# 2023 position statement on improving management for patients with heart failure in Aotearoa New Zealand

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#### **ABSTRACT**

Heart failure affects 1–3% of the population and remains a major public health problem, with high rates of hospitalisation and mortality. Health inequities in the incidence of heart failure have widened over the last 13 years in Aotearoa New Zealand. Urgent action is required to address the inequitable burden of heart failure among Māori and Pasifika. Regional and international heart failure guidelines now provide clear and consistent guidance on the contemporary approach to management for patients with heart failure. The purpose of this position statement is to ensure that all people in Aotearoa New Zealand have access to optimal healthcare delivery and pharmacotherapy for contemporary management of heart failure. Three main areas are addressed, including: 1) access to evidence-based pharmacotherapy for patients with heart failure, 2) the importance of early initiation and titration of pharmacotherapy, and 3) the workforce required to ensure timely delivery of heart failure therapies. Implementation of evidence-based healthcare will ensure all patients with heart failure in Aotearoa New Zealand have opportunity for substantial improvement in health.

eart failure affects 1–3% of the population and more than 10% of those over the age of 70, and it remains a major public health problem.<sup>1</sup> While heart failure incidence rates appeared to be declining, recent Aotearoa New Zealand data have shown that the decline in incidence observed in the 2000s has now plateaued since ~2013.<sup>2</sup> This has been driven largely by an increase in incidence among younger people.

#### **Equity considerations**

Importantly, health inequities in the incidence of heart failure have widened in Aotearoa New Zealand over the last 13 years.<sup>3</sup> Previous data demonstrated that Māori were four times as likely to be hospitalised with heart failure and twice as likely to die from heart failure compared with non-Māori.<sup>4</sup> For Pasifika, hospitalisations due to heart failure were double that of non-Pasifika.<sup>5</sup> Recent national data provide important detail on the persisting health inequities relating to heart failure in Aotearoa New Zealand.<sup>3</sup> Firstly, incident hospitalisations for heart failure for Māori and Pasifika occur at a younger age, with two thirds of the cases occurring under 70 years, compared to one fifth for NZ Europeans.

The disparity in incident hospitalisation rates was most marked for younger people, with Māori and Pasifika below the age of 50 having a six-fold higher risk of hospitalisation than NZ Europeans.<sup>3</sup> Furthermore, the decline in incident rate of hospitalisation for heart failure that has been observed for older NZ Europeans has not occurred for Māori and Pasifika.<sup>3</sup> Urgent action is required to address the inequitable burden of heart failure among Māori and Pasifika.

International guidelines for the management of patients with heart failure have been updated by the European Society of Cardiology in 2021<sup>6</sup> and by the American Heart Association/American College of Cardiology in 2022.7 In 2022 a consensus statement8 was published Australia to provide updated guidance on the new recommendations for pharmacotherapy for patients with heart failure based on randomised trial evidence that had emerged since the 2018 Australian heart failure guidelines published.9 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure was released on 25 August 2023.10 Collectively, these guidelines/consensus statement provide clear and consistent guidance on the contemporary approach to heart failure management.

The purpose of this position statement is to ensure that all people in Aotearoa New Zealand have access to optimal healthcare delivery and pharmacotherapy for contemporary management of heart failure. This will be addressed in the following sections:

- 1. Access to evidence-based pharmacotherapy for patients with heart failure
- 2. Importance of early initiation and titration of pharmacotherapy
- 3. The workforce required to ensure timely delivery of heart failure therapies

## 1. Access to evidence-based pharmacotherapy for patients with heart failure

Recommendations for pharmacotherapy for patients with heart failure can be considered according to the underlying left ventricular ejection fraction [LVEF] phenotype:

### a) Heart failure with reduced ejection fraction (HFrEF)

Optimal therapy includes the following four classes of medications, all of which have Class 1-A recommendations in heart failure guidelines (i.e., recommended for use with data from multiple randomised controlled clinical trials) for use in patients with HFrEF:

