Quantifying cost-savings in the treatment of neovascular age-related macular degeneration in Aotearoa New Zealand

James S Lewis, Matthew Roskruge, John Ah-Chan

ABSTRACT

AIMS: To estimate the cost-impact if faricimab were approved for the treatment of neovascular age-related macular degeneration (nAMD) in New Zealand.

METHODS: A retrospective, single-centre cost-analysis study. Data on intravitreal agent and injection intervals were obtained and statistically compared. Cost estimates were based on internal facility and publicly available data. The current costs of care were compared to two scenarios: one where all eyes receive faricimab, and another where eyes receiving aflibercept switch to faricimab.

RESULTS: A total of 352 eyes from 292 patients were analysed. Present values locally over 10 years were estimated at -$6,776,340 for the first scenario and $5,015,922 for the second, releasing 252 and 176 hours of clinical time per year, respectively. Nationally, the savings extrapolated to -$187,925,737 and $139,104,706, respectively. The analysis indicates significant direct cost savings for the health sector and potential reductions in patient harm due to fewer injections.

CONCLUSIONS: The approval of faricimab for the treatment of nAMD could result in substantial direct cost savings for the health sector. Additional benefits include reducing patient harm and improving ophthalmic health inequalities for Māori and Pacific peoples. Further research in diverse patient populations across multiple centres is needed to estimate the magnitude of cost savings more accurately. This study highlights the potential of faricimab to alleviate the treatment burden and provide a more sustainable healthcare option for nAMD in New Zealand, especially in cases of recalcitrant nAMD, if used in a tailored and patient-specific manner alongside the existing armamentarium of treatments.

Neovascular age-related macular degeneration (nAMD) is an end-stage manifestation of age-related macular degeneration (AMD) and is a leading cause of visual impairment and blindness worldwide.[1] AMD can be divided into early and late stages. Early AMD is characterised by soft drusen and pigmentary changes at the macula, while late AMD is characterised by geographic atrophy and/or choroidal neovascularisations, the latter with retinal haemorrhage, oedema and fibrosis, ultimately leading to significant vision loss. Age is the main risk factor for nAMD, and the incidence is expected to increase with the ageing population.[1]

In New Zealand, there are no contemporary population-based studies of the prevalence of nAMD. Recent publications have extrapolated prevalence from high-quality international studies such as Wong et al.[2] A 2016 report commissioned by Blind Low Vision NZ and prepared by Deloitte estimated the prevalence of early AMD to be 199,140, and late AMD to be 19,847.[3] A 2015 study estimated that in 2026 the prevalence of early AMD would be 208,200 people and late AMD to be 8,600 people.[4] There are no recently published data on the number of intravitreal injections performed for nAMD across New Zealand. Data from our centre shows 2,277 intravitreal injections performed in 2022 for nAMD from a population of 190,000 patients. Data from Auckland suggest 17,000 injections for all indications, with a population of 1.6 million people.[5] These data give a rate of between 1.06 to 1.20 injections per 100 people, meaning the annual number of injections in New Zealand for nAMD is likely to be between 55,985 to 63,137 injections per year, with an expected increase of 15% year-on-year.[6]

Intravitreal injections for the treatment of nAMD have revolutionised the visual prognosis, with proved efficacy and safety in clinical trials.[1] However, the real-world outcomes have often fallen short of those demonstrated in the literature, with lower best-corrected visual acuity (BCVA) gains.[7] The treatment burden of injections as

frequent as every 4 weeks on the patients, caregivers and the healthcare system as a whole may result in undertreatment, and this is thought to be the reason for lower gains in the clinical setting.[8] There is, therefore, a need for treatments that are both effective and durable.

