
- **removes the special authority** process for both of these medications.

In addition, we request PHARMAC commits to:

- providing regular updates on the Medsafe approval process of dulaglutide in Aotearoa
- funding dual prescribing of empagliflozin and dulaglutide as clinically appropriate ;
- a proactive plan to support prescribing in Māori and Pacific communities;
- making it clear that applications are available to pharmacist prescribers and nurse practitioners
- a monitoring and reporting programme on the prescribing of these medications throughout Aotearoa, disaggregated by ethnicity;
- equity and Hauora Māori competencies are a core attribute of member(s) on future PTAC clinical advisory group(s)

Te Rōpū Whakakaupapa Urutā strongly supports the availability of sodium glucose co-transporter 2 (SGLT 2) inhibitors and glucagon like peptide 1 receptor (GLP 1) agonists in Aotearoa SGLT 2 inhibitors have been available globally since 2012 with the first receiving approval by Medsafe in June 2013 Similarly, GLP 1 agonists have been an option in diabetes management internationally for more than a decade, and in Aotearoa to those who can afford to self-fund. The proposal to fund one member of each class is deemed **essential** and **long overdue** Application to PHARMAC for newer diabetes agents has occurred since at least 2007, yet the lack of any advancement in type 2 diabetes prescribing has a dragged out inequity of access to appropriate therapy.

Te Rōpū Whakakaupapa Urutā is disappointed with the **inherent inequity** in the current proposal Key equity issues include: 1) the well documented **inequity in health care access and delivery** in Aotearoa; 2) the **increased need** of Māori and Pacific individuals living with diabetes, and 3) the ways in which this funding proposal will **perpetuate inequity**.

1 The current proposal fails to acknowledge **persisting inequities in healthcare** access, delivery and outcomes throughout Aotearoa.

The current proposal is based on the assumption that the health care system treats all members equally. This is simply not true. The fact that current health care delivery is unfair and unequal is no longer open for debate. In addition to decades of health care research illustrating ethnic inequity, the recent Stage One of the ***Waitangi Tribunal 2575 claim (Health Services and Outcomes Inquiry)***(1) and ***New Zealand Health and Disability System Review(2)*** both articulate the failings of the health care system. Culminating in an unacceptable difference in avoidable death for Māori, these ongoing injustices need active, pro-equity approaches from those holding power,(3) This includes PHARMAC

Inequities exist in type 2 diabetes (4). Specifically, Māori living with type 2 diabetes have reduced access to appropriate preventative health care associated with rates of complications in excess of the difference in prevalence. The 2018/19 New Zealand Health Survey found 41% of Māori and 36% of Pacific individuals reported unmet need in primary healthcare in the past 12 months, with increasing unmet need seen over the past ten years (5) Māori have reduced diagnosis and screening for diabetes, are less like to be prescribed oral hypoglycaemic therapy or be initiated on insulin therapy, and are less like to have an annual diabetes review or regular retinal screening (6) Māori are also likely to have higher HbA1c measurements when the disease is monitored (7). Māori living with type 2 diabetes have less frequent HbA1c measurement, annual albumin creatinine ratio measurement, or a cardiovascular risk assessment (8), **all of which are criteria in the proposed special authority**. This additional barrier in an already overstretched primary health care system will only perpetuate this gap in service. By not acknowledging this, PHARMAC's proposal is an example of **systemic racism** creating criteria for access that, by definition, Māori will be less likely to meet.

2. The current proposal does not recognise **the increased risk of secondary complications** in Māori individuals living with type 2 diabetes

It is now well established that these classes of medication have demonstrated a benefit in cardiovascular disease,(9) renal disease,(10) and heart failure,(9) over and above glycaemic control. The American Diabetes Association (ADA), the European Association for the Study of Diabetes (EASD), and the Royal Australian College of General Practitioners (RACP) all recommend first-line availability, after metformin and lifestyle intervention, of both SGLT 2 inhibitors and GLP 1 agonists in their management guidelines of type 2 diabetes. We know this evidence has been reviewed extensively by PHARMAC as well as the diabetes subcommittee of PTAC and therefore does not need repeating In the decision by PHARMAC to propose to fund these medications it is stated that "(t)his proposal would mean that people who are at high risk of heart and kidney complications from

type 2 diabetes" would have access to these medications. Despite this, the Special Authority criteria unacceptably reduces access for key populations, in particular Māori and Pacific, who are "at high risk of heart and kidney complications". **We argue that Māori and Pacific individuals living with diabetes need to be recognised as having a high risk of heart and kidney complications, and therefore need direct access to these medications.**

Rates of both renal and cardiac complications of diabetes are increased in Māori and Pacific individuals, at higher rates comparative to the increased prevalence of type 2 diabetes in Māori and Pacific peoples.(4) Cardiovascular disease (CVD) is one of the leading causes of death for Māori(11) and one of the largest contributors to avoidable death (along with diabetes) for Māori.(12) The progression to end-stage renal disease for Māori in Aotearoa remains after factoring in higher rates of poverty, increased prevalence of diabetes, hypertension, and CVD (13) Renal decline and CVD occur in Māori earlier in the diabetes journey, and at a younger age. In the proposal to fund these medications, however, this data has been neglected, with Māori being considered alongside all populations. Given the extensive evidence benefit in CVD and renal disease outcomes with SGLT-2 inhibitors and GLP-1 agonists, we argue that there is a significant benefit for Māori and Pacific communities if access can be ensured.

In addition to cardiovascular and renal disease, the proposed funding does not recognise the **pharmacotherapy benefits with respect to heart failure**.(9) The coexistence of diabetes and heart failure imparts a higher risk of hospitalisation, all cause death and CV death (14) Māori have higher risk of heart failure with diabetes, likely to be under-represented given inequitable access to echocardiograms and specialist expertise, and overall have higher rates of heart failure admissions and mortality.(15) Internationally, SGLT2 inhibitors are first-line pharmacotherapy, after metformin and lifestyle intervention, in people living **with diabetes complicated by heart failure or at risk of heart failure**. Furthermore, both GLP-1 agonists and SGLT-2 inhibitors have the added benefit of promoting weight loss

Given the independent benefit of each of these classes, it is inappropriate that the Special Authority criteria limit funded access to only one of the classes of medications. PHARMAC needs an active plan towards ensuring whānau living with diabetes will have access to **both** medications without having to self-fund one of them.

3 The current proposal will **increase ethnic inequity in access to medications**, contravening the PHARMAC goal 'to eliminate inequities in access to medicines by 2025'

By failing to recognise both the perpetual failure of the health care system for Māori and the increased need of Māori, **PHARMAC fails to deliver** on its stated aim of achieving medicines **equity for Māori**

PHARMAC defines the pillars of medicine access as availability, affordability, accessibility, acceptability and appropriateness.(16) By **not applying a pro-equity lens** to funding these agents, inequities in diabetes related conditions are perpetuated Affordability has selectively privileged those who choose to buy these medicines, impacting heavily on the remaining three domains of accessibility; acceptability and appropriateness That there are intended limitations to this 'availability' through the application of a Special Authority process is an alarming plan for exponentially increasing inequity. If the special authority criteria is applied as outlined, an estimated 20% of people with diabetes will be eligible to subsidised supply. The remaining 80% will be required to self fund to access. As a corollary, those who are poorly served in the current system are less likely to be screened and therefore less eligible to access these medicines under the proposed special authority criteria. That vildagliptin (without proven cardiac outcome benefit) is funded without restriction sets an additional path **of differential care for Māori**. This funding proposal demonstrates a significant lack of equity expertise and equity application from PHARMAC Targeted support for Māori to access these medicines could, however, be achieved **through the inclusion of an equity Special Authority criteria**.

