

Medicines Management Programme

Preferred blood glucose test strips with associated meter(s)

Evaluation report



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List of abbreviations

BGTS	Blood glucose test strips
CCG	Clinical Commissioning Group
CDS	Community Drug Schemes
DoH	Department of Health
DP	Drugs Payment (scheme)
GMS	General Medical Services
HCP	Healthcare professional
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
ICGP	Irish College of General Practitioners
ISO	International Organisation for Standardisation
LCD	Liquid-crystal display
LTI	Long Term Illness
MMP	Medicines Management Programme
NCPD	National Clinical Programme for Diabetes
NFC	Near-field communication
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PC	Personal Computer
PCERS	Primary Care Eligibility and Reimbursement Service
QISMET	Quality Institute for Self-Management Education and Training
SMBG	Self-monitoring of blood glucose
USB	Universal serial bus

Definitions

For the purposes of this document, the reimbursement price refers to the price as listed on the reimbursement list, available on the Health Service Executive (HSE) Primary Care Eligibility and Reimbursement Service (PCERS) website (www.pcers.ie). Reimbursement prices are correct as of July 1st 2020, unless otherwise stated.

Acquisition cost, when referred to in this evaluation, refers to the price listed on the PCERS reimbursement list.

For the purpose of this document, diabetes mellitus may also be referred to as diabetes.

Blood glucose test strips (BGTS) and 'test strip' may be used interchangeably.

The term 'supplier' refers to a company that has submitted a BGTS for inclusion in this evaluation process, and may include a manufacturer, distributor or agent for the BGTS.

1. Executive summary

The Health Service Executive (HSE)-Medicines Management Programme (MMP) supports safe, effective and cost-effective prescribing nationally.

In 2019, blood glucose test strips (BGTS) accounted for a total expenditure of approximately €40.6 million on the Community Drug Schemes (CDS). The MMP recognises the potential for savings in relation to BGTS on the CDS.

The aim of this initiative is to identify preferred BGTS with associated meter(s) for adult patients with type 1 and type 2 diabetes mellitus who undertake self-monitoring of blood glucose (SMBG). The use of preferred BGTS will realise efficiencies in this area.

The evaluation process was undertaken in accordance with the *MMP roadmap for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*.

The MMP recommends the following preferred BGTS:

Preferred BGTS		
Reimbursement Code	BGTS*	Reimbursement price (as of 1 st February 2021) (50)
85131	Finetest Lite blood glucose test strips	€6.95
97637	Microdot Max blood glucose test strips	€7.46
85110	Glucomen Areo Sensor test strips	€9.44
97607	Mylife Unio test strips	€10.50
94170	4Sure blood glucose test strips	€11.22
85120	GlucorX Nexus test strips	€11.27
85139	GlucorX HCT glucose test strips	€11.27
85543	Accu-Chek Mobile test cassette (50)	€11.81
15963	Contour Next blood glucose test strips	€14.30
68321	One Touch Verio test strips	€14.30

*Listed in order of ascending reimbursement price

2. Purpose

The purpose of this evaluation is to identify preferred blood glucose test strips (BGTS) with associated meter(s), as part of the HSE-Medicines Management Programme's (MMP) remit to support safe, effective and cost-effective prescribing in the Irish healthcare setting.

3. Scope

This evaluation considers BGTS on the Primary Care Eligibility and Reimbursement Service (PCERS) reimbursement list with associated meter(s) [when the meters are provided free-of-charge], and certain ancillary items (i.e. lancets and blood ketone test strips), that are currently available for supply to the Irish Market. Evaluation under the criteria outlined below is limited to BGTS and associated meter(s) that were submitted for inclusion in the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*, and where the submission included an accompanying cover page (see section 8.1) for the BGTS with associated meter(s).

It is aimed at achieving efficiencies by the identification of preferred BGTS with associated meter(s) for adults with type 1 and type 2 diabetes mellitus.

4. Background

Diabetes mellitus is a chronic disease characterised by the body's inability to produce enough insulin and/or a resistance to its effects. It can be characterised as either type 1 or type 2.⁽¹⁾

Type 1 diabetes is an autoimmune condition that causes destruction of the insulin producing cells in the pancreas. People with type 1 diabetes are dependent on insulin for treatment.⁽²⁾ Type 2 diabetes is characterised by insulin resistance and insufficient pancreatic insulin production.⁽³⁾ Over time diabetes can lead to complications including cardiovascular disease, chronic renal failure, peripheral neuropathy and retinopathy.^(2, 3)

Self-monitoring of blood glucose (SMBG) involves the use of test strips with an associated blood glucose meter ("meter"). SMBG is essential for people with diabetes who are insulin-dependent and may also be beneficial for those who are prescribed other hypoglycaemic agents.

Test strips can be accessed under the Community Drug Schemes (CDS), as they are included on the PCERS reimbursement list.⁽⁴⁾

For test strips to be included on the PCERS reimbursement list, they must have satisfied the certification process, as outlined in the *HSE-PCERS Personal Diagnostic, Monitoring and Delivery*

Devices Guidelines for Suppliers (February 2020), at the time of their addition to the reimbursement list.⁽⁵⁾

The Health Products Regulatory Authority (HPRA) is responsible for the regulation of medical devices on the Irish Market and is designated as the competent authority for medical devices in Ireland. This regulatory role involves the monitoring of medical devices (e.g. test strips and meters) in Ireland including operating a national reporting system for medical devices.⁽⁶⁾

5. Diabetes mellitus – expenditure and utilisation

The PCERS includes diabetes mellitus (excluding gestational diabetes) as an illness eligible under the Long Term Illness (LTI) scheme.⁽⁷⁾ In 2019, total expenditure by the PCERS for diabetes mellitus on the LTI scheme was €205.99 million.⁽⁸⁾ This expenditure reflected utilisation by 143,224 people in Ireland. The majority of expenditure for diabetes is under this scheme with some additional expenditure under the General Medical Services (GMS) and Drugs Payment (DP) schemes.⁽⁸⁾

Total expenditure on BGTS in 2019 was approximately €40.6 million; €36 million on the LTI and DP schemes and €4.6 million on the GMS scheme.⁽⁹⁾ In July 2020, there were 35 individual test strips on the PCERS reimbursement list. Test strips ranged in reimbursement price from €6.17 to €26.50 for a quantity of 50 test strips.⁽⁴⁾ Test strips with a reimbursement price greater than €19.00 for a quantity of 50, accounted for approximately 98% of total BGTS expenditure in 2019 (€39.9 million).⁽⁹⁾

6. Blood glucose testing recommendations for type 2 diabetes

The MMP conducted a review of international evidence and best practice guidelines along with national usage of SMBG, and published a report on self-testing for people with type 2 diabetes in 2016. Research indicated that blood glucose testing has a limited benefit for many people who do not take insulin to manage their diabetes.⁽¹⁰⁾

Table 1: MMP self-monitoring blood glucose testing recommendations for type 2 diabetes

People with Type 2 Diabetes:	Testing Requirements ⁽¹⁰⁾
On insulin therapy (either alone or in combination with other hypoglycaemic agents)	The optimal daily frequency of SMBG may be individualised and may be up to 4 times per day and more frequently if needed (e.g. hypoglycaemic events)
On a sulphonylurea or meglitinide alone or in combination with metformin, thiazolidinedione, DPP-4 inhibitor, GLP-1 analogue, SGLT2 inhibitor	Individuals may test one or two times a day , before food or if they feel hypoglycaemic.*
On oral drugs other than sulphonylurea or meglitinides (i.e. metformin and/or a thiazolidinedione, DPP-4 inhibitor, GLP-1 analogue, SGLT2 inhibitor)	SMBG may not be required. Testing may be considered at a frequency of up to 3 times per week , before food.
Controlled by lifestyle and diet alone	Blood glucose testing is not required . However, if recommended by a physician, testing could be considered on a weekly basis in conjunction with a structured education plan.

