



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
CDS Community Drug Schemes
DP Drugs Payment (scheme)
GMS General Medical Services
HCP Healthcare professional

HPRA Health Products Regulatory Authority

HSE Health Service Executive

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
PC Personal Computer

PCRS Primary Care Reimbursement Service 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 - Primary Care Reimbursement Service website, www.pcrs.ie. Reimbursement prices are correct as of 01/03/2025, unless otherwise stated.

Acquisition cost, when referred to in this document, refers to the price listed on the Primary Care Reimbursement Service reimbursement list.

For the purpose of this document, diabetes mellitus may also be referred to as diabetes. Blood glucose test strips and 'test strips' may be used interchangeably.

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

1. Executive summary

The Health Service Executive (HSE)-Medicines Management Programme (MMP) aims to support safe, effective and cost-effective prescribing in the Irish healthcare setting.

In 2023, blood glucose test strips (BGTS) accounted for a total expenditure of approximately €25.7 million under the Community Drug Schemes (CDS). The MMP recognises the potential for a sustained reduction in expenditure on BGTS under 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 continue to 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 | Reimbursement Code BGTS* | | | | |
| 85131 | Finetest Lite blood glucose test strips | €6.95 | | | |
| 85132 | Accu-Chek Instant test strips | €8.54 | | | |
| 85110 | Glucomen Areo Sensor test strips | €8.63 | | | |
| 97630 | Mylife Aveo test strips | €8.75 | | | |
| 85579 | TD-4183-4363 blood glucose test strips | €10.25 | | | |
| 94170 | 4Sure blood glucose test strips | €11.22 | | | |
| 85120 | GlucoRx Nexus test strips | €11.27 | | | |
| 85139 | GlucoRx HCT glucose test strips | €11.27 | | | |
| 10051 | Freestyle Optium test strips | €13.30 | | | |
| 15963 | Contour Next blood glucose test strips | €13.90 | | | |
| 68321 | One Touch Verio test strips | €13.90 | | | |
| Accu-Chek Mobile test cassette (Code: 85543, Price: €11.81) is considered a list A product | | | | | |

^{*}Listed in order of ascending reimbursement price

for existing users only.

2. Purpose

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

3. Scope

This evaluation considers BGTS on the Primary Care Reimbursement Service (PCRS) 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).

This evaluation is aimed at achieving sustained 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 defined by the World Health Organisation as a chronic, metabolic disease, characterised by elevated levels of blood glucose, which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves. There are different types of diabetes, including type 1 diabetes mellitus, type 2 diabetes mellitus and gestational diabetes.^{1,2}

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 CDS, as they are included on the PCRS reimbursement list.³

For test strips to be included on the PCRS reimbursement list, they must have satisfied the certification process, in accordance with the relevant PCRS guidelines in place at the time of their addition to the reimbursement list. The current guidelines for this process are entitled

HSE-Primary Care Reimbursement Service Diabetes Consumables Guidelines for Manufacturers/Distributors/Suppliers (November 2023).⁴ This process is underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013.⁵

The Health Products Regulatory Authority (HPRA) has a regulatory role involving the monitoring of medical devices (e.g. BGTS) in Ireland.⁶

5. Diabetes mellitus & blood glucose test strips — expenditure and utilisation
The Long Term Illness (LTI) scheme is a non-means tested, condition specific, prescription charge
exempt primary care scheme operationalised by PCRS. The scheme commenced in 1970 through the
Health Act (1970) and was last amended in 1975. The scheme provides medicines and consumable
appliances for the treatment of diabetes mellitus free of charge.⁷ In 2023, total expenditure by the
PCRS for diabetes mellitus on the LTI scheme was €288.82 million. This expenditure reflected
utilisation by 167,118 people in Ireland.⁸ 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.⁹

According to MMP analysis, total expenditure on BGTS in 2023 was approximately €25.7 million; €22.5 million on the LTI and DP schemes and €3.2 million on the GMS scheme.⁹

In March 2025, there were 32 individual BGTS on the PCRS reimbursement list; since the last update of this evaluation, one BGTS has been added to the reimbursement list in 2023, while a number of BGTS were removed from the reimbursement list at the request of the supplier. The range in reimbursement price was €6.95 to €26.50 for a quantity of 50 test strips.³

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 The recommendations in table 1 are supported by the National Clinical Programme for Diabetes (NCPD).¹¹

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')

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.* 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.