Subsidised funding of medications with such universal benefit requires an implementation plan that removes all barriers to prescribing for Māori, Pacific and marginalised populations PHARMAC has a responsibility in optimising prescribing and overcoming clinical inertia for those who are reluctant to go through the special authority process, even when available to 'any relevant practitioner' This requires publicising, educating and actively supporting primary care to prescribe these two classes of medications It may also require PHARMAC to partner with clinicians or groups with expertise in equity and applied pharmacotherapy. Without this, prescribing will remain predominantly in secondary

and tertiary units, which will compound inequity of access. Additionally, PHARMAC requires a fit-for-purpose recording and monitoring programme that is focussed on equity. This requires reports quarterly on the uptake of prescribing of these medications by region and by ethnicity. If PHARMAC is committed to playing their role in eliminating inequities, then they must be able to accurately comment on uptake following these funding decisions.

Lastly, if PHARMAC is committed to equity, each clinical subcommittee of PTAC must have pro-equity and Hauora Māori capability to ensure that issues that have been overlooked do not occur again. Feedback on funding decisions should be sought from units with expertise in the critique of systemic racism, and feedback time should be sufficient for in-depth analysis of funding proposals. Te Rōpū Whakakaupapa Urutā has concerns that there was a mere eight weeks between the closing of this feedback and the proposed start date of delivering the medications (i e early December) This calls into question the validity of the feedback process, and whether a meaningful review will be undertaken by PHARMAC based on the feedback received

Te Rōpū Whakakaupapa Urutā therefore makes the following **recommendations**:

1. The **removal of the special authority criteria** for both of these medications

The proposed special authority needs to be removed or changed to avoid additional inequity through the mechanisms stated above.

2. If PHARMAC persists with the decision to put in place a special authority, then we assert the **addition of equity criteria** to include:

   OR:

   Patient is of Māori or Pacific ethnicity and has an HbA1c above 53mmol/mol

3. If PHARMAC persists with the decision to put in place a special authority, clear messaging about the access to apply includes all primary care prescribers including general practitioners, pharmacist prescribers, nurse practitioners and nurse prescribers.

Pharmacist prescribers, nurse practitioners and nurse prescribers improve access to healthcare in the community We have many examples of such practitioners doing so in a culturally safe manner For many in the population, particularly those already experiencing inequities in access to healthcare, these professionals will be a person's primary prescriber This situation has been heightened during the COVID-19 pandemic. We support the decision PHARMAC has made to include a broader prescribing group in the Special Authority application - i.e any relevant practitioner

We encourage PHARMAC to make this very clear in further communications.

4. Regardless of PHARMAC's decision with respect to Special Authority removal or not, we request PHARMAC commits to an **active plan to ensure equitable prescribing** of these medications.

Equitable prescribing, with or without special authority criteria, will not occur by accident It is the responsibility of PHARMAC to ensure equitable prescribing. This includes, but is not limited to, partnering with Māori experts and expert groups to publicise, educate and support primary care to deliver these new classes of medications to Māori and Pacific communities. In addition to this, PHARMAC requires an active monitoring and reporting programme that regularly reports disaggregated prescribing data by ethnicity and region.

Given that dulaglutide will ideally require regulatory approval before it can be prescribed, PHARMAC should commit to regular updates on this medication's approval progress, so that delays in access can be monitored A plan towards funding the prescribing of both empagliflozin and dulaglutide is needed to truly impact on secondary outcomes of diabetes for Māori and Pacific individuals.

5. That PHARMAC reviews their **processes for equity in funding decisions**

Underpinning our objection to this proposal is that the fact that known equity data in this area do not appear to have been considered in the funding of these medications PHARMAC has a stated goal to "eliminate inequities in access to medicines by 2025",(16) which outlines the control PHARMAC plays in managing equity through decision making processes in investment, funding restrictions or schedule rules.(17)

If PHARMAC had approached the funding of new diabetes therapies with an overarching pro-equity consideration, this situation would not have arisen. We strongly advocate that PHARMAC reflect on their processes and responsibility to Te Tiriti o Waitangi. We would also like to remind PHARMAC of the description of institutional racism in the Waitangi Tribunal's most recent findings,(1) including recommendations for partnership and advocacy, which should underpin the work of PHARMAC.

Lastly, the feedback process should include PHARMAC actively seeking opinion from equity partners, to ensure robust critique of funding proposals. We encourage PHARMAC to facilitate the development of equity reviews for all future funding proposals, but particularly with those proposals with key equity issues. We also recommend that PHARMAC ensure sufficient time following feedback to review, consider and act upon the feedback received.

In summary, type 2 diabetes is a health condition with high prevalence in Māori and Pacific people and significantly higher morbidity. Glycaemic control and cardiovascular risk factor management are necessary for positive outcomes, but barriers restrict Māori from achieving their potential Clinical trial data has demonstrated SGLT-2 Inhibitors and GLP-1 agonists reduce: diabetes-related deaths; progression to end-stage kidney disease; heart failure mortality and hospitalisation; and the risk of cardiovascular events compared with conventional management at equivalent glucose control. The potential for a beneficial outcome with these medicines is greatest for Māori Therefore any process that limits the availability of these medications to Māori will be yet another example of the health care system failing to deliver on Te Tiriti based rights Te Rōpū Whakakaupapa Urutā therefore supports 'availability' (i.e. the addition of these medicines to the pharmaceutical schedule) of these medications, but deems this extremely delayed and complex response as exemplary of the continued failure of PHARMAC to prioritise and target medicines equity for Māori.

Nāku noa, nā

Te Rōpū Whakakaupapa Urutā (National Māori Pandemic Group)
membership available on https://www.uruta.maori.nz/about

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PHARMAC PROPOSAL 9 September 2020 two new treatments for type 2 diabetes

Do you support this proposal?

Yes. As the proposal states, there is now ample worldwide evidence showing improved health outcomes for people with diabetes and we finally welcome the opportunity to optimise patient's medication with therapies that patients around the world have had access to for many years.

What will help people with diabetes and their whanau access these medicines?

Education for all healthcare workers working directly with patients with diabetes so that every opportunity that presents can be used to discuss better therapy options.

Dedicated time for a fully funded medication review at least annually.

Re thinking the clinical decision around the funding of one or the other of the new therapies. Evidence from cardiovascular and diabetes global landmark trials show many patients would benefit from combination therapy

What tools or approaches could be useful to support prescribers and people with diabetes?

It will be very important to have clear special authority conditions. Ambiguity in special authority criteria is extremely difficult to work with under time pressure Special authority consents should be lifelong and should not have to be reapplied for.

Simple flow chart / 1 pagers to assist and support the prescribers in clinical decision making

Education evenings, symposiums etc delivered by endocrinologists will enable interested prescribers and educators to obtain basic information around the new medicines. Following on, it will often be down to the clinical pharmacists in general practice to support the education by providing updates, peer support and drug information to GPs when suitable patients present for therapy changes or when peer meetings are scheduled to enable continuing education within the multi-disciplinary team. Clinical pharmacists will often run queries in the practice to identify patients that could benefit from medication optimisation Prescribing Pharmacists and Clinical Nurse Specialists in diabetes will be at the fore front of prescribing and initiating these therapies and educating generalists within the practice

Therefore, support with dedicated evidence based medicine information for Endocrinologists, Clinical and Prescribing pharmacists, Nurse practitioners and diabetes nurse specialists will be necessary to ensure safe and effective prescribing for patients with diabetes.

How could we specifically support Maori and Pacific people to access these medicines?

By Maori – For Maori. Identify specific barriers and then help primary care break down the barriers.

Transport, opening hours and availability of trusted healthcare professionals to consult with in a timely manner are identified as known barriers to healthcare for our vulnerable populations. Enabling Stat-dispensing so that some of these barriers are removed would improve access

Some of the barriers identified above and are not easily solved by 'cash' or 'increased funding'. Healthcare is not a 9 5 problem and our diabetes patients that will specifically benefit from these therapies are our working population. Getting time off work to access blood tests, prescriptions and doctor's appointments is difficult and is seen as a real barrier to managing long term conditions We need to think outside the square to deliver healthcare in a patient centred manner. With suitably skilled Nurse Practitioners, Nurse Specialists, Clinical Pharmacists and Pharmacist Prescribers, access to healthcare practitioners gradually becomes easier

and relieves pressure on our General Practitioners. The long-term solution is to recruit, train and retain healthcare professionals to become our skilled workforce for the future.

