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Consumer Media

Government subsidises medicine to combat high cholesterol in 'high-risk' Australians

Sydney – 1 August 2021 – Experts are welcoming the Pharmaceutical Benefits Scheme (PBS) listing of a medicine that helps reduce unacceptably high 'bad cholesterol' and the risk of cardiovascular events like heart attack and stroke.[1-3]

Known as Praluent® (alirocumab) and injected once or twice a month, the medicine counters high cholesterol (LDL-C) by targeting a protein in the body called PCSK9 and causing the liver to draw more cholesterol out of the blood stream.[2] It is used in addition to two common cholesterol-lowering medicines (a statin and ezetimibe) [2].

From today, around 20,000 Australian adults,[4] including those with a history of cardiovascular disease symptoms together with an inherited cholesterol disorder or additional high risk factors, and whose LDL-cholesterol remains above 2.6 mmol/L despite dietary therapy, exercise and taking high-dose cholesterol-lowering medicines (a statin and ezetimibe), may be eligible for Praluent under the PBS.[1] Without a subsidy, the therapy would cost up to $6,500 a year.[4]

Associate Professor James Shaw, Cardiologist at The Alfred Hospital in Melbourne, welcomed the PBS listing of Praluent, highlighting that almost 100,000 heart attacks and strokes occur in Australia each year.[5]

"Many patients with a type of cardiovascular disease arising from arteries that have been narrowed by the build-up of fatty deposits have stubbornly high LDL-cholesterol that places them at high-risk of repeat cardiovascular events."[6]

"When it comes to LDL-cholesterol, research shows that lower is better, particularly in people with a history of heart disease," he said.[7]

Australian guidelines for cholesterol management recommend an LDL-cholesterol goal of <1.8mmol/L in patients with very high cardiovascular risk.[8]

"The trouble is that, despite treatment with cholesterol lowering medicines, nearly half of all high cardiovascular risk patients managed by GPs are not meeting the recommended LDL-cholesterol targets,"[6] said Dr Shaw.

"That is why the PBS listing of an additional cholesterol-lowering therapy is very much welcomed," he said.

For Australians who survive a major cardiac event, the risk of a repeat event persists for many years but is highest in the first 12 months.[9] More than a third of all admissions to hospital for acute coronary syndrome (sudden, reduced blood flow to the heart, including heart attack) involve patients who have suffered a previous cardiovascular event.[10]

“There are some patients who find themselves in a pattern of returning to hospital time and time again with heart attack, stroke or other cardiovascular complications,” said Dr Shaw.

“We need greater awareness of the importance of proactive cholesterol management, and of the benefits of combining healthy eating, lifestyle modification and medicine to achieve target levels, especially among people who have already suffered a cardiovascular event,” he concluded.

Sanofi ANZ General Manager Karen Hood welcomed the PBS listing of Praluent and reaffirmed the company’s commitment to help support Australians from the risk of recurring cardiovascular events linked to elevated LDL-C.

“Sanofi has a long and proud heritage in cardiovascular medicine,” she said. “We are pleased to be doing our part in supporting the way unacceptably high cholesterol is managed in people at high risk of repeat cardiovascular events.”

About Praluent

Praluent (75mg/mL and 150mg/mL solution for injection) is indicated as an adjunct to diet and exercise to reduce LDL-C in adults with primary (heterozygous familial or non-familial) hypercholesterolaemia in patients with moderate to very high cardiovascular risk:[2]

- In combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with maximum tolerated dose of a statin,
- alone or in combination with other lipid lowering therapies in patients who are statin intolerant or for whom a statin is contraindicated who are unable to reach LDL-C goals.

Praluent is also indicated to reduce the risk of cardiovascular events (myocardial infarction, stroke, unstable angina requiring hospitalisation) in adults with established cardiovascular disease, in combination with optimally dosed statins and/or other lipid-lowering therapies.[2]

From 1 August, Praluent will be available on the PBS for Australian adults with:[1]

- Non-Familial Hypercholesterolaemia who have symptomatic atherosclerotic cardiovascular disease (ASCVD), additional high-risk factors and LDL-C above 2.6 mmol/L despite the maximum tolerated dose of a statin and ezetimibe for at least 12 weeks; or
- Heterozygous Familial Hypercholesterolaemia with symptomatic ASCVD and LDL-C above 2.6 mmol/L, or without symptomatic ASCVD and LDL-C above 5 mmol/L despite the maximum tolerated dose of a statin and ezetimibe for at least 12 weeks.

Talk to your doctor if you have any questions about high cholesterol or cardiovascular disease.