^{*}Additional testing may be warranted in people with type 2 diabetes on a sulphonylurea or meglitinide as recommended in the 2022 Medical Fitness to Drive Guidelines (Group 1 and 2 Drivers). These individuals must be under regular medical review (available on www.rsa.ie).¹²

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 BGTS 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.

Due to the dynamic nature of the BGTS market in Ireland, and considering the first evaluation process was completed in January 2021, the MMP initiated updates to the evaluation of the preferred BGTS list, completing these updates in December 2021, February 2023 and March 2025.

As part of the evaluation commenced in 2024, a period of consultation with stakeholders was undertaken between 22 August 2024 and 19 September 2024. All suppliers of preferred BGTS and suppliers of new BGTS on the reimbursement list 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. The NCPD was also notified of the consultation period and of the commencement of the evaluation process.

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-Primary Care Reimbursement Service Diabetes Consumables Guidelines for Manufacturers/Distributors/Suppliers (November 2023), including that meters are available free-of-charge.

A copy of the original 2020 cover page is available in Appendix B.

As part of the evaluations undertaken in 2021, 2022 and 2024, updated cover pages were developed. These cover pages are available in Appendices C, D and E respectively.

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. In 2020, the MMP evaluated 11 BGTS from nine suppliers under these criteria (table 2).

Table 2: BGTS submissions received from suppliers during the 2020 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 Diagnostics Ltd. | 85104 | Accu-Chek Aviva test strips | 50 |
| Roche Diagnostics 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 |

In 2020, 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.

In 2021, the MMP evaluated two additional BGTS from two suppliers under the criteria outlined above (table 3).

Table 3: BGTS submissions received from suppliers during the 2021 evaluation process

| Supplier | Reimbursement Code | BGTS | Pack size |
|------------------------|-----------------------|-------------------------------|-----------|
| Abbott Diabetes Care | 10051 | Freestyle Optium test strips | 50 |
| Roche Diagnostics Ltd. | 85132 | Accu-Chek Instant test strips | 50 |

In 2022, the MMP evaluated one additional BGTS from one supplier under the criteria outlined above (table 4).

Table 4: BGTS submissions received from suppliers during the 2022 evaluation process

| Supplier | Reimbursement Code | BGTS | Pack size |
|--------------|-----------------------|-------------------------|-----------|
| Ypsomed Ltd. | 97630 | Mylife Aveo test strips | 50 |

In 2024, the MMP evaluated one additional BGTS from one supplier under the criteria outlined above (table 5).

Table 5: BGTS submissions received from suppliers during the 2024 evaluation process

| Supplier | Reimbursement Code | BGTS | Pack size |
|--------------------------|-----------------------|--|-----------|
| Critical Healthcare Ltd. | 85579 | TD-4183-4363 blood glucose test strips | 50 |

As part of the 2021, 2022 and 2024 updates, the MMP engaged with existing suppliers of preferred BGTS to confirm the accuracy of the information.

8.2.1 Acquisition cost of test strips

In March 2025, there were 32 individual test strips on the PCRS reimbursement list. Test strips ranged in reimbursement price from €6.95 to €26.50 for a quantity of 50 test strips (Figure 1).³

