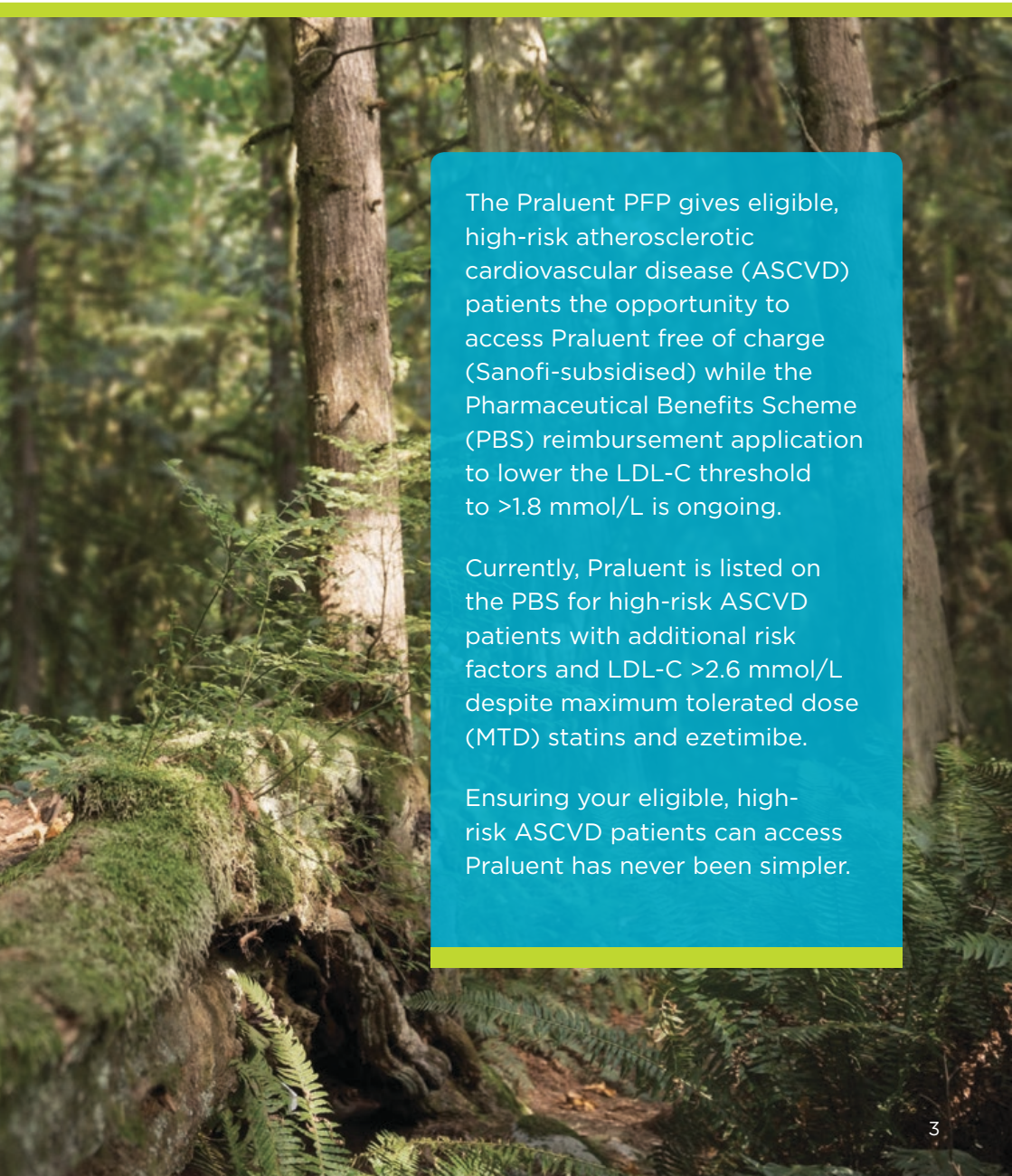
Praluent®
alirocumab

PRALUENT® PHYSICIAN GUIDE

A guide to the Praluent® Product Familiarisation Program (PFP) for Healthcare Professionals.

WELCOME TO THE PROGRAM



The Praluent PFP gives eligible, high-risk atherosclerotic cardiovascular disease (ASCVD) patients the opportunity to access Praluent free of charge (Sanofi-subsidised) while the Pharmaceutical Benefits Scheme (PBS) reimbursement application to lower the LDL-C threshold to >1.8 mmol/L is ongoing.