DPP-4 inhibitor: dipeptidyl peptidase-4 inhibitor ('gliptins')

GLP-1 analogue: glucagon-like peptide-1 analogue (e.g. liraglutide, semaglutide, exenatide)

SGLT2 inhibitor: sodium-glucose co-transporter-2 inhibitor ('gliflozins')

* Additional testing may be warranted in people with type 2 diabetes on a sulphonylurea or meglitinide as recommended in the 2019 Medical Fitness to Drive Guidelines (Group 1 and 2 Drivers). These individuals must be under regular medical review (available on www.rsa.ie).⁽¹¹⁾

These recommendations are supported by the National Clinical Programme for Diabetes (NCPD) and are included in the '*Model of Integrated Care for Patients with Type 2 Diabetes*' published in 2018.⁽¹²⁾ The Irish College of General Practitioners (ICGP) similarly do not recommend routine SMBG in people with uncomplicated type 2 diabetes using oral hypoglycaemic agents.⁽¹³⁾

7. Identification of the preferred blood glucose test strips

The identification of the preferred BGTS was carried out in accordance with the evaluation process outlined in the *MMP roadmap for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*.⁽¹⁴⁾ A copy of the roadmap is available in Appendix A.

7.1 MMP roadmap

The MMP published a draft *roadmap for the identification of a preferred blood glucose test **strip** and **associated blood glucose meter** for adult patients with type 1 and type 2 diabetes mellitus* on 17 December 2019. The MMP sought feedback from stakeholders on this draft roadmap, with the closing date for receipt of feedback on 10 February 2020. This draft roadmap was published on the MMP website and a tweet was issued from the MMP twitter account upon its publication.

The roadmap was then updated following consideration of submissions received from stakeholders, including the evaluation title. The finalised *MMP roadmap for the identification of preferred blood glucose test **strips** with **associated blood glucose meter(s)** for adult patients with type 1 and type 2 diabetes mellitus* was then published on the MMP website on 7 July 2020. The identification of preferred BGTS with associated blood glucose meter(s) was carried out in accordance with the evaluation process in the finalised roadmap.

7.2 MMP evaluation process

As part of the evaluation process for the identification of preferred blood glucose test strips with associated blood glucose meter(s), a period of consultation with stakeholders was undertaken between 7 July 2020 and 13 August 2020. All parties who made a submission in relation to the draft roadmap were emailed to inform them of the commencement of the evaluation process. Information in relation to the evaluation process was published on the MMP website and a tweet was issued from the MMP twitter account.

8. Evaluation

8.1 Cover page

For a BGTS to be considered for inclusion on the preferred list, suppliers were required to complete and sign a cover page, confirming compliance of the submitted BGTS and associated meter(s) with:

- Applicable national standards and European Commission standards
- All applicable laws
- International Organisation for Standardisation (ISO) 15197:2013.

Suppliers were required to confirm that the BGTS with associated meter(s) submitted to the evaluation process, were in line with the published criteria in the *HSE-PCERS Personal Diagnostic, Monitoring and Delivery Devices Guidelines for Suppliers (February 2020)*, including that meters are available free-of-charge.

A copy of the cover page is available in Appendix B.

8.2 Criteria

In line with the MMP *roadmap for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*, the MMP considered the following criteria when identifying the preferred list:

1. Acquisition cost of the test strips
2. Shelf-life of the test strips
3. Availability of patient support services by the supplier
4. Availability of education resources to healthcare professionals by the supplier
5. Robustness of supply of test strips to the Irish Market
6. Associated meter(s)
7. Patient factors
8. Acquisition cost of associated lancets
9. Any other relevant factors

In relation to the submissions received from suppliers during the evaluation process, the nine criteria above were employed in identifying the preferred list. The MMP evaluated 11 BGTS from nine suppliers under these criteria.

Table 2: Submissions received from suppliers during the evaluation process

Supplier	Reimbursement Code	BGTS	Pack size
Ascensia Diabetes Care Ireland Ltd.	15963	Contour Next blood glucose test strips	50
Cambridge Sensors Ltd.	97637	Microdot Max blood glucose test strips	50
Clonmel Healthcare.	94170	4Sure blood glucose test strips	50
Lifescan Ireland Ltd.	68321	One Touch Verio test strips	50
Medicon Ireland Ltd.	85110	Glucomen Areo Sensor test strips	50
Neon Diagnostics Ltd.	85131	Finetest Lite blood glucose test strips	2x25
Roche Diabetes Care Ltd.	85104	Accu-Chek Aviva test strips	50
Roche Diabetes Care Ltd.	85543	Accu-Chek Mobile test cassette	50
Windzor Pharma Ltd.	85120	Glucorx Nexus test strips	50
Windzor Pharma Ltd.	85139	Glucorx HCT glucose test strips	50
Ypsomed Ltd.	97607	Mylife Unio test strips	50

A submission was also received from the HSE Blood Glucose Monitoring Review Group, which was given due consideration throughout this evaluation.

Clinical guidelines and recommendations for SMBG were also considered, along with similar evaluations in other jurisdictions as outlined in this document.

8.2.1 Acquisition cost of test strips

In July 2020, there were 35 individual test strips on the PCERS reimbursement list. Test strips ranged in reimbursement price from €6.17 to €26.50 for a quantity of 50 test strips (Figure 1).⁽⁴⁾ In 2019, test strips with a reimbursement price greater than €19.00 for a quantity of 50, accounted for approximately 98% of total BGTS expenditure in that year (€39.9 million).⁽⁹⁾