All medicines include the risk of adverse events. In the case of Praluent, the most common adverse events include local injection site reactions, upper respiratory tract signs and symptoms, and pruritis (itchy skin). The most common adverse reaction leading to treatment discontinuation in patients treated with Praluent were local injection site reactions.[2]

Praluent should not be taken by somebody who is allergic to the active ingredient (alirocumab) or any of the ingredients. Precautions for use include patients with general allergic reactions, immunogenicity, very low LDL-C levels (long-term effects unknown), during pregnancy or breastfeeding, or in children under the age of 18. Severe liver impairment and severe kidney impairment has not been studied. Interactions with other medicines are not anticipated.[2]

For more information about Praluent, see the Consumer Medicine Information (CMI) available at:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-CMI-01965-1&d=202102231016933

PBS Information: PBS Information: Authority Required.
Non-familial and Heterozygous Familial Hypercholesterolaemia (HeFH).
Criteria apply for certain populations.
Refer to PBS schedule for full authority required information.

MINIMUM PRODUCT INFORMATION
Praluent® (alirocumab (rch) INDICATIONS Primary hypercholesterolaemia: as an adjunct to diet and exercise to reduce LDL-C in adults with primary (heterozygous familial or non-familial) hypercholesterolaemia in patients with moderate to very high cardiovascular risk: - In combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with maximum tolerated dose of a statin, - alone or in combination with other lipid lowering therapies in patients who are statin intolerant or for whom a statin is contraindicated who are unable to reach LDL-C goals. Prevention of cardiovascular events: to reduce the risk of cardiovascular events (myocardial infarction, stroke, unstable angina requiring hospitalisation) in adults with established cardiovascular disease, in combination with optimally dosed statins and/or other lipid-lowering therapies (see full PI). DOSAGE AND ADMINISTRATION 75 mg subcutaneously every 2 weeks or 300 mg every 4 weeks. May increase to 150 mg every 2 weeks if inadequate LDL-C response. Measure lipid levels from 4-8 weeks of initiating/titrating Praluent, to assess response and adjust dose if needed. To administer 300 mg, give two 150 mg injections consecutively at two different injection sites. Inject into thigh or abdomen or upper arm that is not tender, bruised, red or hard (rotate site). Allow to warm at room temperature (up to 25° C) for 30-40 min before injecting; do not warm in any other way. See full PI. CONTRAINDICATIONS Hypersensitivity to the active substance or to any of the excipients. PRECAUTIONS General allergic reactions, immunogenicity, very low LDL-C levels (long-term effects unknown), pregnancy (category B1), lactation, children (<18 years). Severe hepatic (Child-Pugh C) or severe renal impairment (eGFR < 30 mL/min/1.73 m2) not studied. INTERACTIONS Not anticipated. ADVERSE EFFECTS Common adverse reactions: injection site reactions, pruritus, upper respiratory tract signs and symptoms. Others, see full PI. NAME OF SPONSOR Sanofi-Aventis Australia Pty Ltd, 12-24 Talavera Road, Macquarie Park, NSW 2113. DATE OF PREPARATION 14 January 2020. Based on Full Product Information with TGA date of approval of 17 May 2016, with most recent amendment on 10 January 2020.

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About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Media Relations Contact
Rebecca Anable (0404 019 323) or John Morton (0416 184 044) at Ethical Strategies
OR
Name: Amy O'Hara
Position: Communications Manager, Sanofi Australia
Tel.: 0417 861 984
Email: Amy.O-Hara@sanofi.com

References:

1. Hon. Greg Hunt. Media Release, 1 August 2021.
2. Sanofi. Praluent TGA Approved Product Information. January 2020. Accessed at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-PI-01366-1&d=202102221016933
3. Chew, D. et al. National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand: Australian Clinical Guidelines for the Management of Acute Coronary Syndromes 2016, *Heart, Lung and Circulation*, 2016:25, 895–951.
4. Sanofi. Data on file. 2021.
5. Australian Institute of Health and Welfare. Cardiovascular Disease: How many Australians have cardiovascular disease, 2020. Accessed at: https://www.aihw.gov.au/reports/heart-stroke-vascular-diseases/cardiovascular-health-compendium/contents/how-many-australians-have-cardiovascular-disease
6. Baker Heart and Diabetes Institute. *Code Red Report: Overturning Australia's cholesterol complacency*. 2020. https://www.baker.edu.au/-/media/documents/impact/baker-institute_code-red-summary.pdf?la=en
7. Aylward, P. 'Time to lower LDL cholesterol targets after cardiac events'. *MJA Insight*. Accessed at: https://insightplus.mja.com.au/2019/43/time-to-lower-ldl-cholesterol-targets-after-cardiac-events/
8. National Heart Foundation Australia. Cardiac Society of Australia and New Zealand. 2012. Reducing risk in heart disease. An expert guide to clinical practice for secondary prevention of coronary heart disease - summary.
9. Fox, K. et al. From guidelines to clinical practice: the impact of hospital and geographical characteristics on temporal trends in the management of acute coronary syndromes. The Global Registry of Acute Coronary Events (GRACE). *Eur Heart J*. 2003;24:1414-24.
10. Deloitte Access Economics. *ACS in perspective: the importance of secondary prevention.* 2011. Available at: https://www2.deloitte.com/content/dam/Deloitte/au/Documents/Economics/deloitte-au-economics-acs-perspective-importance-secondary-prevention-011111.pdf