Zorginstituut Nederland

Flash Glucose Monitoring (FGM), report summary

In this report *Zorginstituut Nederland* (National Health Care Institute) assesses whether Flash Glucose Monitoring (FGM) complies with 'established medical science and medical practice' for five indication groups within the diabetes population, who could be eligible for rt-CGM. The *Zorginstituut* also assesses whether FGM can be regarded as care that is normally provided by medical specialists, or as care in the form of medical devices.
Due to small adjustments, FGM differs from rt-CGM – which is already regarded as 'established medical science and medical practice'.

Monitoring glucose levels in diabetes is the basis of treatment for diabetes. The treatment strategy is determined based on glucose levels. Poor values can have enormous negative consequences for people with diabetes. Similarly to rt-CGM, FGM offers users insight into their current glucose levels and changes in their glucose levels by means of a trend line.

FGM's mechanism of action, technology, treatment objective and strategy are the same as those of rt-CGM. In fact, FGM is at least technically equivalent to rt-CGM. Nevertheless, there are (small) differences in the technique and use of the device. The most important difference is that FGM demands a proactive role on the part of the user, because the user has to scan his/her current values several times a day in order to determine changes in the glucose values.

In this case the *Zorginstituut* feels that, due to the differences, assessment is necessary of whether FGM's technical accuracy is at least equal to that of rt-CGM. The Netherlands Association of Internal Medicine (NIV) and the Dutch Association of Paediatricians (NVK) state that FGM is a form of rt-CGM, that uses the same technology and which is technically just as accurate. According to the *Zorginstituut,* an intervention can be regarded as a technical variation if it involves a small adjustment in a customarily used intervention that is already regarded as 'established medical science and medical practice'. FGM is thus regarded as a minimum development or minimal technical variation of rt-CGM.

In this report, we establish that the technical accuracy of FGM is comparable with that of rt-CGM. The conclusion is that FGM can be regarded as an effective intervention for the following indications:

- children with type 1 diabetes;
- adults with poorly regulated type 1 diabetes (despite standard control, persistently high HbA1c (>8% or >64 mmol/mol));
- pregnant woman with existing diabetes (types 1 and 2);
- women who want to get pregnant who have preconception diabetes (types 1 and 2).

For the four indications named, FGM complies with 'established medical science and medical practice'.

Although the technical accuracy of FGM is comparable with that of rt-CGM, we conclude that FGM is not an effective intervention for patients with type 1 diabetes who are repeatedly confronted with severe hypoglycaemias and/or who are unable to recognise pending hypoglycaemia ('hypoglycaemia unawareness'). For these patients we feel that using FGM will involve a bigger chance of action being taken too late, as these patients do not sense imminent hypoglycaemia and FGM does not have an alarm function. It is safer for these patients to use rt-CGM, with an alarm function and the possibility of attaching an insulin pump.
Therefore, FGM does not comply with 'established medical science and medical practice' for this group of patients. As a consequence, for this group of patients, FGM is not included among the provisions insured under the Health Care Insurance Act *(Zorgverzekeringswet*, Zvw).

In the opinion of the *Zorginstituut,* FGM is part of care provided in the form of medical devices. A patient who is sufficiently capable of self-management is expected to suffer less severe and less acute dysregulation. Furthermore, the patient can replace the sensor him/herself. In other words, the nature of the medical device requires no back-up function or (emergency) care from a medical specialist.
As a consequence, for the four said indications FGM can be regarded as a provision insured under the Zvw, as defined in article 2.6, section o, of the Health Insurance Regulation. Agreements made by the professional groups and the patients' association about the appropriate use of rt-CGM also apply to FGM.

This outcome of assessment comes into effect on 27 November 2017.

This outcome of assessment is an initial step in the clarification process for the possible reimbursement of FGM via the basic insurance. The two-phase approach is in accordance with agreements made within the Round-Table on Diabetes care[1]. The Round-Table opted to distinguish between FGM as an alternative to rt-CGM and FGM as an alternative to medical devices for standard finger-pricking. In November 2017 the NIV and the NVK established the position of FGM as a variety of rt-CGM. In a special working group, together with patients, the professional groups are currently working on the next step: establishing the indication and what scientific evidence is needed to be able to demonstrate the added value of FGM in comparison with medical devices for standard finger-pricking. Agreement has been reached with parties in the Round-Table that, using the results delivered by the working group, the *Zorginstituut* will provide clarification over FGM.

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The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.

[1] Partnership between the Dutch Diabetes Federation (NDF), the Dutch Diabetes Association (DVN), the BIDON Foundation, medical specialists, GPs, health insurers, manufacturers, and the *Zorginstituut*.