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Supplementary Material

Decision-making on listing new medicines for public funding in New Zealand: the case of 'new' type 2 diabetes medications

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Supplementary file S1. Summary of discussions of the PTAC and the Diabetes Subcommittee and decisions made by PHARMAC regarding applications for funding the new diabetes medicines.

Year	Summary of deliberations /recommendations made (based on Minutes of the meetings of the PTAC & Diabetes Subcommittee)
2007 and 2008[1, 2]	PTAC declines application for funding of exenatide due to limited evidence of additional benefits over funded treatment options, high cost, and an absence of long-term safety and efficacy data.
2009[3, 4]	August. Sub-comm receives first application for vildagliptin and notes exact place in therapy for DPP-4 inhibitors is unclear. Recommends low priority for funding of vildagliptin. August. Sub-comm notes high drop-out rates in some sitagliptin studies to be very high (in some cases around 80% at 2 years). Sub-comm recommends low priority for funding. November. PTAC declines application for vildagliptin for the treatment of patients with type 2 diabetes, noting majority of studies were short in duration and pivotal studies had been omitted from the application. More long-term safety data was necessary. November. PTAC declines application for sitagliptin with/without metformin. Notes the FDA warning on potential adverse effects, and lack of long-term safety data.
2010[5]	August. PTAC declines application for sitagliptin due to no new evidence being provided and likely high budget impact.
2011[6]	November. PTAC recommends low priority for funding of saxagliptin. Also tasks Sub-comm with determining which DPP-4 inhibitor should be considered for funding, and with what restrictions.
2012[7, 8]	April. Sub-comm recommends medium-high priority for funding of DPP-4 inhibitors for patients with special criteria restrictions. April. Sub-comm recommends medium-high priority for funding of GLP-1 analogues as combination therapy for patients with special criteria restrictions. April. Sub-comm notes uncertainty regarding neurological and cardiovascular benefits, as well as the benefits for beta cell function. August. PTAC recommends low priority for funding of liraglutide, noting hypoglycaemic events and concerns regarding superiority of liraglutide over insulin glargine when used in combination with a sulphonylurea. August. PTAC recommends low priority for funding of linagliptin with special criteria restrictions. PTAC also recommends low priority for funding of other previously reviewed DPP-4 inhibitors vildagliptin and sitagliptin.
2013[9]	November. PTAC recommends low priority for funding of dapagliflozin, noting lack of long-term safety data, and that elevated risk of bladder and breast cancer cannot be excluded. Also notes that management of urinary and genital infections in patients treated with dapagliflozin would lead to additional spending.
2014[10, 11]	May. PTAC recommends low priority for funding of lixisenatide. August. Sub-comm reviews all three classes, noting existing low priority recommendations for all. August. Sub-comm amends proposed special criteria restrictions. Sub-comm also notes signals regarding carcinogenicity of all three of the new classes of medicines. August. Sub-comm recommends low priority for funding of canagliflozin noting lack of long-term clinical evidence
2015[12, 13]	February. PHARMAC issues a Request for Information for the new classes of medicines. April. Sub-comm recommends at least one agent from two of the three classes be funded. April. Sub-comm notes safety concerns by FDA regarding the safety of all three classes: awaiting publication on adverse reactions.

2016[14, 15]	May. PTAC declines application for funding of dapagliflozin in combination with metformin, due to no evidence of a reduction in macrovascular and microvascular complications. October. Sub-comm notes results from new clinical trials provide evidence of safety and efficacy of the new antidiabetic agents regarding reduced HbA1c, and additional renal and cardiovascular benefits. Sub-comm notes the change in diabetes treatment paradigms internationally.
2017[16, 17]	February. PTAC agrees to reconsider empagliflozin and liraglutide. PTAC declines a review of the low priority recommendation for dapagliflozin before publication of DECLARE clinical trial results. November. PTAC recommends low priority for funding of prolonged release formulation of exenatide due to lack of evidence of benefit. November. PTAC recommends high priority for funding of empagliflozin in patients with type 2 diabetes and established high cardiovascular risk.
2018[18, 19]	May. PTAC recommends high priority for funding of liraglutide for patients with type 2 diabetes and established high cardiovascular risk. September. PHARMAC agrees to fund vildagliptin (with or without metformin).
2019[20, 21]	February. PTAC recommends medium priority for funding of dapagliflozin, based on DECLARE-TIMI trial. March. Sub-comm notes the shift in international guidelines. Notes class effect for cardiovascular benefits of GLP-1 analogues and SGLT-2 inhibitors. March. Sub-comm notes the large number of ongoing studies likely to be published in the next two years that will help refine the appropriate placement of these newer agents in the treatment paradigm. March. Sub-comm proposes Special Authority criteria for accessing GLP-1 analogues and SGLT-2 inhibitors.
2020[22-24]	January. PHARMAC issues a Request for Proposals for the three classes of medicines. September. PHARMAC agrees to fund empagliflozin (with or without metformin) and dulaglutide (pending product registration). September. PHARMAC seeks feedback on a proposal to fund these medicines, and specifically, access to these medicines for Māori and Pacific people. November. PHARMAC announces decision to delay funding of empagliflozin (with or without metformin) and dulaglutide, needing more time to consider all feedback
2021[25]	Empagliflozin (with and without metformin) funded 1 February 2021 and dulaglutide funded 1 Sept 2021.

Note: In November 2021, PHARMAC established separate terms of reference for Specialist Advisory Committees, previously called Subcommittees, to "make clear that these committees have different, but complementary, roles, expertise and perspectives to PTAC". See https://pharmac.govt.nz/about/expert-advice/specialist-advisory-committees/ for detail.

Abbreviations:

PTAC: Pharmacology and Therapeutics Advisory Committee
PHARMAC: New Zealand Pharmaceutical Management Agency
FDA: the United States Food and Drug Administration
DPP-4 inhibitors: dipeptidyl peptidase-4 inhibitors
GLP-1 analogues: glucagon-like peptide-1 analogues
SGLT-2 inhibitors: sodium glucose cotransporter 2 inhibitors

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