

ENROLMENT FORM FOR DIABETES COSTARS: A PROGRAM TO SUPPORT PATIENTS ON LANTUS (INSULIN GLARGINE 100 units/mL)

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Please send the signed enrolment form via fax or email before or within five working days of your patient seeing the Credentialed Diabetes Educator (CDE). The CoSTARS program provides personalised additional health coaching support for your patient to achieve their prescribed titration goals.

PREScriBER DETAILS PLEASE NOTE: FOR COSTARS REIMBURSEMENT, PRESCRIBER CANNOT BE NOMINATED CDE/NP

Name:		Phone: ()	
Practice:		Email:	
<input type="checkbox"/> GP	<input type="checkbox"/> Endocrinologist	<input type="checkbox"/> Nurse Practitioner	<input type="checkbox"/> Other

Prescription information

Patient current HbA1c:		Patient target HbA1c:	
<input type="checkbox"/> New to Lantus	<input type="checkbox"/> Continuing on Lantus	Duration of time on Lantus: <input type="text"/> YEARS	<input type="text"/> MONTHS

Please choose the titration plan for Lantus:

Plan A: Preset Titration Plan (as per guide on the following page)

Plan B: Preset Titration Plan (as per guide on the following page)

Plan C: Prescriber Custom Plan (please specify FBG target and titration regimen):

Please choose a CoSTARS support level: Telehealth support & CDE interaction OR Telehealth support only

Prescriber signature: MANDATORY FOR ENROLMENT	Print name:
	Date:

CDE/NP DETAILS

Name:	Clinic:
<input type="checkbox"/> I don't have a CDE (Remedy Healthcare can allocate a CDE/NP to the patient). Note: if ticking this option, please attach a referral letter to this enrolment form.	

PATIENT DETAILS

Name:	DOB:
Address:	Email:
	Phone (Preferred): ()
Postcode:	Phone (Alternate): ()

Yes, I have read and agree to the Privacy Statement set out below

Yes, my healthcare provider has explained what is involved in the CoSTARS® support program

Yes, I consent to my Prescriber being kept informed of my participation in the CoSTARS® support program

Yes, I consent to my CDE/NP being kept informed of my participation in the CoSTARS® support program

Yes, I consent to Sanofi using information that it collects as part of the CoSTARS® support program such as FBG, HbA1c and Lantus dose in a de-identified form (e.g. as part of publications or conference presentations).

By signing below I consent to enrolling into the Diabetes CoSTARS® Program

Patients signature: MANDATORY FOR ENROLMENT	Print name:
	Date:

Thank you for your enrolment. You will be contacted by a CoSTARS® Health Coach to commence the program.

MANAGE YOUR PATIENTS STARTING ON LANTUS®

THE CoSTARS PATIENT SUPPORT PROGRAM

The CoSTARS Support Program is for patients that have been prescribed Lantus. As part of this program, your patient will receive:



- Up to two hours CDE interaction time



- Regular calls from the CoSTARS Health Coach based at Remedy Healthcare
- Tailored support to achieve their optimised insulin dose based on the prescribed titration plan
- Tailored support to achieve other health-related goals
- Unlimited inbound calls to CoSTARS Health Coaches, available 9am-5pm AEST
- Welcome pack and supporting information, as required

TITRATION PLANS FOR PATIENTS

Please nominate one of the titration plans below for the CDE/NP to follow.

Start with 10 units of Lantus® once-daily – add it to oral antidiabetic (OADs) drugs.^{2,3} Titrate the Lantus® dose using one of the schedules below^{1,3,5} to achieve a target fasting blood glucose (FBG) of 4-6mmol/L or as determined for the individual (e.g. an elderly patient may require a different FBG target).

The Diabetes CoSTARS® support program is not intended to replace regular patient-doctor consultations. The titration plan below that you select on the enrolment form will be followed by the CDE/NP, under your instruction, to complement your consultations with the patient.