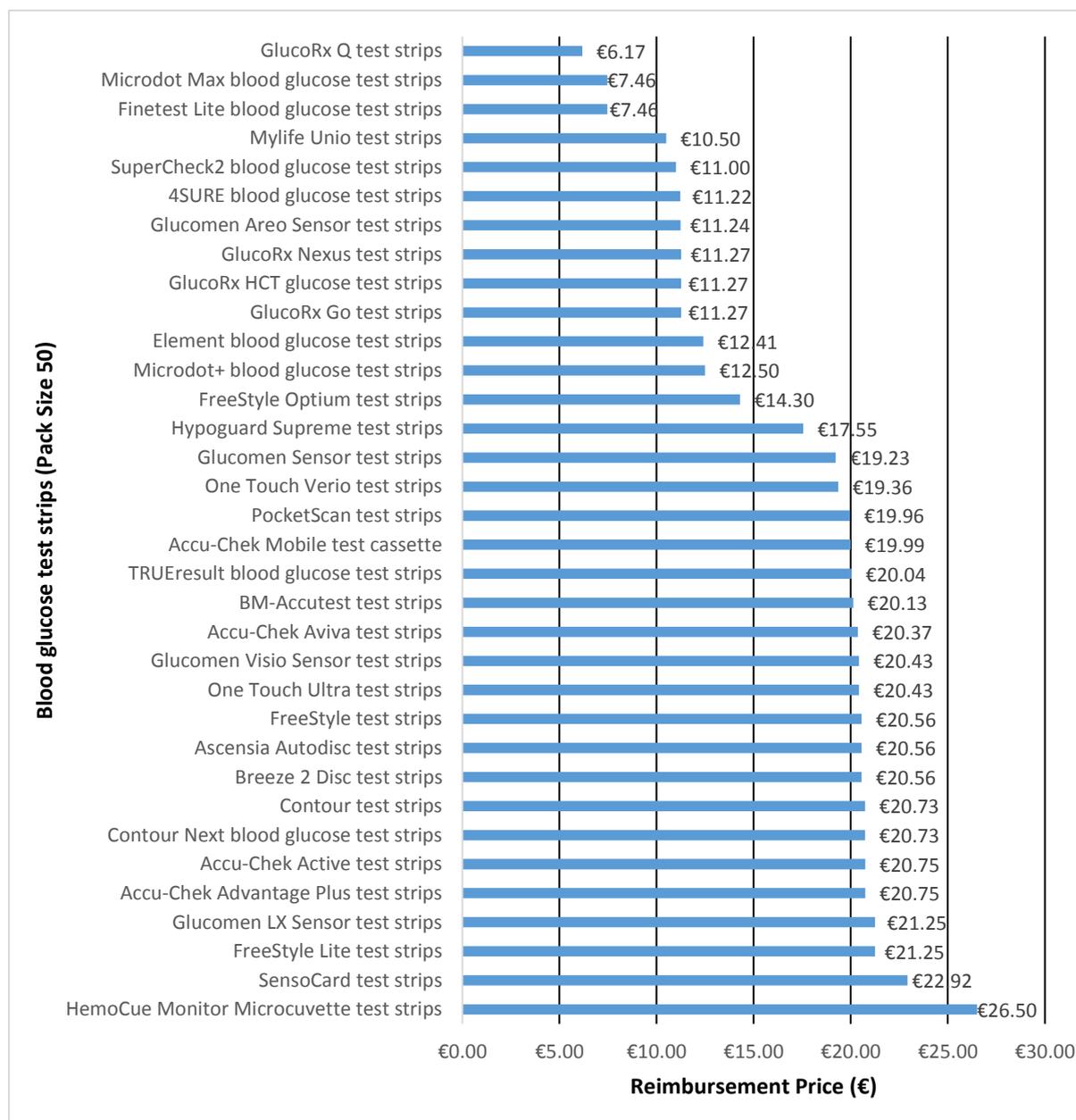


Figure 1: Reimbursement price of BGTS* available on the PCERS reimbursement list (July 2020)

*Accu-Chek Mobile test cassette pack size 100 is omitted from this figure – reimbursement price is double that of the Accu-Chek Mobile test cassette pack size 50.

The majority of test strips currently on the PCERS reimbursement list have a reimbursement price \geq €14.30 per pack of 50.^(4, 9)

The acquisition cost of BGTS on the PCERS reimbursement list (as of July 2020), that were submitted for the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus* were considered.

Several submissions included a revised reimbursement price for some BGTS resulting in significant reductions in the acquisition costs to the HSE, if these strips were to be included in the preferred list of BGTS.

Recommendation

Under this criterion, the MMP is of the view that BGTS with a reimbursement price \leq €14.30 may be considered for inclusion in the preferred list of BGTS, once all other criteria have also been satisfied. The reimbursement price should be a key consideration when prescribing a BGTS with associated meter for individuals.

The MMP recommends the use of a preferred BGTS for all adults with type 1 and type 2 diabetes who require SMBG. An associated meter should be chosen based on individual requirements.

The MMP recommends the use of a preferred BGTS for all adults with type 1 and type 2 diabetes who require SMBG to realise efficiencies in this area. The reimbursement price should be a key consideration when prescribing a BGTS with associated meter for individuals.

8.2.2 Shelf-life of test strips

The shelf-life of the BGTS that were submitted for the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus* were reviewed. Consideration was given to the shelf-life prior to and post-opening the container.

The shelf-life for BGTS submitted for the MMP evaluation are outlined in table 3.

Table 3: Shelf-life of blood glucose test strips

Reimbursement Code	BGTS	Pack size	Shelf-life (expiry date)
15963	Contour Next blood glucose test strips	50	Unopened: up to 24 months Opening does not impact expiry
97637	Microdot Max blood glucose test strips	50	Unopened: up to 24 months Opened: 6 months
94170	4Sure blood glucose test strips	50	Unopened: up to 24 months Opening does not impact expiry
68321	One Touch Verio test strips	50	Unopened: 18 months Opened: 26 weeks (6 months)
85110	Glucomen Areo Sensor test strips	50	Unopened: 18-24 months Opened: 12 months
85131	Finetest Lite blood glucose test strips	2x25	Unopened: 24 months Opened: 6 months
85104	Accu-Chek Aviva test strips	50	Unopened: 18 months Opening does not impact expiry
85543	Accu-Chek Mobile test cassette	50	Unopened: 12 months Opened: 3 months
85120	GlucorX Nexus test strips	50	Unopened: 24 months Opening does not impact expiry
85139	GlucorX HCT glucose test strips	50	Unopened: 24 months Opening does not impact expiry
97607	Mylife Unio test strips	50	Unopened: 24 months Opened: 12 months

Unopened = ex-factory expiry date

For some test strips, expiry date is not affected by opening the container; expiry as printed on packaging is maintained.

For other test strips, a shorter expiry is assigned when the container is opened (i.e. an open-pack expiry). These open-pack expiries vary from between three and 12 months.

Prescribers should be mindful of test strips with a shorter open-pack expiry, when choosing a BGTS for patients who do not test their blood glucose levels frequently.

Manufacturers recommend that the container is closed immediately after retrieving each test strip. Test strips should always be stored only in the original container.

The original product packaging or product information leaflet should be referred to for any specific advice. It is important that BGTS are stored in accordance with the manufacturer's recommendations.

Recommendation

Prescribers should be mindful of open-pack expiry when choosing a suitable BGTS with associated meter, taking into account the frequency of testing.

Overall, in relation to shelf-life, the MMP is satisfied with the range of test strips available and the various options they present in terms of shelf-life in the context of frequency of testing.

In relation to shelf-life, the MMP is satisfied with the range of test strips available and the various options they present in terms of shelf-life in the context of frequency of testing.

8.2.3 Availability of patient support services by the supplier

The availability of patient support services by the suppliers who submitted BGTS, as part of the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*, were considered.

Due consideration was given to services provided by suppliers, which assist patients in using their BGTS with associated meter, including:

- The availability of a phone line providing patient support
- The availability of patient support materials to aid in the use of BGTS with associated meter(s) including supplier's websites, other websites and in printed form
- Suppliers facilitating patients in registering their meter.

Recommendation

Overall, in relation to the availability of patient support services by the supplier, which assist patients in using their BGTS with associated meter, the MMP is of the opinion that there is a similar offering of such services by the suppliers of the submitted BGTS.

In relation to the availability of patient support services, which assist patients in using their BGTS with associated meter, the MMP is of the opinion that there is a similar offering of such services by the suppliers of the submitted BGTS.

8.2.4 Availability of education resources to healthcare professionals by the supplier

The availability of education resources to healthcare professionals (HCPs) by suppliers who submitted BGTS, as part of the *MMP evaluation for the identification of preferred blood glucose test strips with*

associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus, were considered.

Individuals using BGTS with an associated meter require access to a HCP who is competent in their use. Therefore, due consideration was given to the education resources provided by suppliers, which aid HCPs in educating patients on the use of their BGTS and meter, including:

- The availability of a phonenumber
- The availability of support materials to assist in patient training
- Access to training e.g. on site, remotely, via website resources.

Recommendation

Overall, in relation to the availability of education resources to HCPs by suppliers, the MMP is of the opinion that there is a similar offering of suitable resources provided by the suppliers of the submitted BGTS, which aid HCPs in educating patients on the use of their BGTS and associated meter.

In relation to the availability of education resources to HCPs, the MMP is of the opinion that there is a similar offering of suitable resources provided by suppliers, which aid HCPs in educating patients on the use of their BGTS and associated meter.

8.2.5 Robustness of supply of test strips to the Irish Market

The robustness of supply of test strips to the Irish Market, as outlined by the suppliers of BGTS that were submitted for the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*, was considered.

Due consideration was also given to current and future supply of test strips to the Irish Market including planning in relation to Brexit.

Under this criterion, the MMP undertook analysis of the PCERS pharmacy claims database. In 2019, over 152,000 individuals were in receipt of BGTS under the CDS, and the market share of the BGTS that were submitted as part of this evaluation was considered.

Information submitted by suppliers in relation to robustness of supply of test strips to the Irish Market, outlined a range of varying processes demonstrating their individual capacity to supply BGTS to the Irish Market.

