New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

19 February 2021

PHARMAC

By email: consult@pharmac.govt.nz

Funding criteria for rosuvastatin

Dear Colleague

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above proposal. We note that PHARMAC is considering the listing of rosuvastatin on the Pharmaceutical Schedule for patients who meet the following Special Authority (SA) Criteria:

1) Patient has familial hypercholesterolemia, and/or calculated risk of cardiovascular disease of at least 15% over 5 years;
   AND
2) Patient has not reduced their LDL cholesterol to less than 2.0 mmol/L with the use of the maximal tolerated dose of atorvastatin or simvastatin (with or without ezetimibe).

We understand that initial application is to be from any relevant practitioner with approvals valid for 2 years. Renewal is also to be from any relevant practitioner with approvals valid without further renewal unless notified if treatment remains appropriate and the patient is benefitting from treatment.

The NZMA strongly supports the addition of rosuvastatin to the Schedule, a move that we believe is long overdue. However, we are concerned that the proposed SA Criteria that would apply are too restrictive. Indeed, there are compelling grounds for rosuvastatin to be a first-line agent given that it is the most effective and safe statin.

We believe the proposed SA criteria should better align with American and European Guidelines. These recommend high-intensity statins for familial hyperlipidemia (with a target LDL cholesterol <1.4 mmol/L) and after stroke, acute coronary syndrome (ACS) or a peripheral vascular event, with European Society of Cardiology (ESC) guidelines targeting LDL cholesterol <1.4 mmol/L after ACS, revised to <1.0 mmol/L if there are recurrent events within 2 years.

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We offer the following suggestions for PHARMAC's consideration.

- We believe the proposed LDL cholesterol level of 2.0 mmol/L is too high and should be adjusted to align with the ESC guidelines.

- High intensity statins are defined as atorvastatin 40–80mg, rosuvastatin 20–40mg or simvastatin 80mg. However, simvastatin 80mg has a black box warning in the United States because of the increased risk of myalgia and myositis. While simvastatin 80mg should not be initiated, it can be continued if it is tolerated. This is an important consideration that we believe should be acknowledged by PHARMAC when defining the position of rosuvastatin among the statins.

- Intolerance to statins is usually defined by the inability to tolerate at least two statins. While it would be useful to have another statin, it is not expected that there would be less intolerance to rosuvastatin than with existing statins.

- We believe that an initial application for SA is sufficient and suggest PHARMAC waive the proposed requirement for reapplication. We also seek clarification on what is meant by 'any relevant practitioner'. Our view is that this must include vocationally registered GPs.

We hope our feedback is helpful.

Yours sincerely

Dr Kate Baddock
NZMA Chair