Faricimab is a dual VEGF-A and ang-2 inhibitor administered by intravitreal injection. It is a humanised, bi-specific IgG monoclonal antibody, hypothesised to provide superior durability, as well as possibly superior efficacy in the treatment of nAMD due to its dual inhibition of two key pathways in the pathogenesis of this disease. It has been approved by the US Food and Drug Administration, the European Medicines Agency and, recently, the Australian Therapeutic Goods Administration and Medsafe.[9–12] In New Zealand, bevacizumab and ranibizumab are funded by Pharmac for the treatment of nAMD.[13] A third agent, aflibercept, is funded as a second-line agent on application for Special Authority.[14] In the TENAYA and LUCERNE clinical trials, faricimab was found to be non-inferior to aflibercept in terms of preserving BCVA. In addition, at 48 weeks, 80% of patients were on dosing intervals ≥12 weeks, and approximately 45% of patients were on 16-week dosing intervals. Comparatively, 64.1% of eyes treated with aflibercept have been reported as stable on ≥12-week dosing intervals.[15]

Palmerston North Hospital Eye Department, a part of Te Pae Hauora o Ruahine o Tararua Mid-Central, provides specialist ophthalmic care to a total population of around 190,000 patients living in Palmerston North City, Manawatū, Tararua and Horowhenua districts, and the small town of Ōtaki.[16] This study was conducted to investigate the current intravitreal dosing regimens for patients with nAMD and associated costs. A secondary cost analysis was then performed to explore potential cost-savings if faricimab were to be approved and used for the treatment of nAMD.

Methods

This retrospective cost analysis evaluated 396 eyes of 326 patients who had received intravitreal injections at Palmerston North Hospital in 2023. Records from an electronic database were used to generate a list of eyes that had received intravitreal injections for nAMD during 2023. The patient's clinical records were then reviewed to confirm the eye injected, the agent used (aflibercept or bevacizumab), the total number of injections performed in that eye to date and the current interval between injections.

The study has been evaluated by the Health and Disability Ethics Committee and deemed not to require ethics approval.

When calculating the dosing intervals used for cost analysis, 44 eyes of 42 patients were rejected as they had received fewer than four injections, on the assumption that they were receiving an induction series of injections, and the appropriate treatment interval was still being evaluated.

The hospital finance department provided cost estimates for the process of intravitreal injections, nurse-led macula review clinics and consultant clinics. These were assumed to take 20 minutes, 20 minutes and 15 minutes, respectively.

The cost for an intravitreal injection of bevacizumab was calculated as $199.48, aflibercept $1,406.23 and faricimab $1,721.23. The cost for bevacizumab was based on internal data, as it is compounded by an external supplier. The cost for aflibercept is the published price on the Hospital Medicines List. The cost for faricimab is based on the published GST-exclusive list price from Roche. The cost for a nurse-led macula review clinic was $60.62 and the cost of a consultant clinic was $100.85.

For the purposes of net present value calculations, a discount rate of 3.5% was assumed with a 10-year time horizon to align with the Pharmac recommendations for pharmacoeconomics, with sensitivity analyses at 0% and 5%.[17]

Regardless of the agent used, the number of intravitreal injections received was calculated as 52 weeks divided by the dosing interval. It was assumed that in a 52-week period, an individual eye would receive two consultant reviews, and review in the hybrid clinic after every three injections for injection intervals up to 11 weeks. For injection intervals 12 weeks and greater, a review would be conducted following each injection.

The cost scenarios explored were the current treatment model, a treatment model where all eyes were treated with faricimab and a treatment model where faricimab was used instead of aflibercept. The faricimab models assumed that patients treated would achieve the results in the TENAYA and LUCERNE trials, where of 631 eyes, 134 eyes (21.3%) were maintained on an 8-weekly interval, 211 eyes (33.4%) were maintained on a 12-weekly treatment interval and 286 eyes (45.3%) were maintained on a 16-weekly treatment interval.

Microsoft Excel for Mac (Version 16.77.1) was used for data management, and R (version 4.4.1,

The R Foundation for Statistical Computing, Vienna, Austria) along with RStudio (version 2024.04.2+764, RStudio, PBC, Boston, MA) was used for statistical analysis. The "lme4" and "emmeans" packages were utilised for fitting the mixed linear models and generating estimated marginal means, respectively.[18,19] The Bonferroni correction was applied to account for the multiple statistical tests performed, reducing the likelihood of type I errors and ensuring that the overall significance level remains controlled.[20] Specifically, the original significance level ($\alpha = 0.05$) was divided by the number of tests performed (16 intervals), resulting in a corrected α of 0.003125.

Results

In total, 396 eyes representing a cohort of 326 patients receiving injections were used to perform the initial analysis. A total of 225 eyes (56.8%) received bevacizumab and 171 eyes (43.2%) received aflibercept.

