

Evidence for the use of Dexcom ONE+ for people with type 2 diabetes

Studies are underway, where Dexcom ONE+ is specifically used by people with type 2 diabetes. Evidence and guidelines do exist that document the clinical significance of Dexcom ONE+ that can be used to inform healthcare professionals and which support inclusion of the product into national and local guidelines. In this document, Nordic Infucare has summarized the relevant evidence and existing guidelines.

Dexcom ONE/Dexcom ONE+ vs. Freestyle Libre 2/Libre 2 plus

Dexcom ONE+ and its predecessor Dexcom ONE are considered *on par* with Freestyle Libre 2 and Freestyle Libre 2 plus by the policy for CGM for adults by the National Health Services (NHS) in the United Kingdom¹. Dexcom ONE+ and Freestyle Libre 2 and Libre 2 plus are thus recommended for the same patients, and based on this, this policy explicitly states that patients can be switched between the two CGMs (Dexcom ONE+ and Freestyle Libre 2) "where considered suitable" (page 5 in the policy¹). The existing evidence on the relevance of basic CGM for type 2 diabetes is in general good². Transferred to the setting of the Nordic countries, the UK policy supports grouping Dexcom ONE+ with Freestyle Libre 2/Libre 2 plus in the category of "basic CGM", i.e. CGMs with high and low alerts (in contrast to "smart CGMs" like Dexcom G7 with more supportive/smart alerts).

In Sweden, the medical technology product council, the MTP council (MTP-rådet) updated its recommendation for CGM in type 2 diabetes in April 2025³. Previously, only Freestyle Libre 2 (isCGM) was recommended, but now several CGM models can be recommended if they are equivalent to the previously recommended product in terms of function, effect, and annual cost, which Dexcom ONE+ is. Thus, Dexcom ONE+ is recommended on par with other basic-CGMs.

¹ Clinical Policies Group, Hertfordshire and West Essex Integrated Care Board, for the NHS: Continuous Glucose Monitoring for Adults aged 19 and over v2.0. 2024. Available on https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/endocrine-metabolic/continuous-glucose-monitoring-adults-policy/

² Krakauer et al, 2021: A review of flash glucose monitoring in type 2 diabetes. Available on https://dmsjournal.biomedcentral.com/articles/10.1186/s13098-021-00654-3

³ MTP-rådet: Kontinuerlig glukosmätning vid diabetes typ 2. Available on https://samverkanmedicinteknik.se/download/18.4a8a49351969f9911881b35/1746692177587/Freestyle-Libre-250424.pdf

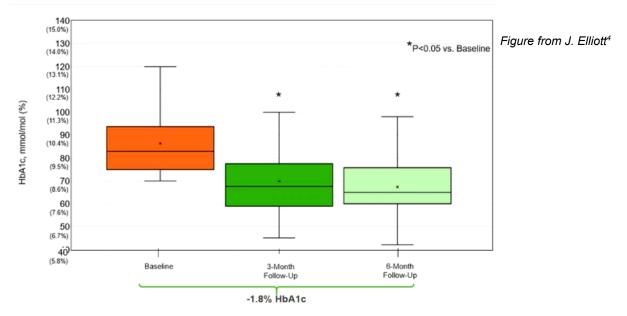


<u>Dexcom ONE evidence specific for type 2 diabetes</u>

There is some evidence on the effects of Dexcom ONE, the predecessor of Dexcom ONE+, in people with type 2 diabetes⁴. People with type 2 diabetes, high HbA1c despite at least two insulin injections per day and mainly a high degree of socio-economic deprivation were using Dexcom ONE for 6 months and were followed by a community diabetes nurse.