Recommendation

In relation to robustness of supply of test strips to the Irish Market, the MMP is of the opinion that having a range of suppliers of preferred BGTS is preferable as it mitigates the potential risks from supply issues with an individual supplier.

The MMP is of the opinion that having a range of suppliers of preferred BGTS is preferable as it mitigates the potential risks from supply issues with an individual supplier.

8.2.6 & 8.2.7 Associated meter(s) and patient factors

The associated meter(s) and patient factors of BGTS that were submitted for the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus* were considered. As meter features are closely related to patient factors these criteria were considered together.

All suppliers who submitted a BGTS for inclusion in the process, completed and signed a cover page, confirming compliance of the submitted BGTS and associated meter(s) with:

- Applicable national standards and European Commission standards
- All applicable laws
- ISO 15197:2013.

Suppliers also confirmed that the BGTS with associated meter(s) submitted to this process, were in line with the published criteria in the *HSE-PCERS Personal Diagnostic, Monitoring and Delivery Devices Guidelines for Suppliers (February 2020)*, including that meters are available free of charge.⁽⁵⁾

Eight of the eleven submitted BGTS offer more than one compatible meter, providing options for users and prescribers in terms of device size, technology, meeting different visual and dexterity requirements, and compatibility with blood ketone test strips and various insulin pumps. Twenty three associated meters, suitable for patient use, and one meter intended for HCP use, from nine suppliers were evaluated under these criteria.

The MMP reviewed information as submitted by suppliers and in cases where further information was required, this was requested as part of the evaluation process. Of the 23 meters submitted for patient use, there were a variety of size options available including smaller ('mini') meters, those considered "palm-sized" and meters with slightly larger dimensions which often signified a specific meter feature

(e.g. strip storage within device or voice and visual impairment specification). There were also meters without screens (dongles) which employ “smart” devices for their utilisation.

Five of the twenty-four (21%) meters reviewed have ketone testing capabilities, and four (16%) had compatibility with a specific insulin pump.

The memory capabilities for individual meters varied from 450 – 2,000 readings with additional memory (and all of the memory in the case of dongle devices) being facilitated through the use of an app on a smart device.

Of the 23 patient meters that were reviewed, an app was available for 15 meters (65%), comprising of 11 different apps, from the 9 suppliers. Two companies had two apps available.

The meters evaluated provide a range of connectivity options including the use of Bluetooth, universal serial bus (USB) and near-field communication (NFC). The majority of suppliers outlined that they had meters that were compatible with Diasend, an online diabetes data management system which provides uploading and visualisation of information from glucose meters and other diabetes management systems, between patient and prescriber. Many meters were compatible with both Diasend and their own personal computer (PC) software, while some meters were only compatible with their own PC software.

Some suppliers outlined that their devices may be suitable for patients with varying levels of visual impairment and manual dexterity with one meter outlined as having been specifically designed for visually impaired patients/children, as the meter “talks”. A number of suppliers also outlined that their meter’s display was a large liquid-crystal display (LCD) screen with illumination. Some meters have a backlit screen while others have results illuminated. One meter has larger corresponding BGTS, which the supplier has indicated may cater for varying levels of dexterity.

Table 4 outlines details of some of the features for BGTS submitted as part of this evaluation that may influence individual user requirements.

Table 4: Comparison of sample size, test range and haematocrit of blood glucose test strips

Reimbursement Code	BGTS	Sample Size*	Test Range (mmol/L)*	Haematocrit Range (%)*
15963	Contour Next blood glucose test strips	0.6µL blood volume required for a reaction in 5 seconds	0.6-33.3	0-70
97637	Microdot Max blood glucose test strips	0.5µL blood volume required for a reaction in 5 seconds	0.6-33.3	0-70
94170	4Sure blood glucose test strips	0.5µL (glucose) / 0.8µL (ketone) blood volume required for a reaction in 5 -10 seconds	0.5-33.3 (glucose) 0.1-8.0 (ketone)	0-70 (glucose) 10-70 (ketone)
68321	One Touch Verio test strips	0.4µL blood volume required for a reaction in 5 seconds	1.1-33.3	20-60
85110	Glucomen Areo Sensor test strips	0.5µL (glucose) / 0.8µL (ketone) blood volume required for a reaction in 5 seconds	1.1-33.3 (glucose) 0.1-8.0 (ketone)	10-70 (glucose) 20-60 (ketone)
85131	Finetest Lite blood glucose test strips	0.5µL blood volume required for a reaction in 5 seconds	1.1-33.3	20-65
85104	Accu-Chek Aviva test strips	0.6µL blood volume required for a reaction in 5 seconds	0.6-33.3	10-65
85543	Accu-Chek Mobile test cassette	0.3µL (min) 0.5µL (max) blood volume required for a reaction in 5 seconds	0.6-33.3	25-55
85120	GlucorX Nexus test strips	0.5µL blood volume required for a reaction in 5 seconds	1.1-33.3	30-60
85139	GlucorX HCT glucose test strips	1.0µL blood volume (glucose), for a reaction in 5 seconds. 1.0µL blood volume (ketone) for a reaction within 10 seconds.	0.5-38.9 (glucose) 0.1-8.0 (ketone)	0 –70 (glucose) 10–70 (ketone)
97607	Mylife Unio test strips	0.7µL blood volume required for a reaction in 5 seconds	0.6-33.3	20-70 (when glucose ≤ 11.1 mmol/L) 20-60 (when glucose > 11.1mmol/L)

* Blood glucose levels unless stated

In relation to blood glucose testing, seven of the 11 BGTS (64%) required a sample size of between 0.5-0.6 μL , while two (18%) required a sample of $< 0.5 \mu\text{L}$ and a further two (18%) required a larger sample size of $> 0.6 \mu\text{L}$. For meters that also tested ketones, a larger blood volume sample size was generally required.

Nine of the 11 BGTS (82%) required a reaction time of 5 seconds, while two of the 11 BGTS (18%), which also test for ketones, required a reaction time of 5 - 10 seconds.

In relation to glucose test range, six BGTS report a range of 0.5/0.6 - 33.3 mmol/L and four BGTS report a range of 1.1 - 33.3 mmol/L. One of the 11 BGTS (with haematocrit correction technology) had a glucose test range of 0.5 - 38.9 mmol/L.

The test range for ketones in meters offering blood ketone levels testing was 0.1 - 8.0 mmol/L.

Haematocrit range for glucose testing varied between the different BGTS with five reporting a wide range from 0 or 10% to 70% with other BGTS reporting narrower ranges (see table 4 for detail).

HCP clinical judgement should be used when choosing a meter for individuals. For this reason, the MMP is of the opinion that a range of BGTS should be considered for the preferred list to provide significant choice in terms of technology and features to suit different user requirements, including consideration of differing levels of visual impairment and dexterity.

Recommendation

Overall, in relation to the criteria of associated meter(s) and patient factors, the MMP is of the opinion that a range of BGTS should be considered for a preferred list to ensure sufficient choice of meters for patients and prescribers.

8.2.8 Acquisition cost of associated lancets

The acquisition cost of associated lancets for the BGTS that were submitted for the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus* were reviewed.

Figure 2 shows the lancets on the PCERS reimbursement list (July 2020).