Currently, Praluent is listed on the PBS for high-risk ASCVD patients with additional risk factors and LDL-C >2.6 mmol/L despite maximum tolerated dose (MTD) statins and ezetimibe.

Ensuring your eligible, high-risk ASCVD patients can access Praluent has never been simpler.

HOW THE PROGRAM WORKS

Once you have determined that your patient is eligible for the Praluent PFP and have discussed it with them, you can prescribe for them using one of the following options.

1. Paper Prescription Template Provided
2. Editable PDF Prescription available. Contact your Praluent Sanofi Sales Representative.
3. The Praluent Access Portal. **www.praluentaccess.com.au**

1

HCP prescribes Praluent using paper prescription, editable PDF or online prescribing portal.

2

ONLINE
HCP provides the patient with the signed prescription.

OR

OFFLINE
HCP emails the signed and dated script to praluentaccess@pharmacyphusion.com.au and provides the patient with the original prescription.

2

3

Praluent Pharmacist Team contacts patient to confirm supply and organises delivery of Praluent PFP stock to the patient's Nominated Pharmacy.

4

Patient goes to Nominated Pharmacy with their original script to collect their Praluent.

5

Praluent Pharmacist Team contacts patient to organise subsequent supplies.

PRALUENT INDICATIONS[1]

PREVENTION OF CARDIOVASCULAR (CV) EVENTS

To reduce the risk of CV events (MI, stroke, unstable angina requiring hospitalisation) in adults with established cardiovascular disease (CVD), in combination with optimally dosed statins and/or other lipid-lowering therapies.

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

LDL-C = low-density lipoprotein cholesterol

References: 1. Praluent Approved Product Information, January 2020

PROGRAM ELIGIBILITY CRITERIA

To be eligible for the Program, your patient needs to meet the current PBS eligibility criteria, EXCEPT for the LDL-C threshold which must be >1.8 mmol/L - 2.6 mmol/L instead of >2.6 mmol/L. Your patient is also required to hold a valid Medicare card and treatment must be initiated by a specialist physician.

Program Eligibility for symptomatic ASCVD patients

The treatment must be in conjunction with dietary therapy and exercise.

- MTD statin for ≥12 consecutive weeks **OR** be intolerant or contraindicated to statins;
- AND Ezetimibe for ≥12 consecutive weeks;
- AND LDL-C >1.8 mmol/L - 2.6 mmol/L with blood test in the most recent 8 weeks;
  - AND One out of the following 5 risk enhancers:
    - 1) Severe multi-vessel coronary heart disease (≥50% stenosis in at least two large vessels);
    - 2) OR ≥2 major adverse CV events in the last 5 years (i.e. MI+, unstable angina, stroke or unplanned revascularisation);
    - 3) OR ASCVD in ≥2 vascular territories (coronary, peripheral or cerebral);
    - 4) OR Diabetes with either: microalbuminuria **OR** aged ≥60 years **OR** Aboriginal/Torres Strait Islander;

- 5) OR TIMI Risk score for secondary prevention of ≥4 (heart failure, hypertension, age 75+, current smoking, kidney dysfunction (eGFR<60), diabetes mellitus, stroke, CABG, peripheral artery disease).

ASCVD = atherosclerotic cardiovascular disease; **CABG** = coronary artery bypass graft; **CV** = cardiovascular; **eGFR**= estimated Glomerular Filtration Rate; **LDL-C** = low-density lipoprotein cholesterol; **MI** = myocardial infarction; **MTD** = maximum tolerated dose; **TIMI** = thrombolysis in myocardial infarction.

DOSAGE & INITIATION[1,2]

STEP 1

Start patients on PRALUENT 75 mg every 2 weeks[1,2]

STEP 2

Monitor response to treatment. If additional LDL-C reduction is needed to achieve individualised target after 4-8 weeks, increase the dose to 150 mg every 2 weeks[1]

PRALUENT 75 mg was used 78% of the total time and PRALUENT 150 mg was used 22% of the time in ODYSSEY OUTCOMES[2]

References: 1. Praluent Approved Product Information, January 2020 **2.** Kastelein JJP *et al. Eur Heart J* 2015;35:2996-3003.