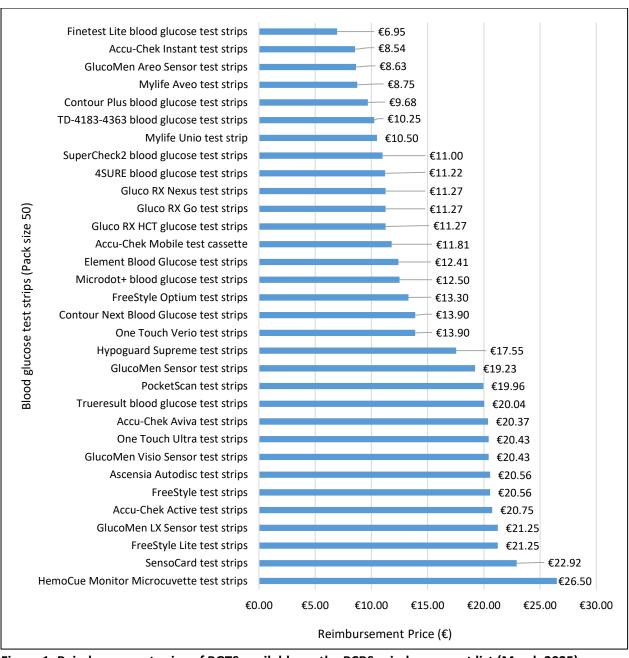


Figure 1: Reimbursement price of BGTS available on the PCRS reimbursement list (March 2025)

The acquisition cost of BGTS on the PCRS reimbursement list, 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.

In 2020 and 2024, several submissions included a revised reimbursement price for some BGTS resulting in 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 in 2025, the MMP is of the view that BGTS with a reimbursement price of less than or equal to €13.90, 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.

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 considered as part of the updated evaluation are outlined in table 6.

Table 6: Shelf-life of blood glucose test strips

| Reimbursement Code | BGTS | Pack size | Shelf-life (expiry date) |
|-----------------------|---|--------------|---|
| 10051 | Freestyle Optium test strips | 50 | Unopened: up to 18 months Opened (i.e. individual foil packet): Use immediately |
| 15963 | Contour Next blood glucose test strips | 50 | Unopened: up to 24 months Opening does not impact expiry |
| 94170 | 4Sure blood glucose test strips | 50 | Unopened: up to 24 months Opening does not impact expiry |
| 85579 | TD-4183-4363 blood glucose test strip | 50 | Unopened: 24 months Opened: 6 months |
| 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 |
| 97630 | Mylife Aveo test strips | 50 | Unopened: 12 months Opening does not impact expiry |
| 85132 | Accu-Chek Instant test strips | 50 | Unopened: up to 21 months Opening does not impact expiry |

| 85543 | Accu-Chek Mobile test cassette | 50 | Unopened: 12 months Opened: 90 days |
|-------|---------------------------------|----|--|
| 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 |

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 a requirement to use immediately or to use within 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.

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 provided 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 phoneline
- 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.

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. Under this criterion, the MMP undertook analysis of the PCRS pharmacy claims database. In 2023, approximately 147,000 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.⁹

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.

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-Primary Care Reimbursement Service Diabetes

Consumables Guidelines for Manufacturers/Distributors/Suppliers (November 2023), including that meters are available free of charge.⁴

In 2024, two additional meters, suitable for patient use by two suppliers were evaluated under these criteria. One meter was associated with a BGTS submitted as part of the 2020 evaluation and one meter was associated with a BGTS submitted as part of the 2024 evaluation.

As part of the 2024 evaluation and update, five of the 12 evaluated 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. One meter evaluated is only available for supply to existing users of this particular meter with its associated test strip.

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 meters evaluated 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. 'talking' capability and visual impairment specification). There was also a meter without a screen (a dongle) which employs "smart" devices for its utilisation.

Five of the meters reviewed have ketone testing capabilities, and two have compatibility with a specific insulin pump. The memory capabilities for individual meters varied from 450 - 1,000 readings with additional memory (and all of the memory in the case of the dongle device) being facilitated through the use of an app on a smart device. Of the patient meters that were reviewed, an app was available for 11 of the meters evaluated in 2024.

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 7 outlines details of some of the features for BGTS evaluated as part of this update that may influence individual user requirements.

