

## **Healthcare Professional Consent**





### The MyStarCare Program

MyStarCare is a program ("**Program**") that supports patients being prescribed a Sanofi-Aventis South Africa (Pty) Ltd ("Sanofi") insulin ("**Medicine**") for the treatment of diabetes, in order to appropriately assist patients in achieving improved management of their diabetes through the use of our Medicine.

The Program is proposed and initiated by Sanofi, and, implemented and managed by Sancreed (Pty) Ltd trading as Guidepost, with registered address 116 Oxford Road, Melrose Estate, Johannesburg, Gauteng, 2196; Registration number 2012/097434/07 ("Service Provider") on behalf of Sanofi.

The Program is defined as a Patient Support Program (PSP) designed to support patients prescribed with Sanofi marketed product, through product and/or disease oriented support.

Participation in the Program is funded by Sanofi-Aventis South Africa (Pty) Ltd for each Patient that is prescribed the Medicine and who is not in hospital, or is an in-patient already in the discharge procedure, at no additional cost to the Patient.

I understand that in order to assist Patients to better manage their condition, the MyStarCare diabetes educators may assist the Patient with education on how to self-titrate their own insulin following the outlined protocols and educator judgement.

To better educate and guide your patients on the principles of titration to reach their individual glycemic targets, the following titration algorithm(s) will be recommended to patients for self-titration on basal and bolus insulin respectively.

### Basal insulin (daily titration based on fasting SMBG):1

Fasting glucose (mmol/l)	Basal insulin Titration change units
≥ 6.1 mmol/l	Add 1 unit
4.0 to 6.0	No change
≤ 3.9	Subtract 1 unit

### Bolus insulin (daily titration based on pre-meal and/or bedtime SMBG):2

		Lunch reading	Dinner reading	Bedtime reading
	Current reading			
	<b>Current dose</b>	units	units	units
Week		Adjust breakfast apida	Adjust Lunch apidra	Adjust Dinner apidra
1	≥7 mmol/l	+1 unit	+1 unit	+1 unit
	4-6.9 mmol/l	No change	No change	No change
	≤ 3.9 mmol/l	-2 units	-2 units	-2 units
	New dose	units	units	units

# Please select one of the two options below:

☐ I consent to my patients receiving education on self-titration.

☐ Do not educate my patients on self-titration. I will educate my patients on my preferred titration schedule

I hereby confirm that I have obtained my patient(s)'s consent and further hereby give consent for patients from my practice who meet the eligibility criteria of the Program to be contacted by Guidepost for the purpose of the Program, and to enrol into the Program, at my patient(s)' discretion. My Patients may be referred by me or an individual to whom I delegate (not a representative of Sanofi). I hereby undertake to obtain each Patient's verbal consent to be contacted by Guidepost before referring that Patient.

I consent to Sanofi and Guidepost handling, processing and storing my information, including my personal information under the Protection of Personal Information Act for the purpose set out in this document and as per the terms laid out.

I have read and understood the terms and conditions of the Program as below and consent to these terms.

I understand that this single consent form will cover every Patient from my practice who I have directed to participate in the Program.

### **Healthcare Professional's Details**

Title*	Initials*	Surname*
Provider type and speciality*		
Signature of Health Care Professional*		HPCSA Number*
Practice Number*	Practice Phone Number*	Practice Email Address*
Date*		Progress reports with sensitive patient information will be sent to this email address. Ensure adequate privacy protection.

PLEASE NOTE that this is a representation of the form that the HCP would complete and sign using Docusign.

To receive a Docusign copy, please contact MyStarCare@Guidepost.net

### **Terms and Conditions**

The MyStarCare program is offered to Patients of the Healthcare Professional under the following Terms and Conditions (MyStarCare HCP Ts and Cs v3). Patients prescribed the Medicine and enrolled on the program are hereafter referred to as "Patients".

The Healthcare Professional hereby gives consent for Guidepost and/or its appointed service providers to retrieve, store and utilise personally identifiable Healthcare Professional Information, and where the Patient has consented thereto, Patient information for all Patients nominated by the Healthcare Professional (whether in the past or after the date of signature of this document), in order to provide diabetes education services to the Patient and notifications to the Healthcare Professional.