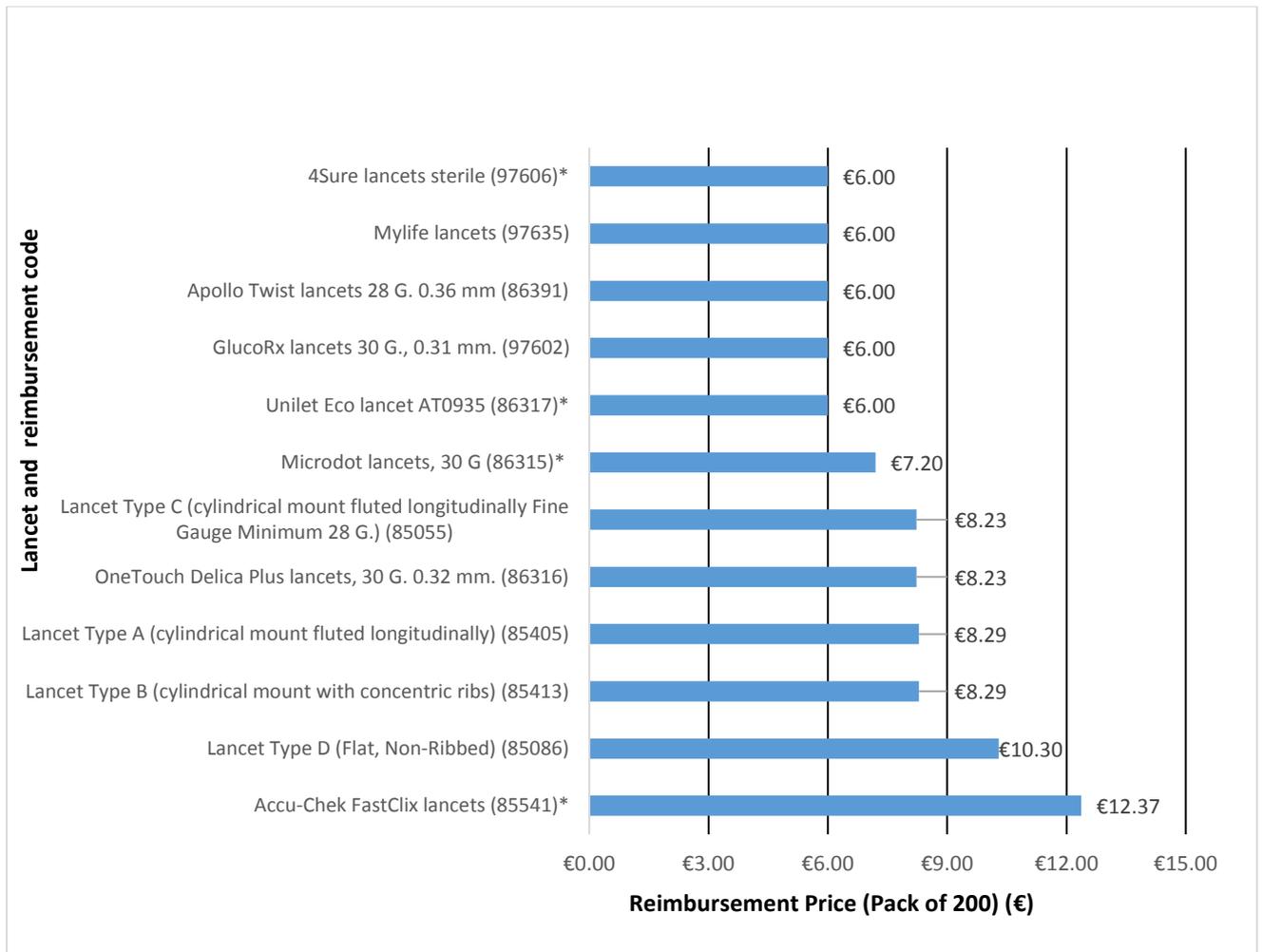


Figure 2: Reimbursement price of lancets available on the PCERS reimbursement list (July 2020)

* Some lancets come in packs of 100 or 204. For the purpose of price comparison, prices are displayed per 200.

Total expenditure on the CDS on available lancets in 2018 was €3.6 million.⁽⁹⁾ There is a wide range of reimbursement prices for lancets from €3 per 100 and €6 per 200 to €12.37 per 200.⁽⁴⁾ Lancets with a reimbursement price of > €7 per 200 account for the majority of expenditure.⁽⁹⁾

Submissions received from suppliers during the evaluation included information in relation to the lancets they also supply. Several submissions included a revised reimbursement price for their associated lancets if their BGTS were listed as one of the preferred BGTS, potentially resulting in reductions in the acquisition costs to the HSE.

Recommendation

Overall, in relation to acquisition cost of associated lancets, the MMP is satisfied that there is a suitable range of lancets on the PCERS reimbursement list costing approximately €6.00 per 200. Lancets at a reimbursement price of approximately €3.00 per 100 or €6.00 per 200 should be prescribed for patients. These are not necessarily the ones supplied with the individual meter.

The MMP recommends the use of a universal lancing device with a lancet at a cost of ≤ €6 per 200, for all patients undertaking SMBG. GlucoRx lancets (pack size 200), include a lancing device.

The MMP recommends the use of lancets at a reimbursement price of ≤ €6 per 200 for all people with diabetes undertaking SMBG.

8.2.9 Any other relevant factors

Any other relevant factors that were appropriate to consider during the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*, were included under this criterion.

The section below outlines other relevant factors that were considered.

8.2.9.1 Status of BGTS from suppliers as part of the MMP evaluation

As part of the evaluation process, the MMP contacted suppliers who had submitted a BGTS as part of the *MMP evaluation for the identification of preferred BGTS with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*, to review the status of BGTS which they did not submit for evaluation (i.e. if the listed strips were still available for supply to this Irish Market). The information supplied was then used to inform the categorisation of BGTS.

8.2.9.2 Blood ketone test strips

Figure 3 below, outlines blood ketone test strips available on the PCERS reimbursement list. This includes blood ketone test strips, which were outlined by suppliers, as being compatible with an associated meter that was submitted as part of the *MMP evaluation for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus*.



Figure 3: Reimbursement price of blood ketone test strips available on the PCERS reimbursement list (July 2020)

If a patient requires blood glucose and ketone monitoring, as part of their diabetes management, there are a range of blood ketone test strips available, costing \leq €11.27 per pack of 10, which are compatible with meters, which have the facility to measure both blood glucose and ketones on the same device.

Consideration was given to information provided by suppliers when categorising BGTS. The availability and cost of blood ketone test strips was also considered under this criterion.

8.2.10 Summary of recommendations

- ✓ The MMP recommends the use of a preferred BGTS for all adults with type 1 and type 2 diabetes who require SMBG to realise efficiencies in this area. The reimbursement price should be a key consideration when prescribing a BGTS with associated meter for individuals.
- ✓ In relation to shelf-life, the MMP is satisfied with the range of test strips available and the various options they present in terms of shelf-life in the context of frequency of testing.
- ✓ In relation to the availability of patient support services, which assist patients in using their BGTS with associated meter, the MMP is of the opinion that there is a similar offering of such services by the suppliers of the submitted BGTS.
- ✓ In relation to the availability of education resources to HCPs, the MMP is of the opinion that there is a similar offering of suitable resources provided by suppliers, which aid HCPs in educating patients on the use of their BGTS and associated meter.
- ✓ The MMP is of the opinion that having a range of suppliers of preferred BGTS is preferable as it mitigates the potential risks from supply issues with an individual supplier.
- ✓ Overall, in relation to the criteria of associated meter(s) and patient factors, the MMP is of the opinion that a range of BGTS should be considered for a preferred list to ensure sufficient choice of meters for patients and prescribers.
- ✓ The MMP recommends the use of lancets at a reimbursement price of \leq €6 per 200 for all people with diabetes undertaking SMBG.
- ✓ Consideration was given to information provided by suppliers when categorising BGTS. The availability and cost of blood ketone test strips was also considered.