Table 7: Comparison of sample size, test range and haematocrit of blood glucose test strips

| Reimbursement | BGTS | Sample Size* | Test Range | Haematocrit |
|---------------|---|---|--|---|
| Code | | | (mmol/L)* | Range (%)* |
| 10051 | Freestyle Optium test strips | 0.6 μL blood volume (glucose) required for a reaction in 5 seconds. 1.5 μL blood volume (ketone) required for a reaction in 10 seconds. | 1.1-27.8 (glucose) 0.0-8.0 (ketone) | 30-60 (glucose & ketones) |
| 15963 | Contour Next blood glucose test strips | 0.6 μL blood volume required for a reaction in 5 seconds. | 0.6-33.3 | 0-70 |
| 94170 | 4Sure blood glucose test strips | 0.5 μL (glucose) / 0.8 μL (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) |
| 85579 | TD-4183-4363 blood glucose test strips | 0.5 μL blood volume required for a reaction in 5 seconds | 1.1 – 36.1 | 20-65 |
| 68321 | One Touch Verio test strips | 0.4 μL blood volume required for a reaction in 5 seconds. | 1.1-33.3 | 20-60 |
| 85110 | Glucomen Areo Sensor test strips | 0.5 μL (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 | 0.5 μL blood volume required for a reaction in 5 seconds. | 1.1-33.3 | 20-65 |
| 97630 | Mylife Aveo test strips | 0.5 μL blood volume required for a reaction in 5 seconds. | 0.6-33.3 | 15-70 |
| 85132 | Accu-Chek Instant test strips | 0.6 μL blood volume required for a reaction within 4 seconds. | 0.6-33.3 | 10-65 |
| 85543 | Accu-Chek Mobile test cassette | Approximately 0.3 µL blood volume required for a reaction in 5 seconds. | 0.6-33.3 | 25-55 |

| 85120 | GlucoRx Nexus test strips | 0.5 μL blood volume required for a reaction in 5 seconds. | 1.1-33.3 | 30-60 |
|-------|---------------------------------------|---|--|---|
| 85139 | GlucoRx HCT glucose test strips | 1.0 μL blood volume (glucose) required, for a reaction in 5 seconds. 1.0 μL blood volume (ketone) required for a reaction within 10 seconds. | 0.5-38.9 (glucose) 0.1-8.0 (ketone) | 0 –70 (glucose) 10–70 (ketone) |

^{*} Blood glucose levels unless stated

In relation to blood glucose testing, nine of the 12 BGTS evaluated required a sample size of between 0.5 - 0.6 μ L, while two required a sample of < 0.5 μ L and one required a larger sample size of > 0.6 μ L. For meters that also tested ketones, a larger blood volume sample size was generally required.

In relation to glucose test range, five BGTS report a range of 0.5/0.6 - 33.3 mmol/L, four BGTS report a range of 1.1 - 33.3 mmol/L, one BGTS reports a range of 1.1 - 27.8 mmol/L and one BGTS reports a range of 1.1 - 36.1mmol/L. One of the 12 BGTS evaluated (with haematocrit correction technology) has a glucose test range of 0.5 - 38.9 mmol/L.

The test range for ketones in meters offering blood ketone levels testing was 0.0/0.1 - 8.0 mmol/L.

Haematocrit range for glucose testing varied between the different BGTS with four reporting a wide range from 0 or 10% to 70% with other BGTS reporting narrower ranges (see table 7 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

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.