Using mixed linear models to account for the correlation between measurements on two eyes of the same patient, the estimated marginal mean (EMM) weekly interval for bevacizumab was 10.46 weeks (95% CI: 9.92 to 11.01 weeks), and for aflibercept, it was 7.26 weeks (95% CI: 6.63 to 7.89 weeks).

The mean difference between the two agents was 3.2 weeks (95% CI: 2.39 to 4.02 weeks), and this difference was statistically significant ($p < 0.0001$).

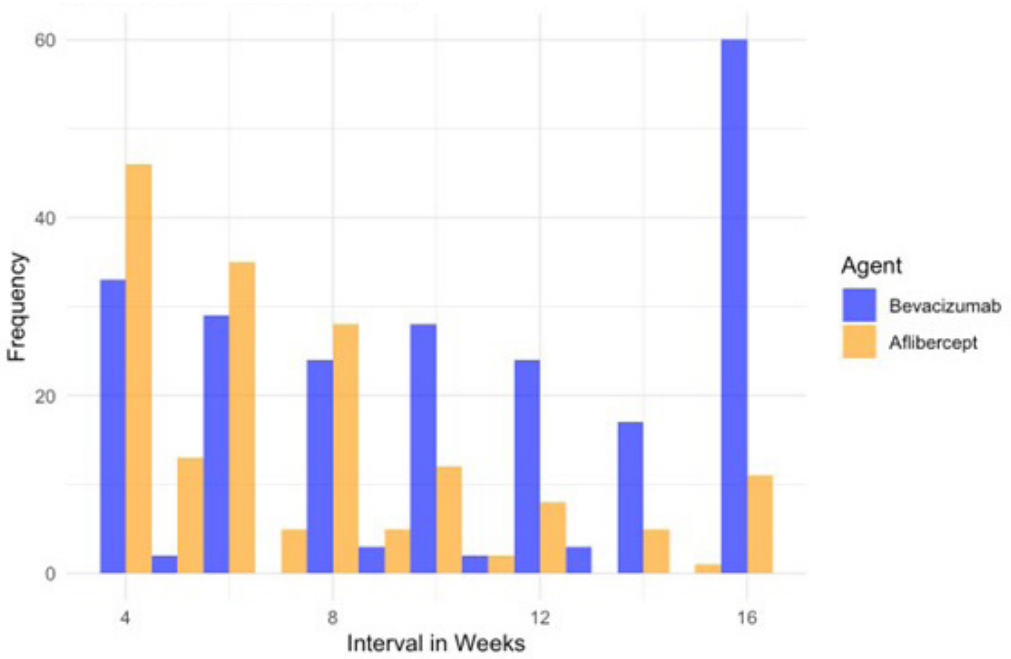
The Bonferroni-corrected p-value was 9.71e-14, which remains highly significant, indicating a robust difference in injection intervals between the two treatments.

The histogram provided shows the differences in injection intervals between the two cohorts.

Under the current treatment model, there is an estimated yearly total of 2,597 injections, with 1,265 bevacizumab injections (48.7%, estimated cost $252,293) and 1,332 aflibercept injections (51.3%, estimated cost $1,873,253). There are 1,211 nurse-led macula review clinics ($73,416) and 792 consultant clinics ($79,873). The estimated total cost is $2,278,835.

Under the option where all eyes receive faricimab, there are 1,704 injections ($2,932,567) yearly. There are 1,339 nurse-led macula review clinics ($81,191) and 792 consultant clinics ($79,873). The estimated total cost is $3,093,631, a yearly cost increase of $814,796 over the current treatment model. The net present value over the 10-year period modelled is -$6,776,340 using a discount rate of 3.5% per annum. Sensitivity testing using discount rates of 5% and 0% provide net present values of -$6,291,642 and -$8,147,964 respectively. A total of 252 hours of clinical time are saved per year.

Figure 1: Frequency distribution of injection intervals between bevacizumab and aflibercept.



Under the option where eyes receiving aflibercept instead receive faricimab, there is an estimated yearly total of 2,001 injections, with 1,265 bevacizumab injections ($252,293) and 736 faricimab injections ($1,266,336). There are 1,274 nurse-led macula review clinics ($77,212), and 792 consultant clinics ($79,873). The estimated total cost is $1,675,714, a yearly cost saving of $603,121 over the current treatment model. The net present value over the 10 years modelled is $5,015,922 using a discount rate of 3.5% per annum. The net present value is $4,657,143 using a 5% discount rate, and $6,031,213 using a 0% discount rate. A total of 176 hours of clinical time are saved per year.

