



# **Report on Self-Monitoring of Blood Glucose (SMBG) in Type 2 Diabetes Mellitus**

**Medicines Management Programme**  
[www.hse.ie/yourmedicines](http://www.hse.ie/yourmedicines)

**Preliminary report submitted: October 2014**

**Update for implementation: January 2016**

## Table of Contents

Introduction .....	1
Background to recommendations .....	1
Steps in the process .....	2
National data review.....	3
Review of clinical evidence .....	4
Review of international guidelines and recommendations.....	6
Recommendations regarding frequency of blood glucose testing.....	8
Recommendations for reimbursement on GMS, LTI and DPS schemes.....	10
Key messages .....	11
Tools for implementation .....	11
References .....	12
Appendix 1. Questions and answers for healthcare professionals.....	15
Appendix 2. Questions and answers for patients .....	18

## List of Tables

Table 1: Numbers of patients who received blood glucose test strips in 2013 according to treatment category (GMS, DPS and LTI schemes).....	3
Table 2: Review of clinical evidence .....	5
Table 3: Summary of international guidelines and recommendations .....	6
Table 4: Blood glucose testing recommendations .....	8
Table 5: Examples of non-insulin medication and risk of causing hypoglycaemia.....	9
Table 6: Recommendation for reimbursement of test strips for PCRS .....	10

## List of Abbreviations

BGTS	Blood Glucose Test Strips
CADTH	Canadian Agency for Drugs and Technologies in Health
CERC	COMPUS Expert Review Committee (Canada)
COMPUS	Canadian Optimal Medication Prescribing and Utilization Service
DM	Diabetes mellitus
DPP-4 Inhibitor	Dipeptidyl peptidase-4 inhibitor
DPS	Drug Payment Scheme
GLP-1 analogue	Glucagon-like peptide-1 analogue
GMS	General Medical Service
HbA1c	Glycated haemoglobin
HSE	Health Service Executive
LTI	Long Term Illness
MMP	Medicines Management Programme
NICE	National Institute for Health and Care Excellence (UK)
NCPE	National Centre for Pharmacoeconomics
NHMRC	National Health and Medical Research Council (Australia)
NMIC	National Medicines Information Centre
PCRS	Primary Care Reimbursement Service
SGLT2 inhibitors	Sodium/Glucose cotransporter 2 inhibitors
SIGN	Scottish Intercollegiate Guidelines Network (Scotland)
SMBG	Self-Monitoring of Blood Glucose

## Introduction

Diabetes mellitus (DM) is a chronic disease characterised by the body's inability to produce enough insulin or to use it properly. Over time this can lead to complications including cardiovascular disease, chronic renal failure, peripheral neuropathy, and retinopathy.<sup>1</sup>

Diabetes can be characterised as either type 1 or type 2. Type 1 DM occurs when the body produces no insulin and so these patients are dependent on insulin for treatment.<sup>1</sup> Type 2 DM occurs when not enough insulin is produced by the body for it to function properly, or when the body's cells do not react to insulin as they should. Therapies in type 2 DM can vary depending on the severity of the disease and individual patient requirements. Treatment generally involves a combination of drug therapy, lifestyle modifications and self-monitoring of blood glucose (SMBG). Some patients will not require drug therapy to manage their diabetes. Managing DM properly is essential to prevent future health complications which may arise from elevated blood glucose levels.