On a very positive and final note, we are delighted that access to these medications will be easier with Pharmacist Prescribers newly accepted as practitioners that can apply for and renew special authority on medicines.

Canterbury District Health Board
Te Poari Hauora ō Waitaha

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2 October 2020

PHARMAC
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Wellington 6143
e: consult@pharmac.govt.nz

RE: PHARMAC proposal to fund empagliflozin and dulaglutide for type 2 diabetes Due 2 October 2020

Summary of proposal
PHARMAC is seeking feedback on a proposal to fund two new medicines (empagliflozin and dulaglutide) for type 2 diabetes for people who are at high risk of heart and kidney complications. Listings would be in Section B and H (community and hospital) of the Pharmaceutical Schedule and would be subject for prescriber and indication restrictions. This proposal also amends the price and contractual arrangements for vildagliptin (with or without metformin) and funding without restriction would continue.

CDHB response:

Benefit: Both treatments improve glycaemic control Glycaemic control is consistently associated with improved macrovascular and microvascular outcomes For both GLP 1 analogues and SGLT2 inhibitors there are large medium duration studies to support their benefits SGLT2 inhibitors, including empaglifozin have additional benefits for heart failure and chronic kidney disease. For dulaglutide, a reduction in the rate of major cardiovascular events (including death), and progression to macroalbuminuria.

Harm: Empagliflozin increases the risk of genital and urinary tract infections; and dulaglutide is associated with gastrointestinal side-effects.

Use: Community dispensing data from July 2018 to July 2019 show that there were 17,930 patients in Canterbury receiving funded oral antidiabetic medicines[1]. Of these, 26 patients were aged 5 to < 15 years. From July 2019 to June 2020 there were 7204 prescriptions for funded oral antidiabetic medicines for CDHB inpatients in MedChart[3]. Of these, 11% and 6% prescriptions were for patients documented with Maori and Pacific ethnicity, respectively. We have not undertaken analysis to determine how many of these patients will be eligible for funded treatment under the proposed restrictions.
Initially lack of health professional familiarity will be a barrier to equitable access. Patients receiving specialist care are likely to access these new treatments before those who have not accessed specialist input We note the rapid uptake of these classes of medicines in Australia.
The proposed restriction criteria will provide access to older patients; and limit use in younger patients with type 2 diabetes. It is younger patients who are likely to receive the greatest health benefits of treatment (longest increase in quality of life and time to progression of renal and cardiac impairment)[1,2].

Cost: There will be costs in terms of increased health professional time when initiating and educating about these new medicines. There will be time cost to clinical and support services developing health professional guidance, and patient focused medicine information Some patients may already have experience with insulin administration; however, time to teach and support patient and/or care giver subcutaneous injection technique will be required for dulaglutide

1. Includes acarbose, glibenclamide; gliclazide; glipizide; metformin hydrochloride; pioglitazone; vildagliptin; vildagliptin with metformin hydrochloride – noting these may have been prescribed for indications other that type 2 diabetes.
2. Tancredi M et al, Excess Mortality among Persons with Type 2 Diabetes. N Engl J Med. 2015 Oct 29;373(18):1720-32. doi: 10.1056/NEJMoa1504347.
3. Nick A Roper et al. Excess mortality in a population with diabetes and the impact of material deprivation: longitudinal, population based study. BMJ. 2001; 322: 1389–1393

Comments:

1. CDHB supports the funding of empagliflozin and dulaglutide for patients with type 2 diabetes.
2. CDHB supports wider access to empagliflozin and dulaglutide. The funding restrictions target short term (5 year) benefit over long term (life time) benefits. This is discordant with clinical guidance.
3. The exclusion of combined use of empaglifozen and dilaglutide does not appear to have a rational basis. A patient with poor diabetes control on one of these medicines should have the same access to these medicines as a patient with poor diabetes control not on either, other things being equal
4. Health professional and patient information will help people with diabetes and their whānau access these medicines.
   - Lack of health professional familiarity will initially be a barrier to prescribing Concise health professional information to increase familiarity with assessment for diabetes, cardiovascular risk and renal impairment will support health professionals to use these medicines safely and rationally.
   - Lack of patient focused medicine and health information is a barrier to patient and whanau management of medicines, diabetes and other related health issues To address this, development of information and translation into the appropriate languages is required. Written and audio forms, as well as a visual formats for sign language, is required if access to this information is to be equitable for Maori, Pacific people, the deaf community and New Zealanders with poor vision and literacy.
   - CDHB has asked MyMedicines (mymedicines.org.nz) to prioritise patient information for these two medicines.
5. The CDHB supports working with Māori and Pacific communities to facilitate access these medicines.

Response from departments: Endocrine, Paediatric, Clinical Pharmacology and Pharmacy Departments.

Regards,
Judy Dalrymple | Medicine Utilisation Pharmacist
Matthew Doogue | Clinical Pharmacologist

1. Includes acarbose, glibenclamide; gliclazide; glipizide; metformin hydrochloride; pioglitazone; vildagliptin; vildagliptin with metformin hydrochloride – noting these may have been prescribed for indications other that type 2 diabetes.
2. Tancredi M et al, Excess Mortality among Persons with Type 2 Diabetes. N Engl J Med. 2015 Oct 29;373(18):1720-32. doi: 10.1056/NEJMoa1504347.
3. Nick A Roper et al. Excess mortality in a population with diabetes and the impact of material deprivation: longitudinal, population based study. BMJ. 2001; 322: 1389–1393

2020-10/001

2nd October 2020

NEW ZEALAND NURSES ORGANISATION
TŌPŪTANGA TAPUHI
KAITIAKI O AOTEAROA

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Wellington 6143

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Tēnā koe

PHARMAC proposal to fund two new medicines for Type 2 Diabetes

Tōpūtanga Tapuhi Kaitiaki o Aotearoa, New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on the above proposal.

NZNO has consulted its members and staff, in particular members of; Aotearoa College of Diabetes Nurses, Te Rūnanga o Aotearoa (Te Rūnanga), professional nursing and policy advisers. NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand, representing 51,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment matters. NZNO embraces Te Tiriti o Waitangi and contributes to the improvements of the health status and outcomes of all people of Aotearoa New Zealand through influencing health, employment and social policy development

NZNO strongly support the intent of the proposal to fund the two new medicines; Empagliflozin and Dulaglutide for type 2 diabetes. From an equity perspective, we have focused on accessing and affordability of the medications to those that suffer the burden of the disease. We have given feedback from that equity perspective, particularly focused on Māori We request further information on funding criteria and equity matrix

Overall, our members are supportive of the changes, however understandably they are concerned with the unintended consequences of the potential increase in medication charges.
Please find specific feedback below

1. We support these medications (SGLT 2 inhibitor and GLP 1 agonist)being fully subsidised for our T2DM patients, as these medications have excellent results in preventing chronic kidney disease (CKD) and End stage renal failure (ESRF). In the past these medications have not been available or accessible to our whānau who live in poverty and could help prevent progression to haemodialysis

2. Te Rūnanga are supportive of the proposal however they require further information about the availability and drug subsidy information. Particularly from an equity perspective, to ensure that Māori complex needs are met with support and education for health and wellbeing.