- Renin-angiotensin system antagonist (ACEinhibitor or angiotensin receptor antagonist
- [ARB] or the ARB and neprilysin inhibitor combination [ARNI])
- Beta-blocker
- Mineralocorticoid receptor antagonist (MRA)
- Sodium-glucose-cotransporter-2 (SGLT2) inhibitor

Specifics comments and recommendations relating to the above guideline-directed medical therapies (GDMT):

 ARNI therapy (sacubitril/valsartan) is recommended to be available as first-line therapy for patients with HFrEF.<sup>8,11</sup> Current Aotearoa New Zealand special authority criteria for access to funded sacubitril/ valsartan require the patient is receiving "concomitant optimal standard chronic heart failure treatments". Recommendation: ARNI therapy (sacubitril/valsartan) is fully funded as first-line treatment for patients with HFrEF without special authority requirements.

ii. SGLT2 inhibitor therapy is recommended as first-line therapy for patients with HFrEF.<sup>6-8,11</sup>

Current special authority criteria for access to funded SGLT2 inhibitor therapy (empagliflozin) is limited to those who have diabetes with specific  $HbA_{1c}$  criteria. With the strength of evidence of benefit for patients with heart failure regardless of diabetes status, many patients with heart failure are being offered this therapy but with the need to self-fund. When access to GDMT is dependent on self-funding this can only perpetuate health inequities in Aotearoa New Zealand.

Recommendation: SGLT2 inhibitors are fully funded for patients with HFrEF without special authority requirements.

iii. MRA therapy in Aotearoa New Zealand is predominately with spironolactone. Spironolactone has a significant side-effect profile, including gynaecomastia in 10% of men, compared with the MRA eplerenone. Sole supply status for eplerenone in Aotearoa New Zealand expired on 30 June 2021 and generic versions of eplerenone are now available internationally.

Recommendation: Eplerenone is fully funded for patients with HFrEF without special authority requirements.

# b) Heart failure with mildly reduced ejection fraction (HFmrEF) and preserved ejection fraction (HFpEF)

The categorisation of patients with heart failure based on the EF phenotype includes two categories where the LVEF is above 40%: HFmrEF LVEF 41–49% and HFpEF LVEF ≥50%.

GDMT that have been successful in improving outcomes for patients with HFrEF (ACE-inhibitors/ARB/ARNI, beta-blockers and MRA) have not had the same efficacy when applied to patients with HFmrEF or HFpEF. The exception to this is the evidence of benefit with SGLT2 inhibitors. Major clinical trial evidence has recently emerged, with publication of the EMPEROR-Preserved trial (empagliflozin) in 2021 and the DELIVER trial (dapagliflozin) in 2022 (see Figure 1 and Table 1 for trial summaries). 12,13 The 2023

**Figure 1:** Summary of the four pivotal randomised controlled trials with SGLT2 inhibitors in patients with heart failure across the EF phenotypes.

#### LV Ejection Fraction Phenotype ≤ 40% ≥ 50% 41 - 49% **HFrEF** HFmrEF **HFpEF DELIVER (2022) DAPA-HF (2019)** Dapagliflozin 10mg daily Dapagliflozin 10mg daily N = 6263N = 4744EMPEROR-Reduced (2020) **EMPEROR-Preserved (2021)** Empagliflozin 10mg daily Empagliflozin 10mg daily N = 3730N = 5988

McMurray et al. DAPA-HF NEJM 2019 DOI: 10.1056/NEJMoa1911303 Packer et al. EMPEROR-Reduced 2020 DOI: 10.1056/NEJMoa2022190 Anker et al. EMPEROR-Preserved 2021 DOI: 10.1056/NEJMoa2107038 Soloman et al. DELIVER 2022 DOI: 10.1056/NEJMoa2206286

Table 1: Summary evidence tables for the key trials of SGLT2 inhibitors in patients with HFpEF.