Plan A: Lantus every 3 days

FBG target	Lantus® dose
FBG 4-6mmol/L ^{1†}	Increase daily dose by 2 units every 3 days* to achieve FBG target ^{1†}

Adapted from Davis et al. 2005.

* If for three days in a row, FBG ≥ 6 mmol/L, increase the dose by 2 units.

† Titration should be reviewed by a healthcare professional at each contact. Titrate only in absence of BGL <4mmol/L. If FBG <4mmol/L, adjust insulin dose at clinician's discretion.

Plan B: Lantus once weekly

Adjust the Lantus® dose once-weekly to achieve FBG target of 4-6mmol/L^{1,3,5}

Mean FBG (mmol/L)	Change in Lantus® dose
< 4	Reduce by 2 to 4 units**
4-5.9	No change
6-6.9	+ 2 units
7-7.9	+ 4 units
8-10	+ 6 units
> 10	+ 8 units

Adapted from Davies et al. 2005, Phillips 2007 and Riddle et al. 2003.

** The insulin dose may be decreased (small decreases of 2-4 units) if there is severe hypoglycaemia (requiring assistance) or the BGL <3.0mmol/L in the preceding week. Do not increase the insulin dose if the fasting BGL <4.0mmol/L at any time in the preceding week.

Plan C: Physician Custom Plan

FBG target	Change in Lantus® dose
Individualised FBG target to be defined by Physician	Customised titration regimen to be prescribed by Physician (specify plan on application form)

INSULIN CARRIES A RISK OF HYPOGLYCAEMIA⁴

The risk of hypoglycaemia is increased if patients:

- accidentally use too much Lantus®
- delay eating meals or snacks or eat too little food
- have too much or unexpected exercise
- are ill

Prescribers are advised to provide guidance on 'hypo' identification and management to patients.⁴

Desired blood glucose levels and the dosage of Lantus® should be individualised and determined based on the Physician's advice in accordance with the needs of the patient, especially those with a history of severe hypoglycaemia, a limited life expectancy, comorbidities or who are elderly.

Notes:

FBG = fasting blood glucose OAD = oral antidiabetic BGL = blood glucose level

Privacy Statement: The CoSTARS Patient Support Program ("Program") is offered by Sanofi-Aventis Australia Pty Ltd ('Sanofi') which is administered on behalf of Sanofi by Remedy Healthcare Group Pty Ltd ("Remedy"), a third party contractor for patient support services.

Remedy (or its authorised third party) will collect and store your personal information (including health information) on behalf of Sanofi for the purpose of fulfilment of services to you as part of this Program. Sanofi is committed to patient safety and carefully monitors potential adverse events relating to its products. In order to fulfil these legal obligations, Remedy (or any authorised third parties) will forward details of any adverse events to Sanofi which may include your personal information. Adverse event information may also be provided to the relevant Australian health authorities in de-identified format as per legal requirements. Remedy may also collect or disclose your personal information from or to your prescribing doctor and diabetes professionals for the purpose of managing your support whilst on the Program. All personal information collected, used or disclosed by Remedy will be treated in confidence and in strict accordance with the Privacy Act 1988 (Cth), the relevant Health Records legislation and Remedy's Privacy Policy available at www.remedyhealthcare.com.au

Sanofi may also use information that it receives from Remedy to advise healthcare professionals of patient experiences with Sanofi's product including via publication in medical journals and presentations at clinical meetings in a de-identified form. All personal information collected, used or disclosed by Sanofi will be treated in confidence and in strict accordance with the Privacy Act 1988 (Cth), the relevant Health Records legislation and Sanofi's Privacy Policy available at www.sanofi.com.au/privacy.

Should you wish to stop the processing of your personal information or withdraw from the Program or later access, correct or delete your Personal Information, you can contact Remedy by email remedy@remedyhealthcare.com.au or in writing to Privacy Officer, Remedy Healthcare, PO Box 33356 Domain LPO Melbourne Vic 3004

Other relevant information: Please note that Sanofi will pay a fee ranging from \$45 to \$180 (exc. GST) to the CDE/NP for the consultation(s) that form part of the program.