The area serviced by Palmerston North Hospital accounts for 3.61% of the population of New Zealand. Without adjusting for differences such as demographic structure, the 10-year national cost impact for the first scenario can be estimated at a net present value of -$187,925,737 using a discount rate of 3.5% per annum. The national cost impact for option two can be estimated at a net present value of $139,104,706 saved using a discount rate of 3.5% per annum.

Discussion

This analysis indicates that there is the potential for significant benefits if faricimab were to be approved for the treatment options for nAMD in New Zealand. In this analysis, faricimab is demonstrated to be a strongly dominant treatment option, resulting in both improved clinical outcomes and cost savings when used in conjunction with the existing treatments rather than standalone.[21]

Clinical superiority is demonstrated in several domains. First, there is the direct harm avoided by reduced administration of intravitreal injections to patients. Endophthalmitis is a rare but devastating complication of intravitreal injections, with a reported incidence of 1 per 1,888 to 1 per 4,897 injections.[22,23] With both alternative treatment models leading to a decrease in the total number of yearly injections performed, the incidence of endophthalmitis would be expected to decrease. Other complications of intravitreal injection include corneal abrasion, subconjunctival or vitreous haemorrhage, retinal tears or detachment, uveitis, myocardial infarction and stroke.[24] The incidence of these complications could similarly be expected to lessen.

Aside from the direct cost savings demonstrated under the second scenario, further financial benefits would accrue to patients, caregivers and society from a reduced number of intravitreal injections performed. The Deloitte report highlighted the costs of reduced employment, productivity and tax revenue as a result of AMD, as well as the costs of informal care for patients receiving treatment.[3] While the calculations provided do not allow an estimate of the magnitude of this change, it is nevertheless a tangible benefit from a reduction in the burden of treatment.

The psychological impact of intravitreal injection treatments on patients also cannot be ignored. The literature suggests that patients receiving injections continue to feel anxious about treatment, including the fear of losing their vision due to complications of the injection and if they have had previous painful experiences of intravitreal injections.[25] It can be concluded that reducing the number of intravitreal injections received per year would ameliorate these feelings to some degree, decreasing the treatment burden for these patients.

Critical to the New Zealand context, a change to the current model of care also has the possibility of alleviating health inequalities between Māori, Pacific peoples and other ethnicities. While nAMD has a low prevalence among Māori and Pacific peoples and has been assumed to be zero for the purposes of prevalence estimates and forecasting,[4] the literature overwhelmingly indicates the urgent ophthalmic health inequalities faced by Māori and Pacific peoples.[26]

Our alternative treatment models indicate that between 176 and 252 hours of clinical time would be released yearly due to a reduction in the numbers of intravitreal injections and nurse-led macula review clinics. This time could then be channelled into these areas of need.

In addition, faricimab is also used for the treatment of diabetic macular oedema (DMO), a disease that disproportionately affects Māori and Pacific peoples.

Results from the YOSEMITE and RHINE clinical trials indicated that at year 1, >70% of patients in the PTI group were on ≥12-week dosing intervals, and 53% (YOSEMITE) and 51% (RHINE) received 16-week dosing intervals, compared with the standard 8-weekly intervals for patients on aflibercept.[27]

As faricimab has been approved for the treatment of nAMD and DMO in the United States, European Union and Australia,[9–11] if faricimab is funded for the treatment of nAMD in New Zealand, it will almost certainly be funded for the

treatment of DMO as well.

The benefits from reduced injection intervals with bevacizumab or aflibercept in this patient group could be expected to be broadly similar to those demonstrated in this study, including cost benefits and clinical benefits. However, we acknowledge that the increased quality of life benefits for Māori and Pacific peoples by freeing up clinical time are speculative. Although the potential for such benefits exists, it is based on the assumption that the freed-up clinical time would be effectively utilised to address these health inequalities.