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www.nzno.org.nz

3. Diabetes & Endocrinology Service nurse practitioner strongly supports the funding of these two medicines, particularly because:
   a These medications are vital for Māori, Pasifika, and South East Asian people with type 2 diabetes who are significantly burdened by type 2 diabetes and its associated complications Funding these medications would be a step in the right direction to enable equitable diabetes care for these high risk populations.

   b. Further, we strongly recommend including Registered Nurse Prescribers (along with medical or nurse practitioners) as a group of clinicians able to complete a special authority Further, long Term Condition Nurses and Diabetes Specialist Nurses often have greater involvement in the care of the patients these medications are proposed for; therefore allowing Registered Nurse Prescribers to complete the special authority would reduce a barrier for the commencement of these drugs.

   c. Additionally, we strongly support that Nursing Council of New Zealand updating the Registered Nurse Prescribing medication list (feedback was sought on this in January 2020) and add SGLT 2 inhibitors and GLP 1 agonists to the list of medications able to be prescribed by Registered Nurse Prescribers

   d. As nurses are most likely the professional to teach patients how to self administer subcutaneous injections for GLP-1 agonists, it is appropriate that the nurse could also complete the special authority, to reduce the number of encounters the patient would need to commence on this drug (i e. wouldn't need to see a doctor or nurse practitioner to have the special authority completed, and then need to book in separately to see a nurse to be taught how to administer the medication). Given diabetics are a vulnerable patient population group, and current inequities that exist in these patients accessing and being able to afford primary care, consideration must be made to address barriers and avoid unintended consequences of any actions.

   e Additionally, an updated national type 2 diabetes treatment algorithm would be extremely useful resource for clinicians to provide guidance on when to utilise these medications. The current outdated treatment guidance is from the New Zealand Guidelines Group (2012) Primary Care Handbook, needs to be replaced.

   f. The criteria of a "Patient that has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months" implies that the patient would need to be on more than one oral agent and/ or insulin to be eligible to go on an SGLT 2 inhibitor or GLP 1 agonist This information, is opposite to international guidance (ADA & EASD 2018 Management of Hyperglycemia in Type 2 Diabetes) that GLP 1 agonists and SGLT 2 inhibitors are recommended as second line medications in most instances (after Metformin) above other oral agents such as sulfonylureas, glitazones, DPP-4 inhibitors and also insulin. This is confusing information and should follow best practice guidelines Clarification is required to advise our patients to commence on inferior or less efficacious medications prior to being able to go on SGLT 2 inhibitors and GLP 1 agonists.

g. Special authority approvals not requiring further renewal is an excellent option. This would reduce a barrier for long term use of these medications.

4 We agreed that the agents from the SGLT 2 inhibitor and GLP 1 agonist classes can provide benefits for people with type 2 diabetes beyond glycaemic control. However the criteria should be in line with EASD and ADA guidelines (i.e. the rest of the Western world) that agents from the SGLT-2 inhibitor and GLP-1 agonist classes be added as second-line treatment after metformin, not after failure on other oral diabetes agents and/or insulin in high risk patients and overweight people

As part of improving equity access and reducing health disparities over time, we recommend that PHARMAC develop a more proactive engagement with the communities to help people with diabetes and their whānau access to these medicines. This includes:

a Facilitating and encouraging prescribers to work with the communities Co-design engagement should be encouraged by getting communities to work in partnership with PHARMAC. What works in Hawkes Bay may not necessarily work in Wellington.

b. Engaging Māori and Pacific nurses' access to the communities to understand what works best for them Some providers prefer to have the drugs on hand at the clinics to hand out to clients as they know that there are issues with pharmacy charges, that patients will not pick up their medications. So there is a distribution problem, between the patient and pharmacy. By understanding some underlying issues, PHARMAC may be able to improve the distribution process.

c. Understanding te Tiriti o Waitangi and engagement strategy with Māori and Pacific communities. Education sessions can be set up in the community in an environment that suits the whānau and the community.

d. Increasing cultural competence such as communicating using tikanga Māori, te reo Māori and Pacifica languages can help bridge the gap Co-design education sessions can be set up in the communities

5. NZNO also recommends that PHARMAC develop a new or strengthen an existing equity framework for assessing unintended consequences of these new medicines This is to ensure cost barrier are reduced and health needs are met especially in Māori and Pacific communities

6. Whilst PHARMAC acknowledged Māori and Pacific people carry the burden of diabetes, our Policy Advisor Māori has ongoing concerns about the medicines affordability and prescription use from an equity perspective This includes:

a. *Will the medicines be fully or partially funded?*
As the cost alone would limit Māori and Pacific and vulnerable whānau from accessing it

b *What are PHARMAC strategy to improve access to or benefits of accessing these medicines?*

The benefits of the medicines will have other disadvantaging effects on the whānau as the ongoing cost (to the household) of the medicines will impact on whānau economic wellbeing i e not everyone can afford to fill the prescriptions, unless fully subsidised Therefore the cost barriers will create persistent inequities on economic and social aspects of the whānau wellbeing.

In conclusion, please note our concerns with any unintended consequences of introducing these drugs, particularly for those with the greatest burden, which may impact on their social determinants of health and wellbeing Please feel free to contact my colleague Leanne Manson, Policy Advisor Māori if you wish to discuss her comments on equity further

Nāku noa nā

Leanne Rahman | Policy Analyst (Acting)
Withheld under section 9(2)(a)

Feed back on Pharmac proposal to fund empagliflozin (Jardiance), empagliflozin with metformin (Jardiamet) and dulaglutide (Trulicity)

Do you support this proposal?

Diabetes New Zealand absolutely supports this proposal as it will significantly improve the outcomes for people with diabetes at risk of heart and kidney disease It will also address equity in prescribing at risk Māori and Pacific people.

What will help people with diabetes and their whānau access these medicines?

It is noted that the criteria set for special authority will target those at highest risk and therefore target the current inequity of prescribing to those that have the greatest need for access.

People with diabetes access most of their medications through their General Practitioner and this would continue to be the easiest way to access these new medications. It will be essential to ensure that education is provided to GPs about the criteria for access, as well as the benefits of lowering cardiovascular and renal disease risk. Access will be assisted by proactive GP's identifying patients who fit the criteria and also finding avenues to ensure people with diabetes and their whānau are well informed as to how these medications will lower their risk of heart and kidney disease. For many people, a once a week injection via a disposable pen where you cannot see the needle may be preferable to commencing insulin daily. For those on Metformin already, to move to Empagliflozin with metformin hydrochloride would mean no increase in the number of tablets taken but with significant additional heart and kidney benefits.

What tools or approaches could be useful to support prescribers and people with diabetes?

To assist prescribing in Primary Health Care, clear criteria for prescribing should be available with similar clear instructions for people with diabetes on how to best take the medication especially with Trulicity. A media advertising campaign would support people with diabetes to understand the heart and kidney benefits of these medications

How could we specifically support Māori and Pacific people to access these medicines?

Media advertising targeted towards Māori and Pacific may encourage them to ask their GPs for these medicines. Adverts with Māori and Pacific in them talking about the benefits and how members of their whānau will live longer to see their moko grow, may encourage them to proactively ask their GP for these medications. All written / visual advertising and education targeting Māori and Pacific Islander Peoples use reader friendly language and images. Information is clear and easy to understand explaining the benefits of the new drug

Media advertising should specifically target where Māori and Pacific Islander Peoples most likely watch (Māori TV, Fresh) and listen i.e. Māori Radio Stations and Pacific Island Peoples radio programmes.

Any advertising is also sent to Wananga, Schools, Runanga and Māori & Pacific Island Peoples Service Providers. Try to reach out to places where the target audience congregate.

GPs should be encouraged to search their Practice Management Systems for Māori and Pacific patients who fulfil the criteria, then phone the patient to recommend the benefits of these new medications to them.

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

2 October 2020 Our ref: KM20-126

PHARMAC
PO Box 10254
The Terrace
WELLINGTON

via email: consult@pharmac.govt.nz

Tēnā koe

Proposal to fund two new medicines for type 2 diabetes

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on the 'Proposal to fund two new medicines for type 2 diabetes'.

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 proposal is to fund empagliflozin alone and in combination with metformin, from 1 December 2020, and to fund dulaglutide as soon as practicable following Medsafe approval. The funding of both treatments would be restricted to people who meet the criteria set in the Special Authority

In accordance with the Special Authority criteria, to be eligible for funded treatment, patients with type 2 diabetes would have to have poor diabetic control as measured by the HBA1c despite 6 months of oral antidiabetic agents and/or insulin. Patients would also need to have either pre-existing cardiovascular disease, diabetic kidney disease or an assessed 5-year cardiovascular risk of 15% or greater1.