	EMPEROR-Preserved trial <sup>12</sup>		DELIVER trial <sup>13</sup>	
Year published	2021		2022	
SGLT2 inhibitor	Empagliflozin 10mg daily		Dapagliflozin 10mg daily	
N	5,988		6,263	
NYHA functional class	II-IV		II-IV	
LVEF inclusion criteria	LVEF >40%		LVEF >40%	
Type II diabetes	49%		48%	
Primary end point	CV death or HF hospitalisation		Worsening HF or CV death	
	Placebo	Empagliflozin	Placebo	Dapagliflozin
Primary end-point events	511 (17.1%)	415 (13.8%)	610 (19.5%)	512 (16.4%)
HR (95% CI)	0.79 (0.69–0.90)		0.82 (0.73–0.92)	
Absolute risk reduction	3.3%		3.1%	
NNT	31 over 26 months		32 over 2.3 years	
Primary end-point composites				
Heart failure hospitalisations	541 (%)	407 (%)	455 (14.5%)	368 (11.8%)
HR (95% CI)	0.73 (95% CI 0.61-0.88)		0.79 (95% CI 0.69-0.91)	
CV death	244 (8.2%)	219 (7.3%)	261 (8.3%)	231 (7.4%)
HR (95% CI)	0.91 (95% CI 0.76-1.09)		0.88 (95% CI 0.74-1.05)	

SGLT2 inhibitor = sodium-glucose-cotransporter-2 inhibitor; NYHA = New York Heart Association function class; LVEF = left ventricle ejection fraction; CV = cardiovascular; HF = heart failure; HR = hazard ratio; CI = confidence interval; NNT = number needed to treat.

European Society of Cardiology Heart Failure Guidelines<sup>10</sup> now reflect this recent clinical trial evidence with a Class 1-A recommendation for SGLT2 inhibitor therapy for patients with HFmrEF and HFpEF.

Thus, the recommendations for SGLT2 inhibitor therapy applies to <u>all patients with heart failure regardless of EF phenotype</u> (with consistent level/strength of evidence across the EF phenotypes).

Recommendation: SGLT2 inhibitors are fully funded without special authority requirements for patients with heart failure with all EF phenotypes.

## 2. Importance of early initiation and titration of pharmacotherapy

Contemporary pharmacotherapy addresses multiple maladaptive pathways in pathophysiology of heart failure independent and additive clinical benefits. The benefits of GDMT with the combined classes listed above has recently been quantified for patients with HFrEF.14 To emphasise this benefit, in a 55-year person with HFrEF, the combined estimated benefit of the four classes of GDMT is to provide 8.3 additional years free of either cardiovascular death or first hospitalisation for heart failure compared with ACE-inhibitor or ARB and beta-blocker. These substantial benefits support the recommendation for combination therapy with ARNI, beta-blocker, MRA and SGLT2 inhibitor.

Despite these established benefits, translation of the evidence into practice remains challenging. Implementation interventions that can improve uptake of GDMT can be considered in three categories: healthcare (policy) interventions, institution/clinically led interventions and patient-level interventions (such as educational tools and electronic prompts). Recommendations have been made in this current position statement regarding policy changes that can favourably impact on access to GDMT.

Recent evidence is now available on strategies that can enable early initiation and appropriate titration of disease-modifying medications for patients with heart failure. The STRONG-HF trial utilised early initiation of GDMT prior to hospital discharge following admission with heart failure. Post-discharge early follow-up was planned with the primary aim of safe optimisation of GDMT. This intervention reduced the risk of death from

any cause or heart failure readmission at 180 days compared with a usual care group (adjusted risk ratio 0.66 [95% confidence interval [CI] 0.50–0.86]).

With proven evidence-based interventions it is now appropriate to shift the emphasis to early initiation of combination GDMT (during hospitalisation and/or at diagnosis) and aim for rapid dose-titration to optimise clinical outcomes for patients with heart failure in Aotearoa New Zealand. This has been addressed with specific recommendations for pre-discharge and early post-discharge follow-up of patients hospitalised with heart failure in the 2023 European Society of Cardiology heart failure guidelines (level of evidence 1-B).<sup>10</sup>

Incorporating these guideline-based recommendations needs strategies that are appropriate to the Aotearoa New Zealand environment and that optimise healthcare delivery and outcomes. Such strategies must follow principles to ensure best-quality care, including, for example, involving patients and whānau (where appropriate), ensuring health literacy principles are followed (simple, clear language, checking patients' understanding and allowing time for questions) and using specific models of care for Māori and Pasifika that minimise barriers to healthcare.