Our research has several limitations. First, it is difficult to establish whether a patient has reached a treatment plateau and is being maintained on a stable dosing interval or is being moved to progressively longer treatment intervals using a "treat and extend" model to find their maximum fluid-free interval.[28]

We attempted to address this concern by excluding eyes from the calculation of dosing intervals that had received less than four injections, on the assumption that these eyes were being inducted into treatment.

Our analysis represents a snapshot of the intervals of treatment at the time the data was collected, and it is possible that this does not reflect the true underlying stable treatment patterns for our patient cohort. Further, our study draws data from a single hospital and may not generalise to other New Zealand settings.

Second, our study assumes that the treatment intervals achieved will be the same as those in the TENAYA and LUCERNE Stage 3 clinical trials. Previous experience shows real-world treatment regimens often fall short of those in clinical studies.[8]

The 6-month results of the TRUCKEE study included a majority of eyes that had been previously treated with anti-VEGF. This trial demonstrated the efficacy of faricimab in the real-world setting, although durability was not assessed.[29]

Additionally, aflibercept is used as a second-line therapy for nAMD in New Zealand. While there are still gaps in the literature regarding the durability of faricimab in treatment-resistant nAMD, emerging research suggests that faricimab offers statistically significant durability over aflibercept, even in this patient population.

One study indicates that patients attained a mean dosing interval of 7.64 weeks with faricimab compared to 5.16 weeks for aflibercept, with 10% of patients achieving dosing intervals of 12 weeks or longer.[30]

A further study found that 31.5% of patients treated with intravitreal faricimab attained a treatment interval ≥8 weeks and had a fluid-free macula on OCT at 12 months.[31] Although the emergence of reliable data on faricimab for the treatment of recalcitrant nAMD would impact the magnitude of cost-savings demonstrated by this study, the available evidence suggests that at least some of these benefits would accrue, and supports the use of faricimab as part of a tailored approach in those patients with treatment resistant nAMD on the basis of extending the injection interval and reducing the possible harm from intravitreal injections.

A final limitation of our study is the lack of a comprehensive sensitivity analysis. While we reached out to additional district health boards to obtain cost data for such an analysis, we have not received responses. We believe that an exhaustive sensitivity analysis may extend beyond the scope of this manuscript. Given that the main cost inputs, such as practitioner time and consumables, remain consistent across different types of injections, an extensive sensitivity analysis might offer limited additional value.

In conclusion, this analysis demonstrates significant differences between treatment intervals for eyes with nAMD being treated with bevacizumab and aflibercept at Palmerston North Hospital.

It highlights the possible cost impact for Health New Zealand – Te Whatu Ora if faricimab were to be funded for the treatment of nAMD, as well as considering the reduction in direct patient harms from a reduced number of injections.

Indirect benefits, from improved quality of life to increased productivity and employment, might also be expected.

There is the possibility of reduced health inequalities for Māori and Pacific peoples as clinical time is liberated, if these resources could be effectively channelled into areas of need.

Faricimab could also lead to expanded treatment options for DMO.

There is a need for further real-world research, particularly in treatment-resistant patient populations, in order to more accurately quantify the expected benefits from approving this medication.

It is hoped that this analysis will add to a body of literature informing the funding of faricimab for the treatment of nAMD in New Zealand, as part of a tailored treatment approach incorporating the existing agents and balancing the possible impacts on a patient's quality of life with our wider duty to prudently manage scarce healthcare resources.

COMPETING INTERESTS
The authors declare that they have no conflicts of interest. There has been no financial support for this work that could have influenced its outcome. In particular, there has been no funding or any form of support from any of the manufacturers of the agents described in this paper. All authors contributed equally to the conception, design and analysis of this study.

AUTHOR INFORMATION
James S Lewis, BCom, MBChB: Registrar, Department of Ophthalmology, Palmerston North Hospital, Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral, Manawatū-Whanganui, New Zealand.
Matthew Roskruge, PhD: Associate Dean; Māori, Massey Business School, Massey University, Albany, New Zealand.
John Ah-Chan, FRANZCO, BMedSci: Consultant, Department of Ophthalmology, Palmerston North Hospital, Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral, Manawatū-Whanganui, New Zealand.

CORRESPONDING AUTHOR
James S Lewis: Department of Ophthalmology, Palmerston North Hospital, Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral, Manawatū-Whanganui, New Zealand. E: James.Lewis@ccdhb.org.nz

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