9. Clinical guidelines and recommendations for SMBG

9.1 National Clinical Guideline: Type 1 diabetes mellitus in adults

The Department of Health (DoH) published a national clinical guideline in 2018 on adult type 1 diabetes mellitus.⁽²⁾ Part of the process of developing this guideline involved contextualising the National Institute for Health and Care Excellence (NICE) guideline NG17, “Type 1 diabetes in adults: diagnosis and management,” for use in Ireland.⁽¹⁵⁾

The guideline recommends that when choosing a meter, the needs of the adult with type 1 diabetes should be considered. All meters should meet current ISO standards. Patients should be aware of potential sources of meter errors, appropriate quality control techniques and the requirement for meter replacement every two years.⁽²⁾

The guideline also recommends that adults with type 1 diabetes should be educated about how to measure their blood glucose level, interpret the results and know what action to take. These skills should be reviewed annually.⁽²⁾

9.2 ICGP Guideline: A practical guide to integrated type 2 diabetes care

The Irish College of General Practitioners (ICGP) issued guidance on integrated type 2 diabetes care in 2016. The ICGP advise that all people with type 2 diabetes should have an annual diabetic review. With regard to SMBG testing, the ICGP guidance outlined the importance of quality control of the meters and recommend that it is checked four times a year at a minimum. They also recommend meters to be changed / upgraded every two years.⁽¹⁶⁾

9.3 NICE Guidelines: Type 2 diabetes in adults: management

NICE guidelines for the management of type 2 diabetes (2015), recommend that if adults with type 2 diabetes are self-monitoring their blood glucose levels, a structured assessment should be carried out at least annually. The assessment should include the person’s self-monitoring skills, the quality and frequency of blood glucose testing, interpretation of the blood glucose results and what action to take, the impact on the person's quality of life, the continued benefit to the person and the equipment (e.g. BGTS with associated meter) used.⁽³⁾

9.4 HPRA: Safety advice for blood glucose meters

In the case of a recall, the HPRA advise that meters are registered by returning warranty cards to the manufacturer. The HPRA also advise that quality control of meters should be undertaken annually. They reiterate the importance of using meters correctly, with appropriate training, to make sure that blood glucose results are accurate.⁽⁶⁾

10. Blood glucose test strip formularies in other jurisdictions

The National Health Service (NHS), under the guidance of PrescQIPP, support Clinical Commissioning Groups (CCGs) in the United Kingdom, to ensure that they allocate their prescribing funds effectively and deliver best patient outcomes for SMBG at a local level.⁽¹⁷⁾

The NHS advise CCGs that there is little variation between the different SMBG meters in their ability to provide an accurate reading of blood glucose and state that it is appropriate to streamline prescribing to include only cost-effective BGTS.⁽¹⁷⁾

Following these recommendations, CCGs selected BGTS with associated meter(s) using ISO standards and identified cost-effective BGTS as those costing ≤ £9.00 (€9.84)/50 strips.⁽¹⁸⁻²⁰⁾

11. Preferred blood glucose test strips

The MMP has identified 10 preferred blood glucose test strips with 20 associated blood glucose meters for adults with type 1 and type 2 diabetes mellitus who require SMBG.

The preferred BGTS are outlined in List A.

Preferred BGTS – List A

Preferred BGTS		
Reimbursement Code	BGTS*	Reimbursement price (as of 1 st February 2021) (50)
85131	Finetest Lite blood glucose test strips	€6.95
97637	Microdot Max blood glucose test strips	€7.46
85110	Glucomen Areo Sensor test strips	€9.44
97607	Mylife Unio test strips	€10.50
94170	4Sure blood glucose test strips	€11.22
85120	GlucoRx Nexus test strips	€11.27
85139	GlucoRx HCT glucose test strips	€11.27
85543	Accu-Chek Mobile test cassette (50)	€11.81
15963	Contour Next blood glucose test strips	€14.30
68321	One Touch Verio test strips	€14.30

* Listed in order of ascending reimbursement price

This list of preferred BGTS offers sufficient choice, including a range of BGTS and meter features to satisfy different user requirements. Increased utilisation of preferred BGTS will lead to significant savings for the HSE.

List A - Associated Meters

Reimbursement Code	Preferred BGTS	Associated meter(s)
85131	Finetest Lite blood glucose test strips	Finetest Lite Finetest Lite Smart
97637	Microdot Max blood glucose test strips	Microdot Max
85110	Glucomen Areo Sensor test strips	Glucomen Areo Glucomen Areo 2K*
97607	Mylife Unio test strips	Mylife Unio Cara** Mylife Unio Neva**
94170	4Sure blood glucose test strips	4Sure SMART 4Sure SMART DUO*
85120	GlucorX Nexus test strips	GlucorX Nexus (TD-4277) GlucorX Nexus mini ultra (TD-4141) GlucorX Nexus Voice (TD-4280) [±]
85139	GlucorX HCT glucose test strips	GlucorX HCT (TD-4279)* GlucorX HCT Connect (TD-4140)* GlucorX HCT Connect <i>i</i> (TD-4140b)*
85543	Accu-Chek Mobile test cassette (50)	Accu-Chek Mobile
15963	Contour Next blood glucose test strips	Contour Next One Contour XT Contour Next Link 2.4**
68321	One Touch Verio test strips	One Touch Verio Reflect

[±]Also available: GlucorX GO (recommended by supplier for use by HCPs, therefore it has not been included in the final patient list).

*Compatible with blood ketone test strips

**Compatible with insulin pump

Any BGTS which is not on list A has been identified as a List B BGTS.

List B consists of BGTS that:

- Did not meet certain criteria as part of the *evaluation for the identification of preferred blood glucose test strips with associated meter(s) for adult patients with type 1 and type 2 diabetes mellitus*
and/or
- Were identified by suppliers as no longer being supplied to the Irish Market
and/or
- Were not submitted for inclusion in the *evaluation for the identification of preferred blood glucose test strips with associated meter(s) for adult patients with type 1 and type 2 diabetes mellitus*.

Non Preferred BGTS - List B	
Reimbursement code	BGTS
85104	Accu-Chek Aviva test strips
10020	Accu-Chek Active test strips
63435	Accu-Chek Advantage Plus test strips
85540	Accu-Chek Mobile test cassette (100)
81516	Ascensia Autodisc test strips
10650	BM-Accutest test strips
15403	Breeze 2 Disc test strips
81537	Contour test strips
85135	Element blood glucose test strips
85001	Freestyle Lite test strips
10051	Freestyle Optium test strips
81601	Freestyle test strips
85114	GlucoRx Go test strips
85137	GlucoRx Q test strips
85015	Glucomen LX Sensor test strips
85158	Glucomen Sensor test strips
85124	Glucomen Visio Sensor test strips
85501	Hemocue Monitor Microcuvette test strips
29238	Hypoguard Supreme test strips
86308	Microdot+ blood glucose test strips
10035	One Touch Ultra test strips
15858	Pocketscan test strips
85102	Sensocard test strips
86392	Supercheck2 blood glucose test strips
12003	True Result blood glucose test strips

12. MMP recommendations for adults with type 1 and type 2 diabetes mellitus

The MMP recommends a preferred BGTS with an associated meter from [List A](#) for:

- ✓ People who are newly diagnosed with diabetes and require SMBG.
- ✓ People with diabetes where continued SMBG is recommended on review.
- ✓ People with diabetes changing current BGTS with an associated meter where SMBG is recommended.
 - HCPs should give due consideration to the use of a preferred BGTS (List A) when commencing SMBG, and when changing BGTS in people who are established on a BGTS not on List A.
 - Review of current prescribing of BGTS and the need for SMBG on an individual basis is recommended.

Initiating SMBG

When initiating SMBG, the HCP should first assess individual requirements. If SMBG is recommended, the HCP should aim to use a BGTS from [LIST A](#) and choose an associated meter that best suits the individual's needs.