Contact Us: Should you wish to access, correct, delete, stop the process of your personal information or withdraw from the Program you can contact Remedy by email remedy@remedyhealthcare.com.au or in writing to Privacy Officer, Remedy Healthcare, PO Box 33356 Domain LPO Melbourne Vic 3004

The Diabetes CoSTARS® support program is designed to supplement (not replace) any existing General Practice Management Plan or Team Care Arrangement.

The scope of the Diabetes CoSTARS® support program is specific only to education on Lantus® pen-device use and assistance in optimising blood glucose levels (via CDEs/NPs using appropriate dose titration plans as specified by the prescriber).

Prescribers enrolling patients into the Diabetes CoSTARS® support program should ensure that hypoglycaemia, hyperglycaemic emergencies and sick day protocols are understood by patients and their carers, and that a knowledgeable resource person is contactable at all times (e.g. the patient's GP or associate, endocrinologist, diabetes resource centre).

PBS Information: Lantus® SoloStar® and Lantus® cartridges are listed on the PBS as a long acting insulin analogue for the treatment of type 1 and type 2 diabetes.

Please review full Product Information before prescribing.

Full product information available from

http://products.sanofi.com.au/aus_pi_lantus.pdf

LANTUS® (insulin glargine) Indications: Once-daily subcutaneous administration for type 1 diabetes mellitus patients (adults and children) and type 2 diabetes mellitus patients (adults) who require insulin for control of hyperglycaemia. **Contraindications:** Hypersensitivity to insulin glargine or any excipient. **Precautions:** Hypoglycaemia; hepatic, renal and visual impairment; lipodystrophy and other injection site reactions; antibody production; intercurrent conditions; not studied in children <6 years, pregnancy category B3, lactation; not intended for IV use; not recommended for treatment of diabetic ketoacidosis; LANTUS® MUST NOT BE DILUTED OR MIXED WITH ANY OTHER INSULIN OR SOLUTION. Instruct patient to check insulin label before each injection to avoid accidental mix-ups between insulins. **Interactions:** Oral antidiabetic agents; cardiovascular, analgesic, anti-inflammatory, neurological, antipsychotic agents (see full PI); antibiotics; corticosteroids, other hormonal therapies (see full PI); diuretics; protease inhibitors; sympathomimetic agents; lithium; alcohol; sympatholytics including β-blockers; others, see full PI. **Side effects:** Hypoglycaemia; injection site reactions; visual disturbances; others, see full PI. **Dosage and Administration:** Subcutaneous, once-daily. Lantus® is equipotent to human insulin. Initial dose determined depending on desired blood glucose levels and doses and timing of any antidiabetic medication. For changeover from once-daily NPH or ultralente, initial dose usually not changed; for changeover from twice-daily NPH to once-daily Lantus®, initial dose usually reduced by approximately 20% compared to total daily NPH dose; for initiation of type 2 patients, initial dose usually approximately 10IU. For changeover from once daily insulin glargine 300 units/mL to once daily Lantus, recommended initial dose is approximately 80% of insulin Glargine 300 units / mL that is being discontinued. Please review full Product Information before prescribing Lantus®.

References: 1. Davies M et al. Diabetes Care 2005; 28(6): 1282-1288. 2. Lantus® Product Information. Approved 25 March 2014. 3. Phillips P. Medicine Today Supplement: KISS 'keep insulin safe and simple' 2007;8:23-4. 4. Lantus® CMI, November 2010. 5. Riddle MC et al. Diabetes Care 2003;26:3080-86.

Reference Document: PI, 06 November 2015 Date prepared September 2016 SAANZ.GLA.16.03.0054a

Enrolment pad for patients on Lantus®. For more information about the Diabetes CoSTARS® support program, please call 1800 LANTUS (1800 526 887) or visit <http://www.co-stars.com.au/>

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