

FreeStyle Libre Reimbursement Support Program Patient Consent Form



Please **E-MAIL** the completed consent forms to: **AbbottDiabetesCareSA@supportwindow.co.za**

I _____ hereby give consent to be enrolled onto the FreeStyle Libre Reimbursement Support Program (“**Program**”) that is managed on behalf of Abbott Laboratories S.A (Pty) Ltd. (“**Abbott**”) by Health Window (“**Program Administrator**”), an independent third-party contracted by Abbott to administer the Program.

The Program includes services to assist and follow up with my medical scheme on my behalf and give feedback regarding any reimbursement issues that I might experience in order to obtain reimbursement for the FreeStyle Libre Flash Glucose Monitoring System. This may entail more than one instance of motivation to the scheme, including re-motivations, escalations, appeals and or ex-gratia applications, whichever may be necessary. Abbott reserves the right to modify or terminate the Program at any time without prior notice.

I hereby give consent and declare:

1. I confirm that my doctor has provided me with the diagnostic, treatment and care options, the benefits risks and costs of each, and I have freely and voluntarily agreed to the FreeStyle Libre Flash Glucose Monitoring System.
2. I understand that participation, or not, in the Program will not affect my rights to treatment with FreeStyle Libre Flash Glucose Monitoring System or any other product or therapy. I can consent to the FreeStyle Libre Flash Glucose Monitoring System without providing consent to the reimbursement support. I understand that I may also, if so decided by me, discontinue treatment.
3. I have been given the opportunity to discuss this Program with my Healthcare Provider after I consented to the use of the FreeStyle Libre Flash Glucose Monitoring System.
4. I understand that I do not have to provide this consent, and my participation in the Program is voluntary. If I choose not to participate, this will not impact my treatment or care. However, if I do not sign this form, I will not be able to participate in the Program and receive assistance from the Program Administrator, as described above.
5. I understand and agree that the Program Administrator will have to collect my Personal and Health Information from, and share information with, my Healthcare Providers and their staff, including my doctor, nurse(s), the courier pharmacy and/or distributor of FreeStyle Libre, as well as healthcare providers employed or retained by the Program Administrator for the purposes of the Program, as well as any auditors required to, for example, verify my consent to participate in the Program.
6. I understand that the Program Administrator will never share my information with any third party, and also, will not share it with Abbott. They will, however, share de-identified and aggregated patient and provider data to enable Abbott and/or the Program Administrator to assess and improve the support provided to patients. Abbott may use such de-identified and aggregated information to undertake research in future and/or as otherwise permitted by law.
7. The information collected and shared may include my contact information, date of birth, prescription, medical condition and other health information, as well as my information included on the form used for reimbursement purposes and all communications between me and the Program Administrator (collectively, “Personal Information”).

Duty to consult with my Healthcare Provider:

8. I understand and agree that I may be contacted by the Program Administrator in order to provide me with services under the Program, by email, phone or otherwise, using the contact information that I provide. If re-motivation is needed, or if my scheme has queries, I may be contacted more than once.
9. I understand that the Program is not intended to provide any medical advice, diagnoses and/or treatment. I agree and undertake to always seek the advice of my doctor or other qualified healthcare provider if I have health concerns, health questions and not to disregard professional medical advice based on information read or conveyed as part of the Program.

Adverse Event reporting:

10. I acknowledge that all Potentially Reportable Events (PRE) and Adverse Events (AE) should be reported directly to Abbott by contacting the Diabetes Care Customer Support Line – Telephone: 0800 222688 (Monday to Friday 09:00-17:00) and email address DiabetesCareSouthAfrica@abbott.com. I understand that, by law, the Program Administrator must report to Abbott any suspected adverse event that may come to their attention during the course of rendering the reimbursement services. I also understand that the Program Administrator will have to report such matters to Abbott. This is a legal requirement placed on all medical device companies. I understand Abbott may receive my Personal and Health Information for adverse event reporting purposes.

Consent to information recording and storage:

11. If Abbott appoints a new third party to replace the Program Administrator, I agree that my Personal Information may be transferred to such third party in their capacity as the new Program Administrator.
12. I understand the file containing my Personal Information will be maintained at the offices of the Program Administrator. Authorized employees, agents and mandatories of the Program Administrator will have access to my Personal Information as necessary for the purposes of administering the Program. I understand and acknowledge that my Personal Information may be stored or processed outside of South Africa, where it may be subject to the laws of foreign jurisdictions. The Program Administrator shall ensure that such jurisdictions apply the same, or stricter levels of personal and health information protection and where they do not, have agreements in place to ensure compliance with the minimum levels of data privacy as required by South African Law.

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Right to withdrawal of consent, security and destruction:

13. I have the right to opt out of the Program, or to opt out of treatment. Opting out of treatment must be discussed with my Healthcare Professional and I understand that it would then also mean that I also opt out of this Program. I understand that I may revoke this consent at any time by contacting the Program, at (010) 786 0316. I understand that withdrawing my consent will result in the termination of my enrolment in the Program. When I have opted out, all my identifiable information will be permanently removed from all systems and all hard copies will be destroyed, save for this consent, which will be saved as proof of my original agreement, and the subsequent instruction of withdrawal.
14. I may request access to, or correction of, my Personal Information at any time by contacting the Program Administrator by email to AbbottDiabetesCare-SA@supportwindow.co.za or in writing to Patient Support Operational Manager, Building B, 1st Floor, 41 De Haviland Crescent, The Woods, Persequor Park, Pretoria.

To contact the Program Administrator, please call (010) 786 0316.

I now hereby confirm that I have read and understood the information provided about the Program included on this **FreeStyle Libre Reimbursement Support Program** Enrolment Form. I have also read and understood the Patient Consent section of this form which describes data and service consent, how my Personal Information will be collected, used or disclosed, and I consent to participate in the FreeStyle Libre Reimbursement Support Program.

Patient's Details

Patient's Full Name & Surname			
Identity Number			
Contact Numbers	Work	Cell	
Email Address			
Physical Address			
Medical Scheme & Option			
Medical Scheme Number			
Principal Member Name & Surname			
Principal Member Identity Number			
Patient / Guardian's Signature		Date	
Medical Practitioner's Name			
Contact Number	Work	Cell	