Diabetes and equity

Diabetes is one of the drivers of health inequities. Ministry of Health data from 2013 14[2] reveal that the self reported prevalence of diabetes among Māori is about twice that of non-Māori. There are also much higher disparities between Māori and non-Māori for diabetes complications such as renal failure and lower limb amputation

The College wishes to commend PHARMAC on publishing a discussion piece on equity in 2019 *Achieving Medicine Access Equity in Aotearoa New Zealand: Towards a Theory of Change*.[3] We consider funding empagliflozin and dulaglutide is an important step towards addressing the inequalities of health outcomes resulting from type 2 diabetes.

[1] https://www.pharmac.govt.nz/news/consultation-2020-09-09-diabetes-agents/ accessed 30/9/2020
[2] https://www.health.govt.nz/our-work/populations/maori-health/tatau-kahukura-maori-health-statistics/nga-mana-hauora-tutohu-health-status-indicators/diabetes accessed 30/9/2020

[3] https://www.pharmac.govt.nz/assets/achieving-medicine-access-equity-in-aotearoa-new-zealand-towards-a-theory-of-change.pdf

Level 4, 50 Customhouse Quay, Wellington 6011, PO Box 10440, Wellington 6143, New Zealand
Tel: +64 4 496 5999 Fax: +64 4 496 5997 Email: rnzcgp@rnzcgp.org.nz Website: www.rnzcgp.org.nz

Progress, however, will be dependent on these medications being accessed by all patients who are eligible. The College is pleased to see that PHARMAC intends to monitor the uptake of empagliflozin (with and without metformin) and of dulaglutide to see whether the medicines are being accessed by the people with highest need (for example Māori and Pacific peoples). PHARMAC is also intending to seek clinical advice on whether the equity of access could be improved over time, and how PHARMAC could support this. The College would be happy to provide further input on these issues if requested.

Education for prescribers

Empagliflozin and dulaglutide belong to classes of medications, dipeptidyl peptidase-4 (DPP-4) inhibitors, and SGLT-2 inhibitor and GLP-1 agonists respectively, which have not previously been funded in New Zealand. Therefore, quality unbiased practitioner education needs to be made available. We are pleased the consultation document states that PHARMAC will support the implementation of this change The College encourages PHARMAC to ensure education to support the safe use of these medications is available to practitioners.

Special Authority requirement

The proposal includes a Special Authority provision which would see empagliflozin and dulaglutide funded only for patients with poorly controlled type 2 diabetes who have a high level of cardiovascular risk or have existing cardiovascular or kidney disease. The College looks forward to the future removal of the Special Authority requirement as this will enable a greater proportion of patients with type 2 diabetes to benefit from treatment with these medications.

Conclusion

The College supports the proposal to fund empagliflozin and dulaglutide These medications will be a welcome addition to the pharmaceutical options available for the management of type 2 diabetes. They hold promise to not only manage blood glucose levels but, most importantly, to reduce the cardiovascular complications of diabetes

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

Kylie McQuellin
Head of Membership Services

From: Pan Pacific Nurses Association NZ <panpacificna@gmail.com>
Sent: Friday, 2 October 2020 2:04 pm
To: Consult <Consult@Pharmac.govt.nz>
Cc: Withheld under section 9(2)(a); Pauline Fuimaono Sanders <Withheld under section 9(2)(a)>; Withheld under section 9(2)(a) Withheld under section 9(2)(a) Manogi Eiao <Withheld under section 9(2)>
Subject: Feedback on the PHARMAC Proposal to fund two new medicines for type 2 diabetes

Dear Board Members of PHARMAC,

It is with great pleasure that the Pan Pacific Nurses Association of NZ, submit our views on the proposal to fund two new medicines for type 2 diabetes.

Please find attached our feedback on our views of how this could be aligned to improve the health of all Pacific people with type 2 diabetes.

Please feel free to contact us if you have any questions.

Kind Regards

Manogi Eiao and Pauline Fuimaono Sanders
Pan Pacific Nurses Association of NZ
Directorate

PHARMAC Proposal to fund two new medicines for type 2 diabetes

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THE PAN PACIFIC NURSES ASSOCIATION of NEW ZEALAND

The Pan Pacific Nursing Association of New Zealand (PPNA) was founded in August 2015 which brought together a unique collaboration of Pacific nurses who are connected through post-graduate studies with the desire and intention to improve Pacific health outcomes through applied knowledge, experience and relationships

The purposeful integration of advanced nursing knowledge with the traditional and ever-evolving Pacific cultural knowledges will create a new paradigm to benefit Pacific peoples within the Aotearoa New Zealand context

panpacificna@gmail com

2 October, 2020

Pharmaceutical Management Agency (PHARMAC)
Te Pātaka Whaioranga
consult@pharmac.govt.nz

Talofa lava
Re: Proposal to fund two new medicines for type 2 diabetes.

The Pan Pacific Nurses Association of New Zealand (PPNA) would like to thank PHARMAC for the opportunity to provide feedback on this important proposal. PHARMAC proposes to fund two new treatments for type 2 diabetes empagliflozin, empagliflozin with metformin and dulaglutide As stated, the funding of both treatments would be restricted to people with type 2 diabetes who are at high risk of heart and kidney complications The proposal also includes amendments to the price and contractual arrangements for vildagliptin and vildagliptin with metformin which would continue to be funded without restrictions

- PPNA supports NZ aligning with the diabetes medicines available in other first world countries
- Enabling prescribing clinicians across the system of care to prescribe modern, first world diabetes treatments is a cost-effective way of reducing the burden on other parts of the healthcare system
- We request the criteria with which to use these pharmaceutical tools are aligned with the needs of the population Specifically, the populations that experience significant health inequities related to diabetes Pacific Peoples
- We also request a review of how these medicines are accessed to achieve equitable access for prescribing clinicians and the populations they serve
- We look forward to continued engagement with PHARMAC to ensure the communities that are most affected by diabetes receive treatments that will improve quality and length of life for themselves and their families

Acknowledgements to the following PPNA members who consulted and prepared this feedback on behalf of the Pan Pacific Nurses Association:

- Pauline Fuimaono Sanders, Clinical Nurse Director
- Manogi Eiao Predialysis and Transplant Nurse Specialist
- Alisa Ili, Nurse Manager
- Fakaola Otuafi Nurse Practitioner, Renal & Associated Long Term Conditions
- Doana Fatuleai Acting General Manager, Pacific Health Development Unit
- Harriet Pauga Acting Service Manager, Pacific Health Development Unit/Diabetes Nurse Specialist

PPNA gives permission to have their organisation included in the list of submitters

Thank you again for the opportunity to feedback on this important proposal

Ia manuia

Safaatoa Fereti
President
Pan Pacific Nurses Association

PPNA supports the availability of these medicines in New Zealand (NZ) as it will align diabetes treatments with first world countries internationally These medicines improve life expectancy, slow progress of diabetes kidney disease and have minimal side effects that patients commonly experience presently which include weight gain, hypoglycaemia and gastrointestinal upset The new medicines remove the need for finger prick blood glucose monitoring as there is no risk of hypoglycaemia Overall, this makes the treatment of type 2 diabetes easier to administer, easier to adhere to with long term health and life benefits for people with type 2 diabetes

This is significant, particularly for Pacific communities, whom disproportionately experience the highest incidence of diabetes and complications compared to other ethnic groups in NZ.