- The Healthcare Professional agrees s/he has obtained consent from his/her Patient that Guidepost may contact the Patient, the Healthcare Professional and/or their staff or service providers in order to obtain information pertinent to providing the Program.
- 2. The Healthcare Professional warrant that he/she prescribed the patient(s) he/she refers into the Program with the Medicine, and that this medication is in his/her opinion, the most appropriate clinical choice for the patient(s).
- 3. Guidepost may contact the Healthcare Professional to discuss issues identified during interactions with the Patient and to obtain feedback on the outcomes of the Program.
- 4. Guidepost will only provide services to Patients who meet the clinical eligibility criteria of the Program and Guidepost has the right to terminate a Patient's membership to the program in case of abuse and / or misuse of the Program or its staff.
- 5. Guidepost will not share personally identifiable information about the Patient or Healthcare Professional with any other party, including pharmaceutical manufacturers, unless required to do so by law or if the Patient or Healthcare Professional have given their express and explicit consent to such sharing of information.
- 6. The Healthcare Professional consents that data may be securely stored in a location outside of South Africa, where data protections are at par or better than that prescribed by South African law, or where Sanofi and/or Guidepost has ensured that those data will be stored in a manner adequate with South African law. Subject to applicable law, the Healthcare Provider and the Patient may at any time request that Guidepost delete or rectify their personal information.
- 7. Patients have the right to terminate their own consent at any time by contacting Guidepost directly. Should a Patient terminate their consent, that Patient's historical information will be stored for the legally prescribed period for medical records (de-identified to the extent possible).
- 8. Guidepost will only provide services to Patients that are using the Medicine in compliance with the products' labelling information as determined by the South African Health Products Regulatory Authority. Patients who are found to be using the Medicine off-label will be suspended from the Program until such time as they are no longer using the Medicine in an off-label manner.
- 9. The services provided by Guidepost as part of the Program are not medical consultations and do not replace consultations with Healthcare Professionals. The structured education and information provided to the Patient by Guidepost should not be taken in isolation.
- 10. Accountability for healthcare outcomes remains the accountability of the Patient and neither Guidepost nor Sanofi accepts liability for health outcomes.
- 11. Guidepost does not provide emergency management services. In an emergency, the Patient must contact a Healthcare Professional.
- 12. This agreement shall commence on the date of signature by the Healthcare Professional and continue in perpetuity. Either party may cancel the agreement at any time by providing written notification to the other

party. Patient agreements existing at time of cancellation will not be affected and Guidepost will continue to provide services to Patients unless the Patient terminates their subscription to the Program.

- 13. If a Patient experiences an adverse event or reaction, request a medical information or report a product technical complaint, this will be reported to Sanofi's Pharmacovigilance, Medical Information and/or Quality Department. Personal information may be collected, processed and retained by the Sanofi Pharmacovigilance department and/or Sanofi's appointed third parties, in which case the Patient's personal information will be protected by Sanofi and/or Sanofi's appointed third parties from unauthorised access and remain confidential at all times. The Sanofi Pharmacovigilance, Medical Information and/or Quality department may contact the Healthcare Professional regarding adverse events or reactions while the Patient is on the program. The Healthcare Professional consents that in the interest of patient safety, the data he/she communicates, which may include personal information, may be processed, shared and stored by Sanofi's Quality, Medical Information and Pharmacovigilance Departments for follow-up in the event of safety data being reported.
- 14. Find further information and terms & conditions on <a href="www.guidepost.net/za/terms">www.guidepost.net/za/terms</a>, email <a href="mailto:mystarcare@quidepost.net">mystarcare@quidepost.net</a> or call 087 2500 431.

## MyStarCare is available 08:30-19:00 Monday to Friday and 08:30-12:30 on Saturday mornings. Closed on Sundays and Public Holidays.

#### **Notification Email**

Optional. For use by Sanofi. If an email address is captured into this field then a second notification email will be sent to that address to confirm submission of this form.

- Ref: Gerstein HC, Yale JF, Harris SB, Issa M, Stewart JA, Dempsey E. A randomized trial of adding insulin glargine vs.avoidance of insulin in people with Type 2 diabetes on either no oral glucose-lowering agents or submaximal doses of metformin and/or sulphonylureas. The Canadian INSIGHT (Implementing New Strategies with Insulin Glargine for Hyperglycaemia Treatment) Study. Diabet Med. 2006 July;23(7):736-42.
- Rodbard HW, Visco VE, Andersen H, Hiort LC, Shu DH. Treatment intensification with stepwise addition of prandial insulin aspart boluses compared with full basal-bolus therapy (FullSTEP Study): a randomized, treat-to-target clinical trial. Lancet Diabetes Endocrinol 2014;2:30–37

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www.sanofi.com.

For Medical Information Enquiries kindly contact ZA.Medinfo@sanofi.com

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PLEASE NOTE that this is a representation of the form that the HCP would complete and sign using Docusign.

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