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PACEF Advice Flash Glucose Monitoring System Freestyle Libre®

Summary of PACEF advice

Device, Dressing or Drug	Indication(s)	Traffic Light and *Joint Formulary* Status
Freestyle Libre®	Flash Blood glucose Monitoring System	Amber 2 Approved for inclusion on to the Joint Formulary initiation of treatment restricted to diabetic specialist service and GPSIs . Freestyle Libre® should only be initiated in patients who have been assessed at meeting at least one of the treatment criteria. Use of the device should only be continued beyond an initial trial period of 6 months if there is sustained benefit in at least one of the agreed patient outcomes.

PACEF approve the use of Freestyle Libre® in line with the recommendations made by the Regional Medicines Optimisation Committee (North) .
It is recommended that Freestyle Libre® should only be used for people with type 1 diabetes , aged four and above, attending specialist type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and deemed to meet one or more of the following:

- Patients assessed at requiring intensive blood glucose monitoring ≥ 8 times daily.
- Those who meet the current NICE criteria for insulin pump therapy (HbA1c > 8.5 % (69.4mmol/mol) or disabling hypoglycaemia as described in NICE TA 151) where a successful trial of Freestyle Libre® may avoid the need for pump therapy.
- Those who recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre® does currently not have that function.

- Frequent admissions >2 per year with DKA or hypoglycaemia.
- Those who require third parties to carry out monitoring and where conventional blood testing is not possible.
- Pregnant patients with type 1 or type 2 DM on a basal bolus insulin regimen and in type 1 patients actively trying to conceive. (Patients developing gestational diabetes are excluded from this recommendation unless they meet other criteria above). Pregnant patients will be expected to return to their previous method of blood glucose testing once they have given birth.

In addition all patients (or carers) must be willing to undertake training in the use of Freestyle Libre® and commit to ongoing regular follow-up and monitoring.

Adjunct blood tests

The decision to start Freestyle Libre® will only be made by the diabetic specialist (secondary care based specialist or General Practitioner with a specialist interest in Diabetes (GPSI). It will be provided either by the specialist team or the patient's GP and initially on a 6 month trial.

Use will only be continued at the discretion of the diabetic specialist if there is sustained benefit in patient outcomes whilst they are using the device of one or more of the following:

- Reductions in severe / non severe hypoglycaemia episodes.
- Reduction in HbA1c of 0.5% or more within 6 months.
- Agreed reduction in use of self monitoring of blood glucose test strips.
- Reduction in episodes of diabetic ketoacidosis.
- Reductions in admission to hospital.

If there has not been sufficient improvement in one or more of the above areas over a 6 month period then the use of Freestyle Libre® should be discontinued and an alternative method of monitoring should be used.

Patients already purchasing Freestyle Libre® who clearly do not meet the criteria here for initiation or continuation will not be entitled to NHS prescriptions for this device.

Those patients who are already purchasing Freestyle Libre®, before 1st November 2017, who may meet the criteria here for continuation of the use of this device need to be reviewed by a secondary care based diabetes specialist or GPSI to confirm ongoing funding eligibility.

All patients requesting a Freestyle Libre® Device, who have not previously used the device before from 1st November 2017 will need to be assessed by the diabetic specialist (secondary care based specialist or General Practitioner with a specialist interest in Diabetes (GPSI).

PACEF has requested that diabetes specialists collect audit data on the outcomes of patients who are prescribed Freestyle Libre® and have indicated that it wishes to review this audit data in a year's time – November 2018.

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References

Regional Medicines Optimisation Committee (RMOC). Flash Glucose monitoring Systems Position Statement

Formulary and Managed Entry Subgroup. GMMMG. Freestyle Libre Flash Glucose Monitoring Systems

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