PPNA *DOES NOT* support the narrow restrictions that are being proposed by PHARMAC to access these medicines The proposed restrictions support inequitable access to medicines, particularly for Pacific people who often live in high deprivation – both having higher incidence of diabetes These narrow restrictions limit access for prescribing clinicians in Aotearoa which will exacerbate inequitable access to these medicines and the benefits from these for Pacific people

The reasons PPNA do not support these restrictions are outlined below (1) equitable access to medicines for Pacific Peoples in Aotearoa, (2) equitable access to medicines for prescribing clinicians in Aotearoa, and (3) benefits for Pacific Peoples as a result of accessing these medicines

1. Equitable access to medicines for Pacific Peoples in Aotearoa

PHARMAC [1] refers to achieving equitable access to medicines in relation to the health need/burden of disease PHARMAC highlights there are significant barriers in accessing and utilising medicines for certain groups and Pacific people have been identified as one of these groups including Maori, those living in high socioeconomic deprivation and rural/isolated areas and people from former refugee backgrounds

There is a clear correlation between poorly controlled diabetes and complication rates Individuals with poorly controlled diabetes risk developing blindness, heart disease, stroke, renal impairment and in some cases limb amputations These complications have a negative impact on the individual, their whanau and our society as a whole Current direct costs related to the management of adult obesity and Type 2 diabetes was estimated to be in the region of $303 million dollars per annum As an example, diabetes is the most common cause for patients requiring dialysis in New Zealand The direct cost associated with dialysis for one person is approximately $55,000 per year The indirect costs add to this, when considering reduced ability to work and reduced life expectancy

This is significant for Auckland as it is home to one of the largest populations of Pacific peoples in the world 67% of NZ's Pacific population with over half residing in the Counties Manukau Health district [2] Of added significance in Counties Manukau is that over half of Pacific people live in overcrowded houses, earn low income or are unemployed and limited education [2] These factors impact on health choices and access to healthcare and medicines for Pacific peoples but also have compelling effects on how the health system responds to this unique combination of context and needs

Disparities in health and service outcomes for Pacific compared with non Māori non Pacific peoples in New Zealand have persisted and been reported in health system reports for more than two decades There has been some improvement, but the gaps are not closing. The 2019 health equity review Tofa Saili [3] highlights the significant health challenges experienced by Pacific peoples:

- The proportion of all deaths considered ***potentially avoidable*** is twice as high in Pacific (47 3%) compared to non Māori non Pacific populations (23.2%).
- In 2015, the diabetes prevalence rate was ***20% for Pacific adults in NZ (20-79 years), the highest of all ethnic groups*** (Māori 10%, Asian 8% and NZ European 6%) and far above the OECD average of 7%.
- These percentages mask substantial disparities in the prevalence of diabetes by age: by the age of 65 years, ***more than half of all Pacific peoples are living with diabetes.***
- The high rates of diabetes in Pacific peoples in younger age groups is a particular concern: younger people diagnosed with type 2 diabetes (e g before the age of 40 years) have a higher risk of premature death, CVD, chronic kidney disease and retinopathy than older adults with type 2 diabetes
- This is largely because people diagnosed younger have diabetes for longer and are therefore exposed to more risk, but also because glycaemic control tends to be worse and younger people are more likely to have sporadic contact with healthcare services
- Pacific peoples with diabetes are more likely to live four to five years less on average and are more likely to have other LTCs As a result, Pacific will most likely experience more complications including blindness, amputations, kidney failure, as well as mental health problems.
- The literature also shows that, in addition to the physical consequences of disease, patients face significant challenges associated with managing the burden of complex treatment
- Data about diabetes medication and testing is not routinely publicly reported However, a 2012 report on the health status of Pacific peoples in the Auckland region reported similar levels of guidelines based care for Pacific diabetics and the total diabetic population and similar attendance rates for diabetes review
- Other studies, however, have noted that people living in deprived communities are less likely to receive diabetes education and support services from the non governmental sector

- Whatever the case, this 'equality' in clinical levels of care has not led to similar outcomes for example, the proportion of people with good blood sugar control is up to 15% lower than the NMNP diabetic population

This represents a ***substantial equity gap for Pacific peoples*** and an important area for focus for the health system
Additional supporting evidence on the incidence and effects experienced by Pacific peoples with diabetes can be found in Appendix I (testsafe data and Diabetes Foundation Aotearoa submission evidence), II (end stage kidney disease) and III (obesity and bariatric surgery)

2. Equitable access to medicines for prescribing clinicians in Aotearoa

Primary care is well positioned to manage diabetes as a long term condition but can only be successful with tools that support providing gold standard care Other countries with healthcare systems comparable to ours have successfully introduced these additional pharmaceutical options At present, GPs and practice nurses are trying to manage diabetes with patients using a very limited array of sub optimal medications. Opening access to these new medicines with criteria that will not hinder Pacific Peoples access will significantly improve health outcomes for those living with diabetes.

People already have established therapeutic and trust relationships with their primary care team and seeing health professionals that they are familiar with Patient preference, priorities, values, experiences, culture and beliefs are considered together with clinical expertise and best available clinical evidence.

PPNA requests that PHARMAC fund Metformin XR, an SGLT 2 inhibitor, and a GLP 1 receptor agonist for the treatment of type 2 diabetes ***with open access for all prescribing clinicians*** This will enable prescribing clinicians to support the management of Pacific Peoples with established diabetes but also start medicines early and prevent life changing complications and life shortening effects from the progression of diabetes These reasons are outlined below:

- Avoid delays in initiating the new medicines The current requirement for an endocrinologist leads to delays in scheduling an appointment in the Specialist diabetes service or the patient does not turn up to their appointment with Specialist diabetes service or communication delay/failure between the Specialist diabetes service and primary care team

- The Specialist diabetes services or secondary care not overwhelmed, allow them to provide service for complex patients and provide support to hospital and primary health care services

- Providing greater choice and convenience for patients with weekend/after hours appointments available at their GP practices and deliveries of care (National Telehealth Service, mobile clinic, home visit etc)
- Prevent the development of complications by starting medicines early, improve the quality peoples' lives and have savings across the health system in many areas

PHARMAC [1] states that access refers to medicines being available, that medicines can be access and used by the population and that medicines achieve outcomes aligning with quality, relevance and effectiveness of prescribing and also dispensing PHARMAC [1] also refers to access for people prescribed medicines for the first time or for long term condition management Pacific Peoples experience significant health challenges in relation to the effects of diabetes and also the determinants of health Therefore, availability of these medicines AND that available for prescribing clinicians to access these openly is critical

The proposed restrictions, using the current criteria, supports the status quo of accessing medicines and therefore continuing the current prescribing and access inequities that we currently experience This is ***inequity at a system level.***

PHARMAC has an opportunity to be a significant contributor in addressing the inequities experienced by Pacific Peoples in relation to diabetes

3. Benefits to Pacific Peoples in accessing these new medicines in Aotearoa

Pacific Peoples are disproportionately affected by type 2 diabetes and the complications of disease progression There are many benefits to Pacific Peoples in having access to these first world medicines. Some of these are:

- Reduction in the number of tablets needed would improve adherence of medications, reduce polypharmacy amongst Pacific people
- Dulaglutide is a prefilled syringe device and is generally given as a once weekly injection, again improving adherence
- Reduction of hypoglycaemic episodes will decrease the fear factor for Pacific people
- Reduced need to check blood sugar levels via finger pricking
- Dulaglutide has been shown to improve cardiovascular and kidney outcomes in people with type 2 diabetes who are at high risk of these complications (see Appendix II and III)
- Significant reduction in the incidence of diabetic nephropathy and complications
- Reduction in appetite would improve weight loss for Pacific Peoples, reducing the need to have bariatric surgery
- Improved Quality of Life due to reduced side effects of these new medications
- Shared management of diabetes across the health sector and ability to prevent complications early

- Overall cost savings to the health system that can be reinvested in other areas of healthcare services

APPENDIX I TESTSAFE DATA

- Diabetes disproportionately affects Pacific, Indian and Maaori, with 15% of Pacific peoples 15 years and over affected compared with 12% of Indian, 9% of Maaori and 5% of NZ European or other[4].

- High socioeconomic deprivation increases risk substantially, with 12% prevalence of diabetes in the most deprived quintile versus 3% in the least deprived quintile[4].