PROGRAM LOGISTICS

Praluent will be supplied free of charge to eligible patients until 28 February 2023 (provided treatment remains in accordance with the Praluent Product Information), or until PBS listing, whichever date comes first. The Praluent Pharmacist Team will manage payment of a nominal fee of $20 and delivery to a local pharmacy nominated by the patient, which is necessary due to the cold-chain (requires refrigeration) nature of Praluent.

PATIENT SUPPORT

Patients will have access to a suite of resources located online at www.mypraluentcoach.com.au

My Praluent Coach is an injection training and support program for patients prescribed PRALUENT:

PEN TRAINING PROGRAM
One-on-one sessions delivered by qualified pharmacists from our partners at Pharmacy Phusion

PHARMACIST ON CALL
Ongoing phone support for the first 6 months from our team of pharmacists

MY PRALUENT COACH WEBSITE
Access to a How-to-Use video and a suite of online resources

To register, patients can visit MyPraluentCoach.com.au or scan the QR code printed on their PRALUENT pack

FAQs

HOW DO I PRESCRIBE FOR MY PATIENTS?

Use either the Praluent PFP dedicated prescription or the online prescribing portal to prescribe for your patients. If you are using the portal for the first time, contact your Sanofi Sales Representative for your login details or to assist with self-registration. If you self-register, your details will need to be validated, which may take one to two business days.

WHAT DO I DO WITH THE PRESCRIPTION?

If you have written a paper prescription or editable PDF please email the signed and dated prescription to praluentaccess@pharmacyphusion.com.au to initiate supply for your patient. The Program Pharmacist Team will automatically receive a copy of the prescription if generated via the portal. All prescriptions must be signed, dated and supplied to your patient for dispensing at their Nominated Pharmacy.

FAQs (continued)

Q HOW MANY PATIENTS CAN I ENROL INTO THE PROGRAM?

You are able to enrol up to 10 patients in the Praluent PFP.

Q WHAT IS THE CURRENT REIMBURSEMENT CRITERIA OF PRALUENT? HOW DO I FIND OUT IF MY PATIENT IS ELIGIBLE?

Praluent is currently PBS-listed for HeFH and symptomatic ASCVD patients with additional risk factors and with LDL-C >2.6 mmol/L despite MTD statins & ezetimibe. For further information on PBS criteria, refer to the PBS infographic, visit www.praluentPBS.com.au to use Sanofi's online interactive tool or visit the official PBS website at www.pbs.gov.au.

WHAT ARE THE CRITERIA TO ACCESS THE PRALUENT PFP?

To be eligible for the Program, your patient needs to meet the current PBS eligibility criteria, EXCEPT for the LDL-C threshold which must be >1.8 mmol/L - 2.6 mmol/L instead of >2.6 mmol/L.

HOW CAN MY PATIENT ACCESS PRALUENT IF THEY DO NOT MEET ELIGIBILITY REQUIREMENTS FOR PBS REIMBURSEMENT OR THE PRALUENT PRIVATE ACCESS PROGRAM?

Patient can privately fund Praluent. Contact your Sanofi representative to discuss PBS eligibility criteria and accessing Praluent privately.

FAQs (continued)

WILL MY PATIENTS BE CHARGED FOR THEIR PRALUENT?

There is no charge to patients who receive Praluent through the PFP.

DOES MY PATIENT HAVE TO PAY ANYTHING AT THE NOMINATED PHARMACY?

No, Pharmacy Phusion will pay a dispensing fee directly to the Nominated Pharmacy. Your patient simply collects their Praluent from the Nominated Pharmacy.

WHERE DOES MY PATIENT COLLECT THEIR PRALUENT?

Praluent is a cold chain injectable, which requires cold chain transportation and refrigeration. For this reason Praluent will be delivered to a Nominated Pharmacy of your patient's choice for collection.

WHAT SUPPORT IS AVAILABLE FOR MY PATIENT?

Free Pen Training Consultations are available to patients by calling 1300 783 956 or visiting www.mypraluentcoach.com.au.

- One-on-one injection training delivered by qualified pharmacists
- Ongoing phone support for 6 months
- Access to How-to-Use video and a suite of online resources

Just scan the QR Code on the back of the Praluent pack to visit www.mypraluentcoach.com.au

WHEN WILL THE PBS LISTING OF PRALUENT BE EXTENDED TO INCLUDE PATIENTS WITH LDL-C >1.8 MMOL/L - 2.6 MMOL/L?