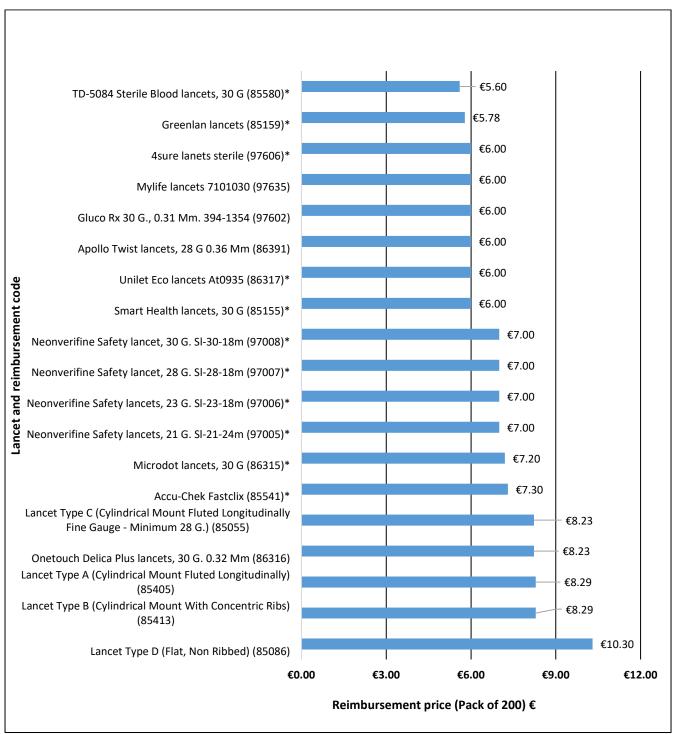


Figure 2: Reimbursement price of lancets available on the PCRS reimbursement list (March 2025)

^{*} 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 2023 was approximately €3.0 million.⁹ There are a wide range of reimbursement prices for lancets from €2.80 per 100 and €6 per 200 to €10.30 per $200.^3$ 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.

Recommendation

Overall, in relation to acquisition cost of associated lancets, the MMP is satisfied that there is a suitable range of lancets on the PCRS reimbursement list costing approximately €6.00 per 200. Lancets at a reimbursement price of approximately €3.00 per 100 or €6.00 per 200 or less 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 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 PCRS reimbursement list.³ 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.

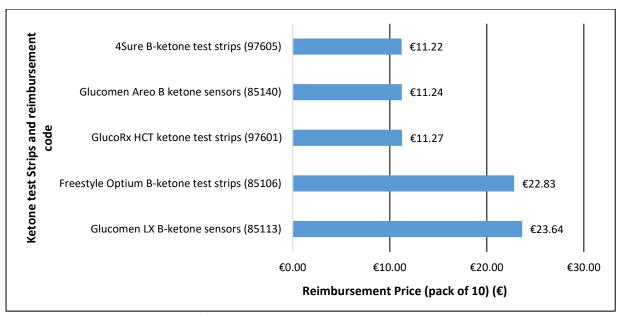


Figure 3: Reimbursement price of blood ketone test strips available on the PCRS reimbursement list (March 2025)

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, which are compatible with meters, which have the facility to measure both blood glucose and ketones on the same device, and which should be chosen based on an individual's requirements.

Recommendation

In relation to the criterion of other relevant factors, 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.

9. Blood glucose test strip formularies in other jurisdictions

The National Health Service (NHS) England published *Commissioning recommendations following the* national assessment of blood glucose and ketone meters, testing strips and lancets in 2023 with an update in 2024. The intent of the national assessment process was to support the delivery of the NHS long term plan for diabetes management.¹⁴

10. Survey undertaken in relation to preferred blood glucose test strips

The MMP conducted a survey in June 2022, to gauge awareness and understanding among healthcare professionals of the preferred BGTS initiative for adults with type 1 and type 2 diabetes mellitus.

The findings of this survey are used to inform updates to the preferred BGTS list.

11. Preferred blood glucose test strips

The MMP has identified 12 preferred blood glucose test strips with 18 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 (table 8).

Table 8: Preferred BGTS - List A

| Preferred BGTS | | |
|---|---|------------------------------------|
| Reimbursement | Reimbursement BGTS* | |
| Code | | (as of 1 st March 2025) |
| | | (50) |
| 85131 | Finetest Lite blood glucose test strips | €6.95 |
| 85132 | Accu-Chek Instant test strips | €8.54 |
| 85110 | Glucomen Areo Sensor test strips | €8.63 |
| 97630 | Mylife Aveo test strips | €8.75 |
| 85579 | TD-4183-4363 blood glucose test strips | €10.25 |
| 94170 | 4Sure blood glucose test strips | €11.22 |
| 85120 | GlucoRx Nexus test strips | €11.27 |
| 85139 | GlucoRx HCT glucose test strips | €11.27 |
| 10051 | Freestyle Optium test strips | €13.30 |
| 15963 | Contour Next blood glucose test strips | €13.90 |
| 68321 | One Touch Verio test strips | €13.90 |
| Accu-Chek Mobile test cassette (Code: 85543, Price: €11.81) is considered a list A product for existing users only. | | |

This list of preferred BGTS offers sufficient choice, including a range of BGTS and meter features to satisfy different user requirements.