- When standardised for age, ethnic disparity also exists for diabetes control, with Pacific and Maaori considerably more likely to have an HbA1c ≥75 mmol/mol than NZ European/other (41%, 37% and 23%, respectively)[4]. For many people this poor control lasts for years.

- Maaori and Pacific peoples with poorer control are less likely to be dispensed with insulin than European/other. For example 44% of Pacific patients and 48% of Maaori with an HbA1c of ≥75 mmol/mol receive insulin, versus 60% of European/other. A similar pattern is seen at a lower HbA1c with Pacific people with diabetes typically 30-40% less likely to receive insulin than European/other in most HbA1c bands from 50 54 upward[4].

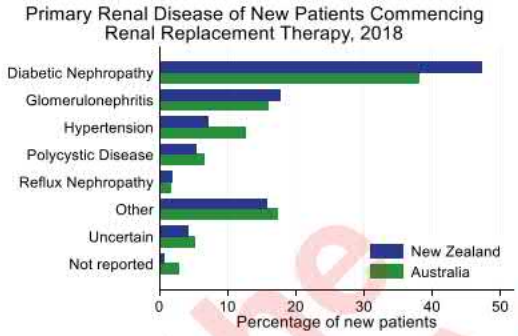
- Maaori and Pacific patients with type 2 diabetes are disproportionately affected by complications, such as end stage renal disease[5] and lower limb amputations[6].

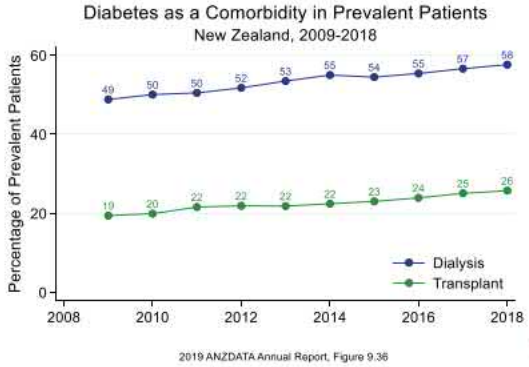
- It could be argued that metformin extended release should also be funded in NZ, on the basis of equity. Maaori and Pacific patients in NZ have lower adherence to metformin than Asian, and European and other ethnicities[7]. While the reasons for this need to be explored, the extended release metformin can modestly increase adherence[8], and is better tolerated.

- Further evidence can be found in 'A New approach to the management of type 2 diabetes' by the Diabetes Foundation of Aotearoa, Dr John Baker PHARMAC submission [9].

APPENDIX II - END-STAGE KIDNEY DISEASE

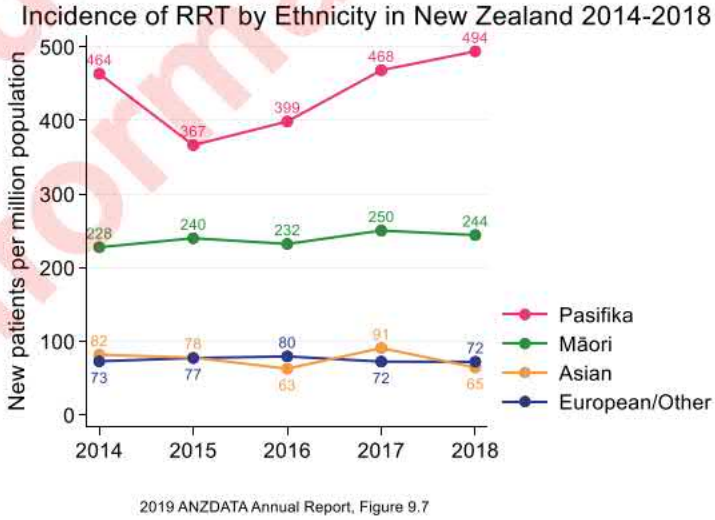
The leading cause of end stage kidney disease in New Zealand in 2018 was diabetes (47%) This has ethnic variation with diabetic nephropathy the cause of ESKD in 2018 in 19%, 67%, 64% and 55% of European/Other, Māori, Pasifika and Asian New Zealanders respectively[10]

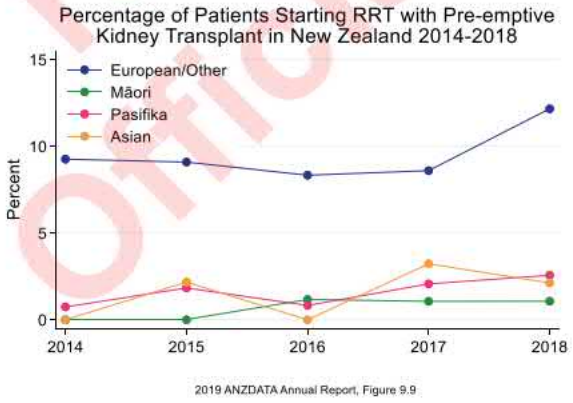




The percentage of prevalent dialysis patients with diabetes as a comorbidity has increased by 9 percentage points over the previous decade

The incidence of renal replacement therapy is markedly higher among Pacific Peoples compared to all other ethnic groups.





Pacific people have low rates of pre-emptive kidney transplant due to family members that may also have similar co morbidities such as diabetes Therefore Pacific people are over represented in the dialysis population due to the low uptake of kidney transplantation

APPENDIX III - OBESITY AND BARIATRIC SURGERY

There is a higher incidence of Pacific Peoples who are overwieght and obese which contributes to a higher prevalence of Type 2 diabetes. Diabetes is almost three times higher in Pacific Peoples compared to non Pacific and non Maori ethnic groups in New Zealand. Bariatric surgery has been one treatment option for obesity which has positive effects not only related to weight loss but also the recovery from type 2 diabetes and improved quality of life and health outcomes[11,12].

In 2007, the National Service and Technology Review Committee (NSTRC) undertook a comprehensive review of current practice in the management of adult morbid obesity in the New Zealand Public Health system. The business case was developed using the Services Planning and New Zealand Intervention Assessment Planning (SPINIA) Framework. Part of the justification for the review was the finding that the current direct costs related to the management of adult obesity and Type 2 diabetes was estimated to be in the region of $303 million dollars per annum.

Data from the New Zealand Health Information Service suggests disparity in Pacific access to publicly funded bariatric procedures; for example of the 149 procedures that were funded in 2007/08, the rate was for Pacific at 18.7 per 100,000 population with a BMI over 35 kg/m^2 compared with 51.9 per 100,000 population with a BMI over 35 kg/m^2 in the combined New Zealand European and Other group.

Although access to and through health services and specifically bariatric surgery is an important and under researched issue in New Zealand. Research findings suggest that those most in need of services are least likely to get the care they require.

A nationwide survey in 2016 showing patients who received publicly funded bariatric surgery were predominantly European, with 21 % Maori and only 9 % Pacific. The significant barriers Pacific people face in accessing healthcare are already well documented including costs of healthcare services, and healthcare interactions.

The introduction of publicly funded bariatric procedures identified that a number of patients could benefit from such surgery and the treatment would result in significant improvement in the health status of many of these patients including type 2 diabetic related conditions.

Pacific Peoples are continually disadvantaged in accessing treatments as criteria is often based on volumes rather than health needs, complexity and complications. Access to bariatric surgery is one example of this and is important it has wider health implications, particularly related to the positive effects on type 2 diabetes and potential complications.

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9 Diabetes Foundation Aotearoa 'A new approach to the management of type 2 diabetes' PHARMAC Submission, May 2020 (attached below)

10 ANZDATA Annual Report 2019 - Chapter 9 End Stage Kidney Disease in Aotearoa/New Zealand

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PDF

Diabetes Foundation Aotearc

Clinical Advisory Pharmacists Association (CAPA)

To: Pharmac

From: Penny Clark, Chair, CAPA

Date: 1 Oct 2020

Subject: Feedback on Proposal to fund two new diabetes medicines for type 2 diabetes

---

Tēnā koe

Thank you for the opportunity to feedback on your consultation

CAPA is the Clinical Advisory Pharmacists Association which is an association of pharmacists with postgraduate qualifications and includes many pharmacists working in general practice, and the primary care pharmacist prescribers.