Recommendation: Following hospitalisation for heart failure, patients with HFrEF should have early initiation of low-dose, combination GDMT. Appropriate models of healthcare are required to support immediate transition from hospital to the community and to facilitate subsequent rapid titration of GDMT to optimise therapy.

#### 3. The workforce required to ensure optimal outcomes for patients with heart failure

Multidisciplinary heart failure management programmes have been shown to reduce heart failure hospitalisations and improve survival. Multidisciplinary management can ensure timely access to correct investigations and enable diagnoses, ensure implementation of GDMT and provide education and support for self-management. The 2009 Aotearoa New Zealand heart failure guidelines<sup>17</sup> recommended the following:

"A structured approach to chronic disease management is recommended for patients with heart failure, especially

for those at high risk, such as those with recent hospitalisation (level of evidence 1: grade of recommendation A)."

Structured heart failure management programmes should be flexible and adapt to the needs of the patients and local healthcare environment. Importantly, such programmes in the Aotearoa New Zealand healthcare environment need to ensure patient- and whānau-focussed care can be delivered to appropriately support people affected by this long-term condition. People need to be empowered with self-management support programmes to be able to work in partnership with their healthcare team(s). Communication and health literacy principles need to be followed to ensure patients and their whānau can achieve this partnership.

There is a clear role for specialist-trained heart failure nurses for the success of any such programme. In addition, the 2009 heart failure guidelines highlighted that adequate funding to sustain such management programmes is required. Recommendations from the United Kingdom are that the minimum requirement of specialist heart failure nurses is two full-time equivalent [FTE] per 100,000 population for management of patients with HFrEF, increasing to four FTE per 100,000 population if all ejection fraction phenotypes are to be managed.18 A recent survey of the heart failure nursing workforce in Aotearoa New Zealand (personal communication: in an email from H McGrinder following presentation at the CSANZ Regional Meeting 2023) has shown that there are only 0.79 FTE per 100,000 population, and only three District Health Board populations

had  $\geq 2$  FTE per 100,000 population (although this combined population only represented 5% of the total Aotearoa New Zealand population). Increasing this workforce will help to reduce inequity based on domicile, which is especially important where ethnic disparities exist.

Finally, we need to recruit more Māori and Pasifika healthcare professionals into the cardiac workforce, not just for delivery of care but to provide leadership, cultural experience and diversity, which are vital to engaging underserved populations.

#### **Recommendations:**

- Heart failure nursing FTE is increased to a of minimum of 2 FTE per 100,000 population for the whole of Aotearoa New Zealand to optimise clinical outcomes for patients with heart failure.
- Nurse practitioner internship pathways be made mandatory for regional cardiology services as part of workforce development.

In summary, this position statement aims to provide clear guidance on key aspects of health-care for patients with heart failure. Access to fully funded evidence-based pharmacotherapies, implementation strategies to deliver high-quality care and the workforce required to deliver this will reduce inequities and ensure that all patients in Aotearoa New Zealand have the opportunity for improved quality of life, reduced hospitalisations and improved survival. Action is urgently required to address these three important aspects of healthcare delivery.

#### **COMPETING INTERESTS**

None.

#### **ACKNOWLEDGEMENTS**

This document was reviewed and endorsed by the Cardiac Society of Australia and New Zealand NZ Regional Committee (Committee members: Stiles M, Barr P, McClean D, Rice K, Webber M, Fairly S, Neilson S, Diedrichs-Farnan Z, Rossiter S, Wickham J, Eddington R, Boddington D, Johnson KA; authors indicated with \* are also members of the CSANZ NZ Regional Committee) and has been endorsed by the New Zealand Cardiac Network.

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#### URL

https://nzmj.org.nz/journal/vol-137-no-1590/2023-position-statement-on-improving-management-for-patients-with-heart-failure-in-aotearoa-new-zealand

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