^{*} Listed in order of ascending reimbursement price

Table 9: Preferred BGTS (List A) - Associated Meters ^Ω

| Reimbursement Code | Preferred BGTS | Associated meter(s) |
|---------------------------------|---|--|
| 85131 | Finetest Lite blood glucose test | Finetest Lite |
| | strips | Finetest Lite Smart |
| 85132 | Accu-Chek Instant test strips | Accu-Chek Instant |
| 85110 | Glucomen Areo Sensor test strips | Glucomen Areo GK* |
| 97630 | Mylife Aveo test strips | Mylife Aveo** |
| 85579 | TD-4183-4363 blood glucose test strips | TD-4183 |
| 94170 | 4Sure blood glucose test strips | 4Sure SMART |
| | | 4Sure SMART DUO* |
| 85120 | GlucoRx Nexus test strips | GlucoRx Nexus |
| | | GlucoRx Nexus Mini Ultra |
| | | GlucoRx Nexus Voice |
| 85139 | GlucoRx HCT glucose test strips | GlucoRx HCT* |
| | | GlucoRx HCT Connecti* |
| 10051 | Freestyle Optium test strips | Freestyle Optium Neo* |
| 15963 | Contour Next blood glucose test | Contour Next One |
| | strips | Contour Next |
| | | Contour Next Link 2.4** |
| 68321 | One Touch Verio test strips | One Touch Verio Reflect |
| Accu-Chek Mobile test cas only. | sette (Code: 85543, Price: €11.81) is con | nsidered a list A product for existing users |

 $^{^{\}Omega}$ Does not include the Accu-Chek Mobile meter, as following a change in this meter's supply, the Accu-Chek Mobile test cassette is considered a list A product for existing users only.

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.

^{*}Compatible with blood ketone test strips

^{**}Compatible with insulin pump

Table 10: Non Preferred BGTS - List B

| Non Preferred BGTS - List B | | |
|-----------------------------|--|--|
| Reimbursement code | BGTS | |
| 85104 | Accu-Chek Aviva test strips | |
| 10020 | Accu-Chek Active test strips | |
| 81516 | Ascensia Autodisc test strips | |
| 85156 | Contour Plus blood glucose test strips | |
| 85135 | Element blood glucose test strips | |
| 85001 | Freestyle Lite test strips | |
| 81601 | Freestyle test strips | |
| 85114 | GlucoRx Go test strips 399-6899 | |
| 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 | |
| 97607 | Mylife Unio 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 <u>List A</u> 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.

- ✓ 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 has not 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 2016¹).

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

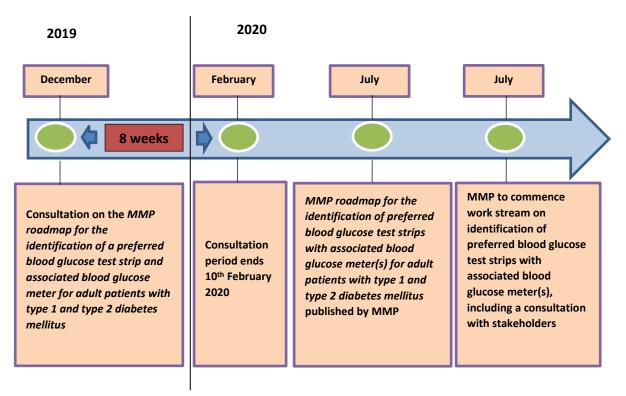
The MMP will undertake an evaluation to identify preferred test strips with associated meter(s) to support safe, effective and cost-effective prescribing. The MMP will publish Prescribing and Cost Guidance for the use of preferred test strips with associated meter(s) to include prescriber and patient 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

- Report on Self-Monitoring of Blood Glucose (SMBG) in Type 2 Diabetes Mellitus. January 2016. Available: https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/mmpreport-on-self-monitoring-of-blood-glucose-in-type-2-diabetes.pdf
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Appendix B: Cover page for submissions 2020

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) |
|-----------------|--------------------------------|--|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

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 Signatu | re: |
|---------------------------|-----|
| 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, Dublin 8.