It is very much appreciated that these two medicines will be available for our people with diabetes, and in particular, that they are medicines primarily for reducing the complications of diabetes, perhaps more that reducing blood glucose *per se*, though they are moderately effective at this.

Feedback from our members has identified that there is a risk of increasing inequity, although obviously Māori and Pacific people with diabetes will greatly benefit. Our points are as below.

- Needing maximal tolerated oral antihyperglycaemic medicines before a person is eligible will delay the use of medicines that are beneficial for reducing the complications of diabetes. It would be helpful to separate the lowering of blood glucose (maximal oral therapy for more than six months) from the reduction of renal and cardiovascular complications The prescribing process is no longer linear but rather two paths.

- While it is understandable that there needs to be some determinant, and threshold, of glycaemic control, there are people with prediabetes who have established microalbuminuria who may benefit from the introduction of a SGLT 2 inhibitor earlier than waiting for diabetes, and then maximising other antihyperglycaemics. The concept of controlling blood glucose first is problematic. It would be preferable to have criteria that the person has a confirmed diagnosis of diabetes or prediabetes **and** microalbuminuria or confirmed cardiovascular disease (secondary prevention)

- Maximising oral antihyperglycaemic medicine also means using the DPP-4 inhibitors (vildagliptin) prior to initiating a SGLT 2 inhibitor or a GLP 1 agonist. The use of a GLP 1 agonist with a DPP-4 inhibitor is not recommended in the international

guidance. While they can be used together, there is basically no improvement in glycaemic control and hence a waste to use this combination

- International guidance (European and USA) is that after metformin (currently), then the presence of microalbuminuria or cardiovascular disease indicates that a GLP 1 agonist or a SGLT-2 inhibitor should be used, before other agents. Maximising therapy with other antihyperglycaemics delays valuable treatment aimed at lowering the renal and cardiovascular complications complications that are particularly prevalent in Māori and Pacific people

- It is notable that the result for delaying the progression of albuminuria is at the earlier stages and there is less benefit when greater harm has been done i.e. the benefit is present but as renal function deteriorates the absolute benefit reduces.

- There will be increased inequity through the non funding of a GLP-1 agonist for people already on a SGLT-2 inhibitor. The people who will receive dual therapy are those who can afford an unfunded GLP 1 agonist, rather than many Māori and Pacific people who are in the lower socioeconomic groups.

- Our pharmacist prescribers and clinical paramcists are already seeing people, and especially our Māori and Pacific people, who are not on maximal antihyperglycaemic medicine yet, but have microalbuminuria and may also be at high cardiovascular risk. These are the people that we need to be able to treat immediately with a SGLT 2 inhibitor (renal) or GLP 1 agonists (cardiovascular).

- There is also the added benefit for SGLT-2 inhibitors with the reduced rate of hospitalisation with heart failure This is a very important aspect as heart failure often co exists with diabetes in our high risk populations.

- Although we understand the need to be cognisant of the financial implications, ideally it would be helpful to remove the Special Authority. If this were not acceptable in the short term, then removal of the Special Authority for the SGLT 2 inhibitor would be a good start. Failing both these options, then lowering the threshold by removing the need for maximal oral antihyperglycaemic would improve equity; and allowing use for people with diabetes or prediabetes, with no HbA1c threshold would also improve equity. From our perspective, for reducing inequity, it would be preferable to have a SGLT-2 inhibitor over a gliptin such as vildagliptin.

Pharmacist prescribers and clinical pharmacists in primary care roles have a far reaching impact on supporting other prescribers and people with diabetes.

Our members have already started work to update our colleagues, GPs, nurses and nurse practitioners on these new medicines and new approaches to the way type 2 diabetes medicines can be individualised for the patient, as we did when vildagliptin was funded This includes group nurse and GP education, both in house and regional across PHOs and working with local diabetes clinics, and bulletins will be soon produced and shared, which further broadens the reach

In addition and importantly, pharmacist prescribers and clinical pharmacists work individually with patients It has been shown that Māori are more likely to be receptive to medicines and to take them if they have been well explained so that they can make an informed choice. This is an area that is ideal for pharmacist prescribers and clinical pharmacists to work in to help reduce inequity as expertise in pharmacotherapy is our core skill, and our focus is for

person centred optimising medicines to reduce medicine related harm, reducing inequities with medicines and optimising clinical and person centred outcomes.

Unfortunately, there are only pockets of prescribing pharmacists and clinical pharmacists in primary care across NZ so far, although they make an impact on inequity in their regions. Support to grow these roles in primary care would have a long lasting and sustainable effect on helping Māori and Pacific peoples to access these medicines and strive for medicines equity in Aotearoa New Zealand

Thank you for your consideration

Penny Clark
CAPA Chair
Withheld under section 9(2)(a)
Withheld under section 9(2)(a)

From: Kate <info@cardiacsociety.org.nz>
Sent: Monday, 5 October 2020 10:19 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: Consultation/feedback on proposal to fund two new medicines for type 2 diabetes

To whom it may concern:

As cardiovascular physicians and nurses managing high cardiovascular risk patients, with or without heart failure, we are aware that diabetes (in particular Type 2) often co exists and complicates management and increases risk The outcomes are particularly poor in the Māori and Pacific populations, socio economically deprived and rural populations. Lifestyle management is challenging and with limited impact in many such patient groups. In addition primary care and health support access can be inadequate The newer medications for T2DM are a huge step forward to improving outcome in these patients The evidence base is large and continuing to grow.

Thus, we fully support funding of sodium glucose co transporter 2 (SGLT 2) inhibitors, however would make the following suggestions:

That funding is extended to heart failure patients (with or without diabetes). The recent EMPEROR-Reduced trial showed that empagliflozin is superior to placebo in improving HF outcomes among patients with symptomatic stable HFrEF (EF ≤40%) on excellent baseline GDMT, irrespective of diabetes status. (August 29, 2020DOI: 10.1056/NEJMoa2022190)

That Empagliflozin be funded, but a second agent in the same class also be available, with similar CV outcome evidence (Dapagliflozin)

That they be used in preference to dipeptidyl peptidase-4 (DPP-4) inhibitors, due to the greater proven CV outcome evidence Dulaglutide, the proposed, but not yet Medsafe approved, long acting GLP 1 receptor agonist, also has a much less convincing CV evidence base.

We envisage that most prescribing will be from primary care and trust that there will be adequate, non-biased education and support to enable appropriate safe choice of the medication types.

Dr Raewyn Fisher
Cardiologist
Northland DHB
Co-Chair CSANZ Heart Failure Working Group

Kate Ward
Executive Officer
Cardiac Society of Australia and New Zealand
NZ Region, PO Box 14092, Kilbirnie, Wellington 6241

From: Noel Wright <Withheld under section 9(2)(a)>
Sent: Tuesday, 6 October 2020 12:24 pm
To: Consult <Consult@Pharmac.govt.nz>
Cc: Withheld under section 9(2)(a)
Subject: Consultation feedback: Diabetes medications

To whom it may concern

This response is later due to our waiting on a response from PHARMAC from 16 September 2020 (response received today after further enquiry) relating to price decreases on Galvus and Galvumet

We endorse the introduction of the new medications without question.

However the price reduction for Galvus and Galvumet is unacceptable (imposing a trading loss on stock in the supply chain), unless it has the same Price Change conditions that apply to Tenders, RFP and RFT. (Schedule 5, Clause 3)

That is to ensure price support is provided to the supply chain to ensure the price to providers is effective from the 22nd of the preceding month

Without this clause or similar there will potentially be supply issues, which will result from the supply chain reducing stock to avoid substantial losses on existing stock.

Can you please consider implementing the suggest clause in this proposal

Have a great day

STAY WELL – STAY STRONG – STAY SAFE

Kind Regards

Noel Wright
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