## Background to recommendations

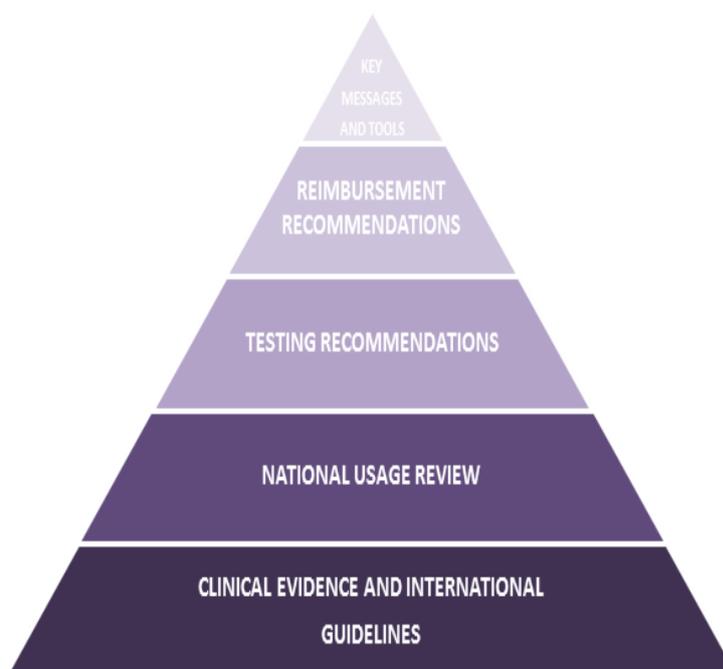
In 2013, the HSE's multi-disciplinary Medicines Management Programme (MMP) was established. The MMP provides sustained national leadership relating to issues such as the quality of the medicines management process, access to medicines and overall expenditure on medicines. As part of its role the MMP undertakes initiatives aimed at enhancing safe, evidence-based and cost-effective prescribing nationally. As total HSE-funded expenditure on blood glucose test strips (BGTS) was €46.6 million in 2013 (GMS: €26.3 million; LTI: €19.5million; DPS: €0.8m)<sup>2</sup> the MMP initiated a review of their use in type 2 diabetes. Total expenditure remained at this level for 2014 (total of €46.8 million with GMS: €20.1 million; LTI: €25.9 million; DPS: €0.8 million).

SMBG is accepted standard practice for people with type 1 diabetes and gestational diabetes mellitus. SMBG for people with type 2 diabetes can guide adjustment of insulin or other medication as part of a comprehensive package of diabetes care and education.<sup>3</sup>

Evidence to support the benefit of routine testing for type 2 DM patients not treated with insulin is lacking.<sup>4,5,6</sup> Some research has also shown that SMBG can have a negative impact

on quality of life and has been associated with negative psychological outcomes and anxiety.<sup>7,8,9</sup> Recommendations were made for use of SMBG in type 2 diabetes based on clinical evidence and international guideline review. In November 2015 the National Clinical Programme for Diabetes (NCPD) launched recommendations for blood glucose testing in type 2 DM.

## Steps in the process



- 1) Review clinical evidence and international guidelines
- 2) Carry out analysis of national usage of blood glucose test strips (BGTS) for 2013, focusing for this review on patients with type 2 DM who were not on insulin
- 3) Compile appropriate SMBG testing recommendations based on evidence
- 4) Compile recommendations for reimbursement for patients with type 2 DM who are not using insulin.
- 5) Produce key messages for prescribers and patients and provide tools to assist in dissemination of the message regarding SMBG in type 2 diabetes

## National Data Review

In 2014 the MMP reviewed national pharmacy claims data from the HSE Primary Care Reimbursement Service (PCRS) database for all months in 2013. The total HSE-funded expenditure on blood glucose test strips (BGTS) was found to be €46.6million in 2013. This figure comprises 26 BGTS products reimbursed by the PCRS as of December 2013 and equates to expenditure of approximately €3.9million per month.

Pharmacy claims for all patients who received at least one box of BGTS were reviewed and five mutually exclusive patient categories were identified (Table 1).

**Table 1: Numbers of patients who received blood glucose test strips in 2013 according to treatment category (GMS, DPS and LTI schemes)**

Patient group	Patient numbers	Description
1 – Received insulin	37,796	Patients who received insulin at any point in 2013, with or without other blood glucose lowering drugs.
2 – Received sulphonylurea	31,868	Patients who received a sulphonylurea drug, with or without other blood glucose lowering drugs, but who did not receive insulin.
3 – Metformin, no sulphonylurea or insulin	37,599	Patients who received metformin but did not at any point in 2013 receive sulphonylureas or insulin.
4 – Other (e.g. meglitinides, thiazolidinedione, DPP-4 inhibitor or GLP-1 analogue (no metformin, no sulphonylurea, no insulin)	881	Patients who did not receive insulin, sulphonylureas or metformin in 2013, but did receive other blood glucose lowering drugs.
5 – Test strips only	14,017	Patients who received blood glucose test strips but did not receive insulin or other blood glucose lowering drugs.

This review was focused on examining test strip utilisation among patients with non-insulin dependent diabetes. As such, only data for patients who did not receive insulin in 2013 was considered further.