Reviewing Regimen

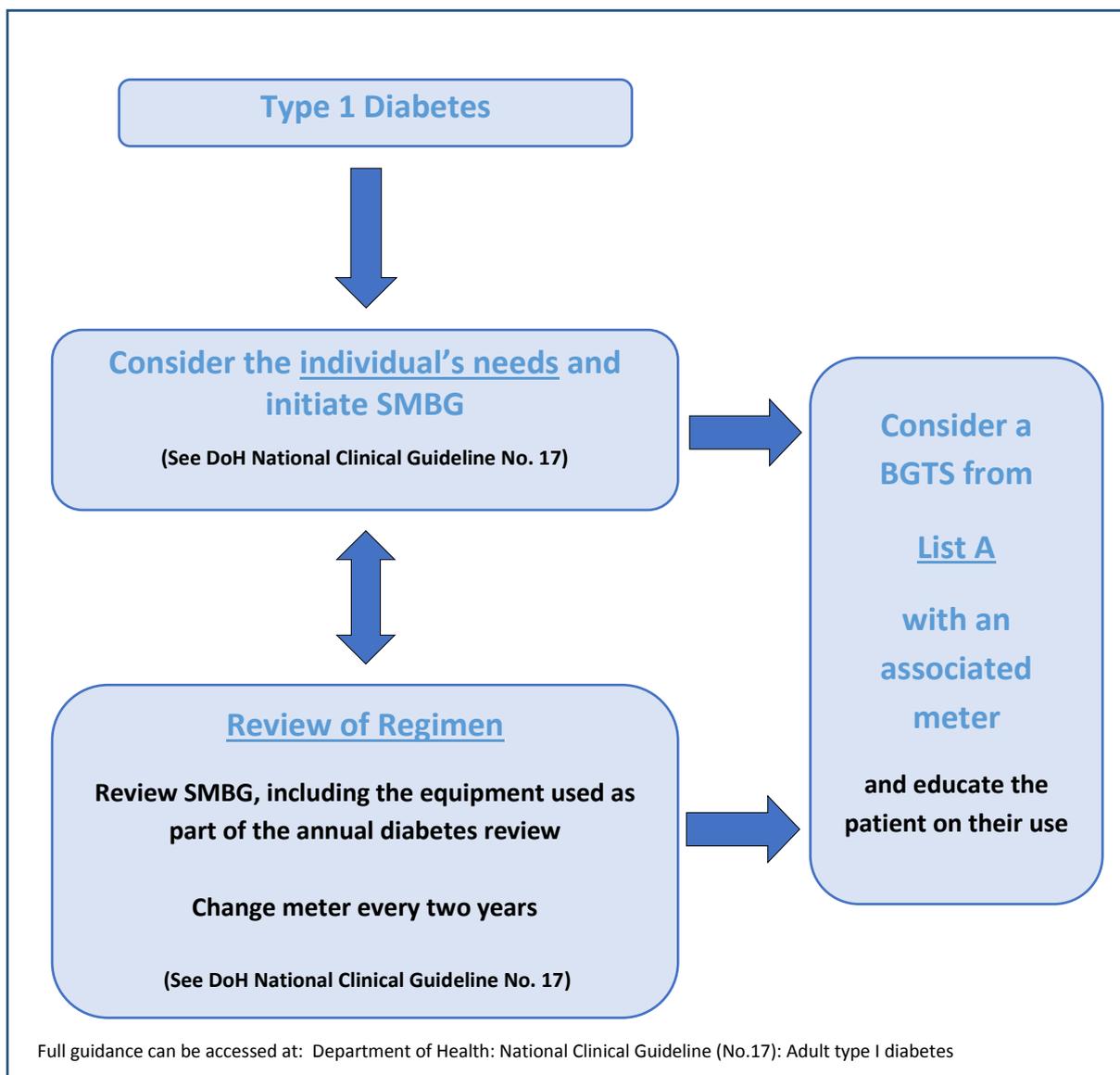
When reviewing current SMBG regimen, the HCP should re-assess individual requirements. If ongoing SMBG is recommended, the HCP should aim to use a BGTS from [LIST A](#) and choose an associated meter that best suits the individual's needs.

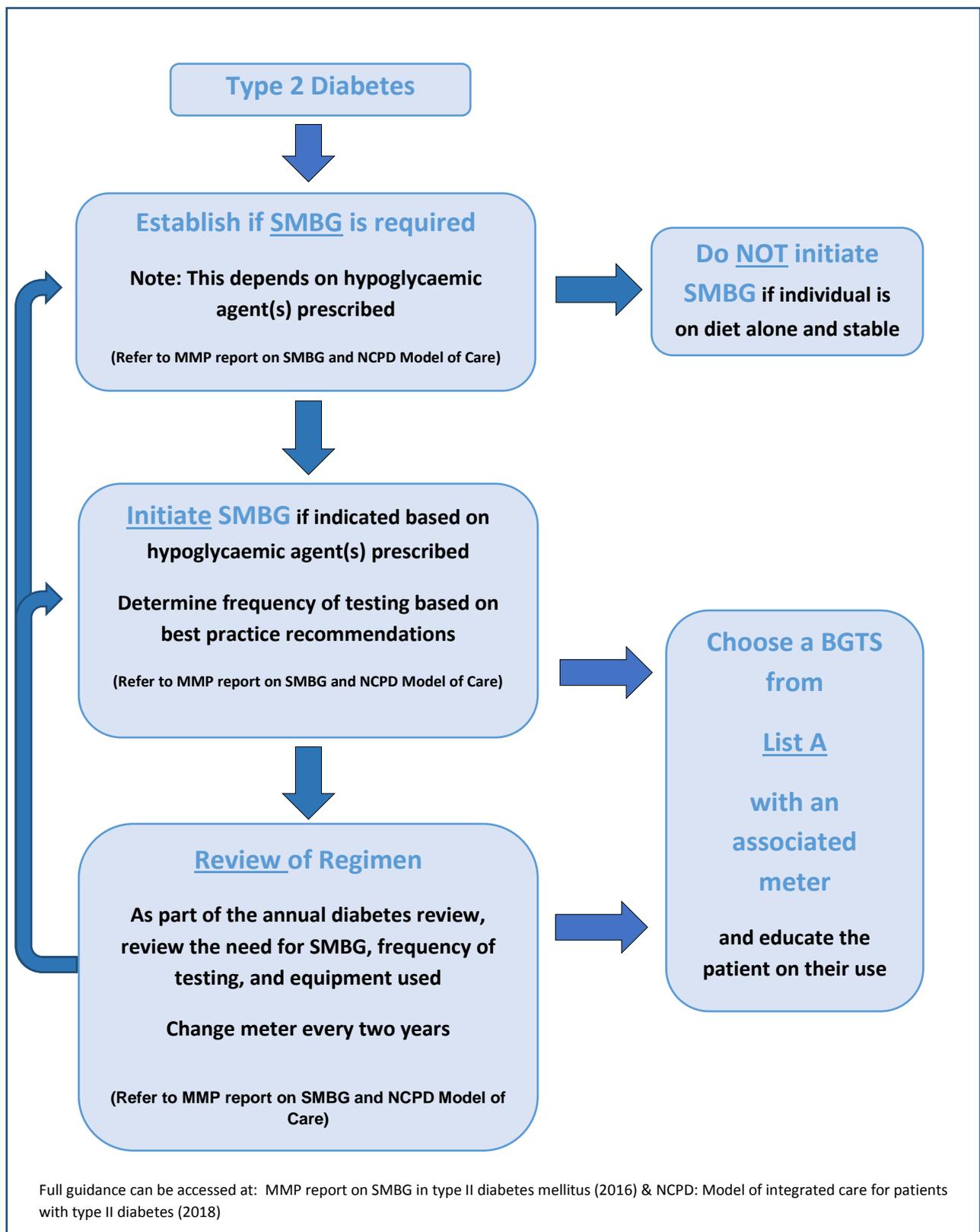
Changing BGTS/meter

When changing a BGTS, the HCP should assess individual requirements. If ongoing SMBG is recommended, the HCP should aim to use a BGTS from [LIST A](#) and choose an associated meter that best suits the individual's needs.