Dexcom ONE was found to reduce HbA1c by approximately 18 mmol/mol after 3 months, with the effects lasting to the end of the study.⁴

The nurses and participants were also interviewed, and both reported that the use of Dexcom ONE informed the consultations and made them more efficient, i.e. it was less time consuming to manage the participants. It was also reported that the use of Dexcom ONE gave participants a better understanding of the interplay between meals, physical activity and insulin. Finally, an important finding was that particularly the alerts in Dexcom ONE helped participants feel safer with regards to avoiding hypoglycemia.⁴



General Dexcom evidence within type 2 diabetes

In the Steno2tech study, a Danish randomized controlled trial (RCT) published in 2024, people with T2 with HbA1c > 58 mmol/mol and treated with basal or basal and meal insulin were using Dexcom G6 for 12 months. Their outcomes and changes from baseline were compared with

⁴ J. Elliott: The value of patient engagement - in a socioeconomically deprived population. Conference of the European Association for the Study of Diabetes (EASD). 2024.



those of a control group using blood glucose meters (BGM/fingerstick). The participants were to a large extent treated with modern pharmacological approaches like GLP-1 receptor antagonist and SGLT inhibitors, in addition to insulin.⁵

Time in the desired range (3.9-10 mmol/l) improved from baseline for the CGM group but not for the BGM group, and the effect was sustained during the 12 months of the study. The same was the case for HbA1c, as the CGM group reduced 9.4 mmol/mol more in HbA1c compared with the BGM group after 12 months.⁵ These results were achieved with reduced insulin doses (mean: 10.6 units/day) and reduced weight (mean: 3.3 kg) in the CGM group compared with baseline, whereas there were no changes in the BGM group.⁵ Finally, glucose monitor satisfaction (GMSS) increased during the use of Dexcom G6.⁵

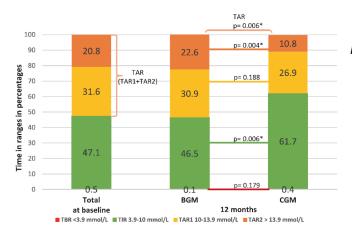


Figure from Lind et al., 2024⁵

Figure 1: CGM-derived metrics at baseline and 12-month follow-up.

While Dexcom G6 has more supportive features than Dexcom ONE+ relating to preventing hypoglycemia (urgent low alert (3.1 mmol/l) always activated, urgent low soon alert and fall alert), there was a very low occurrence of hypoglycemia already at baseline (approximately 0.5 % time below 3.9 mmol and almost no time below 3.0 mmol/l). The hypoglycemia preventing alerts in Dexcom G6 would therefore be triggered only very rarely, and a CGM without these alerts, such as Dexcom ONE+, could therefore likely lead to similar results in terms of improvements in glycemic results, insulin use, weight and glucose monitoring satisfaction.

Summary

Dexcom ONE and Dexcom ONE+ is considered on par with Freestyle Libre 2 and Freestyle Libre 2 plus in the British health services, and people with diabetes already on a basic CGM can change freely between brands as considered suitable upon consultation with their health care

⁵ Lind et al, 2024: Comparing Continuous Glucose Monitoring and Blood Glucose Monitoring in Adults With Inadequately Controlled, Insulin-Treated Type 2 Diabetes (Steno2tech Study): A 12-Month, Single-Center, Randomized Controlled Trial. Available on https://diabetesjournals.org/care/article-lookup/doi/10.2337/dc23-2194



provider. In Sweden, Dexcom ONE+ is now included among recommended products for people with type 2 diabetes.

Dexcom ONE gives very promising results in people with type 2 diabetes and as Dexcom ONE+ gives even more functionality and options, it is reasonable to assume results to be comparable or even better with Dexcom ONE+.

Dexcom G6 is also found to improve glycemic control and patient satisfaction in people with type 2 diabetes, and the hypoglycemia preventing features in Dexcom G6 but not in Dexcom ONE+ are not as crucial to this population as in type 1 diabetes.

Dexcom is manufactured by Dexcom, Inc. 6340 Sequence Drive, San Diego, CA 92121 USA. dexcom.com Dexcom ONE+ is CE-marked according to MDR (EU) 2017/745