^{*}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-reimbursement-guidelines-feb-2020.pdf.

Appendix C: Updated Cover page for submissions 2021

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 and section B 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.

Section A:

| Test strip name | PCRS 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.

For first submissions by suppliers who have not engaged with this process previously, information in relation to all the criteria as set out in the Medicines Management Programme (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 should be outlined.

For subsequent submissions by suppliers (e.g. those who currently have a blood glucose test strip identified as one of the preferred products) if appropriate, a number of criteria can be confirmed in the table below. The remaining criteria as set out in the MMP roadmap should be outlined.

I confirm that the information previously submitted in relation to the following criteria, is applicable to the products being submitted as part of this updated evaluation:

| Criteria | | No |
|---|--|----|
| Availability of patient support services by the supplier | | |
| Availability of education resources to healthcare professionals by the supplier | | |
| Robustness of supply of test strips to the Irish Market | | |

| 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, Dublin 8. The MMP will issue confirmation of receipt within 72 hours. Please contact the MMP if you do not receive confirmation of receipt after this time.

Appendix D: Updated Cover page for submissions 2022

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 and section B 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.

Section A:

| Test strip name | PCRS 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. Version 4 March 2022. Available: https://www.hse.ie/eng/about/who/cpu/non-drug-reimbursement-applications/personal-diagnostic-monitoring-and-delivery-guidelines/revised-guidelines-personal-diagnostic-monitoring-and-delivey-services.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.

For first submissions by suppliers who have not engaged with this process previously, information in relation to all the criteria as set out in the Medicines Management Programme (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 should be outlined.

For subsequent submissions by suppliers (e.g. those who currently have a blood glucose test strip identified as one of the preferred products) if appropriate, a number of criteria can be confirmed in the table below. The remaining criteria as set out in the MMP roadmap should be outlined.

I confirm that the information previously submitted in relation to the following criteria, is applicable to the products being submitted as part of this updated evaluation:

| Criteria | Yes | No |
|---|-----|----|
| Availability of patient support services by the supplier | | |
| Availability of education resources to healthcare professionals by the supplier | | |
| Robustness of supply of test strips to the Irish Market | | |

| Managing Director Signature Managing Director Name: | e: |
|--|----|
| 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, Dublin 8. The MMP will issue confirmation of receipt within 72 hours. Please contact the MMP if you do not receive confirmation of receipt after this time.

Appendix E: Updated Cover page for submissions 2024

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 and section B 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.

Section A:

| Test strip name | PCRS 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 Reimbursement Service (PCRS) Diabetes Consumables Guidelines for Manufacturers/Distributors/Suppliers Version 5 November 2023.

Available: https://www.hse.ie/eng/about/who/cpu/non-drug-reimbursement-applications/personal-diagnostic-monitoring-and-delivery-guidelines/revised-guidelines-personal-diagnositic-monitoring-and-delivery-services.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.

Please choose the relevant option

- 1. For first submissions by suppliers who have not engaged with this process previously, information in relation to all the criteria as set out in the HSE-Medicines Management Programme (MMP) <u>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 should be outlined.</u>
- For subsequent submissions by suppliers (e.g. those who currently have a blood glucose test strip identified as one of the preferred products), if appropriate, a number of criteria can be confirmed in the table below. The remaining criteria as set out in the MMP roadmap should be outlined.

I confirm that the information previously submitted in relation to the following criteria, is applicable to the products being submitted as part of this updated evaluation:

| Criteria | | | No |
|---|---|-----------------------|---------------------------|
| Availability of patient support services by the supplier | | | |
| Availability of education resources to healthcare professionals by the | | | |
| Robustness of supply of test strips to the Irish Market | | | |
| Managing Director Signature: Managing Director Name: Company name: Date of submission: | Submissions of mmp@hse.ie. confirmation of Please contact receive confirmatime. | The MMP receipt withi | n 72 hours. you do not |