Implementation of the preferred BGTS will lead to significant savings for the HSE, in the order of millions of euros.

- ✓ Choose a BGTS from List A and associated meter when initiating SMBG.
- ✓ Regularly review BGTS and associated meter being used and change to a BGTS and suitable associated meter on List A if current meter hasn't been replaced in the previous two years, or if current BGTS and associated meter is on List B.
- ✗ Do not choose a BGTS from List B and associated meter when initiating SMBG, unless clinically justified.
- ✗ Do not choose a BGTS from List B and associated meter when changing, unless clinically justified.





13. References

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14. Appendices

Appendix A: MMP roadmap for the identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus

Self-monitoring of blood glucose (SMBG) involves the use of blood glucose test strips (“test strips”) with an associated blood glucose meter (“meter”). Patients can access test strips under the Community Drug Schemes, as they are included on the HSE-Primary Care Eligibility and Reimbursement Service (PCERS) list of reimbursable items.

SMBG is essential for patients with diabetes mellitus who are insulin-dependent and may also be beneficial for patients who are prescribed other hypoglycaemic agents (see previous MMP guidance: *SMBG in type 2 diabetes mellitus, January 2016*¹).

There are currently 35 individual test strips on the HSE-PCERS list of reimbursable items. Test strips range in cost from €6.17 to €26.50 for a quantity of 50 test strips.² Total expenditure* on test strips on the Community Drug Schemes exceeded €40.6 million in 2019. Test strips with a reimbursement cost greater than €19.00 for a quantity of 50, accounted for approximately 98% of this expenditure (€39.9 million).³

For test strips to be included on the list of reimbursable items, they must have satisfied the certification process, as outlined in the *HSE-PCERS Personal Diagnostic, Monitoring and Delivery Devices Guidelines for Suppliers*⁴, at the time of their addition to the reimbursement list. The Health Products Regulatory Authority (HPRA) has a regulatory role involving the monitoring of medical devices (e.g. test strips and meters) in Ireland including operating a national reporting system for medical devices.

The MMP aims to identify preferred test strips with associated meter(s) for adult patients with type 1 and type 2 diabetes mellitus who undertake SMBG, using the criteria outlined below.

Evaluation Process

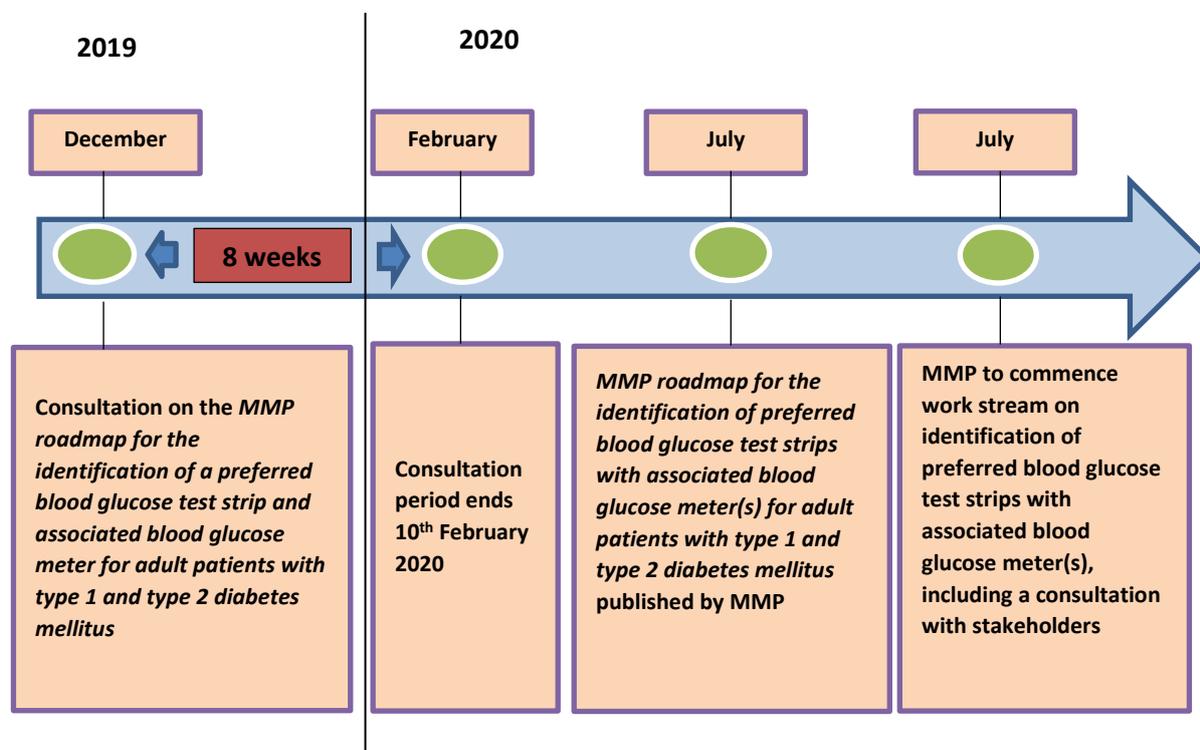
The MMP will undertake an evaluation to identify preferred test strips with associated meter(s) to support safe, effective and cost-effective prescribing. The MMP will publish Prescribing and Cost Guidance for the use of preferred test strips with associated meter(s) to include prescriber and patient support material. A collaborative approach involving clinicians, nurses, pharmacists, patients and the health service will be required to implement utilisation of the preferred test strips with associated meter(s).

A number of criteria may be considered by the MMP in identifying preferred test strips with associated meter(s), including:

1. Acquisition cost of the test strips
2. Shelf life of the test strips
3. Availability of patient support services by the supplier
4. Availability of education resources to healthcare professionals by the supplier
5. Robustness of supply of test strips to the Irish Market
6. Associated meter(s)
7. Patient factors
8. Acquisition cost of associated lancets
9. Any other relevant factors

Work Plan

In July 2020, the MMP will commence work on the identification of preferred test strips with associated meter(s), using the process as outlined in this roadmap. This will include a consultation period, where submissions are invited from relevant stakeholders. This process will be limited to test strips on the HSE-PCERS list of reimbursable items, and associated meters that are currently available for supply to the Irish Market (and provided free of charge).



Definitions

***Total expenditure** includes ingredient cost and VAT, where applicable, based on claims submitted by pharmacists.

References

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Appendix B: Cover page for submissions

Identification of preferred blood glucose test strips with associated blood glucose meter(s) for adult patients with type 1 and type 2 diabetes mellitus

Cover Page for Submissions

For all submissions relating to particular test strips with associated meter(s), section A must be completed and included as the cover page for the submission. All test strips and associated meter(s) included in the submission must be listed in the table below.

In addition, suppliers of test strips with associated meter(s) must also complete section B, and include as the cover page for the submission.

Section A:

Test strip name	PCERS reimbursement code	Associated meter(s) compatible with test strip (must be in line with published criteria* including availability free of charge to patient)

*HSE-Primary Care Eligibility and Reimbursement Service Personal Diagnostic, Monitoring & Delivery Devices Guidelines for Suppliers. February 2020. Available: <https://www.hse.ie/eng/about/who/cpu/non-drug-reimbursement-applications/personal-diagnostic-monitoring-and-delivery-guidelines/personal-diagnostic-monitoring-and-delivery-reimbursement-guidelines-feb-2020.pdf>.

Section B:

I, the undersigned, confirm compliance with:

- *Applicable national standards and European Commission standards*
- *All applicable laws*
- *ISO 15197:2013*

for all products (test strips and meters) listed in the table above.

Managing Director Signature: _____

Managing Director Name: _____

Company name: _____

Date of submission: _____

Submissions can be emailed to mmp@hse.ie and/or delivered to: Prof. Michael Barry, Medicines Management Programme, Department of Pharmacology and Therapeutics, Trinity Centre for Health Sciences, St. James's Hospital