Sanofi is committed to seeking reimbursement for this category of your patients. Your Sanofi representative can keep you updated on this.

FAQs (continued)

Q WILL ALL PATIENTS WHO PARTICIPATE IN THE PFP BE ELIGIBLE FOR SUBSIDISED PBS SUPPLY IF PRALUENT BECOMES PBS LISTED?

This will depend on the future PBS listing that is approved.

Q WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE PROGRAM?

You can contact the Praluent Pharmacist Team via phone on 1300 819 062 or by email praluentaccess@pharmacyphusion.com.au

Q WHO DO I CONTACT IF I REQUIRE ADDITIONAL PRESCRIPTION TEMPLATES?

Contact your Sanofi representative who will order additional supplies for you.

PRESCRIBER TERMS AND CONDITIONS OF THE PROGRAM

- The Product Familiarisation Program is sponsored by [Sponsor] and managed by Pharmacy Phusion Pty Limited
- Patient must meet eligibility criteria outlined to be enrolled in the program
- [Medicine] is not currently subsidised on the PBS for [indication].
- I understand that [Medicine] will be supplied FOC to eligible patients in accordance with the [medicine] PI until PBS listing or until [proposed Program end date], whichever date comes first
- I understand that eligible patients enrolled will only be supplied FOC [Medicine] until [Program closure date] or until PBS-listing, whichever date comes first.
- If [Medicine] is not PBS-listed, [Sponsor] will [outline proposed response e.g. close Program on x date]
- I consent for my personal information to be collected and handled as described in privacy policy
- I may be contacted by Pharmacy Phusion
- I understand I may be contacted by [Sponsor PV]
- I understand that I am entitled to enrol maximum [x] number of patients
- Enrolment is open until [timing e.g. period of time from start of Program; specific date]

- I agree to provide information about [Medicine] and/or [Program] to eligible patients I enrol in the Program
- I agree to obtain required patient consent prior to providing Pharmacy Phusion with patient information
- I agree to disclose any conflict of interests to the patient regarding [Program]
- I understand that eligible patients enrolled will only be supplied FOC [Medicine] until [Program closure date] or until PBS-listing, whichever date comes first.
- I understand that Sanofi reserves the right to review and amend the terms of the Praluent Patient Familiarisation Program (PFP), including the right to terminate the program at any time. Should amendments to current reimbursement criteria occur, Sanofi cannot guarantee that your patients will meet the criteria, however the Praluent PFP will close for all patients at this time

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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.

Please review full Product Information before prescribing.
For full Product Information visit https://secure.guildlink.com.au/gc/ws/sw/pi.cfm?product=swppralu
or by contacting Sanofi Medical Information on 1800 818 806.

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 m^2) 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. Based on Full Product Information with TGA date of approval of 17 May 2016, with most recent amendment on April 2022.

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If you have any questions about this Program please call or email the Program Manager or contact your Sanofi representative.

If you have an enquiry about Praluent or would like to request additional medical information you can contact Sanofi Medical Information on 1800 818 806.

Sanofi is responsible for monitoring and reporting on the safety of its products.

If your patient experiences an Adverse Event (AE) whilst using Praluent we ask you to report this immediately to the Sanofi Pharmacovigilance team.

Program Manager

Tel: **1300 819 062**
Email: **praluentaccess@pharmacyphusion.com.au**

Sanofi Medical Information

Tel: **1800 818 806**
Email: **medinfoanz@sanofi.com**

Sanofi Pharmacovigilance Team

Tel: **+61 2 8666 2123**
Email: **ae@sanofi.com**
Fax: **+61 2 8666 3050**

The Praluent® (alirocumab) private access program is coordinated by Pharmacy Phusion on behalf of sanofi-aventis Australia Pty Ltd trading as Sanofi. Sanofi and Pharmacy Phusion will manage your personal information in accordance with this Statement and the Privacy Act 1988 (Cth). Privacy policies are available upon request at: www.sanofi.com.au/en/privacy-policy or at: privacy@pharmacyphusion.com.au Postal: PO Box R484, Royal Exchange, NSW, 1225. The Privacy Policy explains how we will collect, use, store and disclose your personal information, and the way in which you can access and seek correction of your personal information or complain about a breach of the Privacy Act. Pharmacy Phusion may share de-identified reports of your data with Sanofi.

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