Following calculation of existing BGTS usage and expenditure in patient groups 2-5 (Table 1), it was possible to conduct scenario analyses under varying conditions of BGTS allowances for these patient groups. Potential scenarios of BGTS allowances were based on recommendations from various jurisdictions regarding appropriate SMBG in patients with type 2 diabetes (see sections 4 and 5 below).<sup>10, 11</sup>

A previous Irish study (Usher *et al*, 2012) also estimated potential cost savings with rationalisation of test strip usage in different patient cohorts.<sup>12</sup> Based on this review it was estimated that significant cost savings could be achieved if reimbursement recommendations from other jurisdictions were adopted.

## Review of Clinical Evidence

A number of international reviews of evidence have been carried out in recent years resulting in recommendations regarding SMBG in type 2 diabetes. The Canadian Agency for Drugs and Technologies in Health (CADTH) conducted a systematic review, meta-analysis, and cost-effectiveness evaluation on the use of BGTS in 2009.<sup>13</sup> As part of this study the researchers from the COMPUS Expert Review Committee (CERC) reviewed results from seven randomised controlled trials comparing SMBG non-use and use in non-insulin treated patients. Published results showed that the improvement in HbA1c following SMBG was statistically significant but not clinically significant.<sup>6</sup> A systematic review by Malanda *et al*. for the Cochrane collaboration in 2012 found a minimal effect of SMBG on glycaemic control for up to six months after initiation with the effect subsiding after 12 months.<sup>4</sup> Another meta-analysis by Farmer *et al*. in 2012 found similar results.<sup>5</sup> Two studies carried out in 2007 and 2008, both lasting one year, showed no significant benefit of SMBG in glycaemic control

and suggested a lower quality of life associated with testing.<sup>7,8</sup> Another study which was carried out over 6 months showed a small benefit but was deemed of limited clinical relevance.<sup>17</sup> Relevant reviews and studies are summarised in Table 2.

**Table 2: Review of Clinical Evidence**

Publication	Date	Main findings	
<b>Systematic review / meta-analysis</b>			
Malanda et al. (Cochrane systematic review) <sup>4</sup>	2012	Minimal effect of SMBG on glycaemic control for 6 months after initiation. Effect subsides after 12 months and clinical benefit is limited.	
Farmer et al. (Meta-analysis of individual patient data) <sup>5</sup>	2012	Statistically significant reduction in HbA1c observed. Clinically meaningful effect unlikely.	
COMPUS <sup>13</sup>	2009	Statistically but not clinically significant decrease in HbA1c	
<b>Clinical trials</b>			<b>Country</b>
STeP <sup>14</sup>	2011	No deterioration in attitudes to condition or its management with SMBG 0.9% reduction in HbA1c at 12 months	USA
ROSES <sup>15</sup>	2011	SMBG beneficial and HbA1c reduced if combined with intensive education	UK
ZODIAC-17 <sup>16</sup>	2010	SMBG in the absence of education not beneficial	Netherlands
DINAMIC-1 <sup>17</sup>	2008	Decrease in HbA1C levels of 0.25% at 6 months	USA
ESMON <sup>7</sup>	2008	No reduction in HbA1c or change in health outcomes SMBG group had higher scores on a depression subscale	Northern Ireland
DiGEM <sup>8</sup>	2007	No significant benefit from SMBG SMBG associated with a reduced quality of life Lack of cost-effectiveness	UK

A number of international cost-effectiveness reviews did not confirm an advantage in more intensive blood glucose testing in type 2 diabetes.<sup>6, 8, 18, 19</sup>

In June 2014, a report was published by the UBC Centre for Health Services and Policy Research in British Columbia. This report synthesised much of the previous analyses and also looked at utilization patterns and reimbursement options for test strips in the Canadian healthcare setting.<sup>20</sup> It also highlighted a 2012 post-market review by the Australian Department of Health and Ageing and the University of South Australia. This review found that most international guidelines by professional organisations and health technology assessment agencies acknowledged the lack of evidence in support of routine SMBG in non-insulin treated patients with diabetes.<sup>21</sup>

## Review of international guidelines and recommendations

As part of this report recommendations from the United Kingdom (England and Scotland), Canada, New Zealand, Australia and Ireland were reviewed including guidelines from the International Diabetes Federation.

**Table 3: Summary of International Guidelines and Recommendations**

Agency and Country	Guideline	Recommendation
NICE, UK	Clinical Guideline 66 (partial update 87), 2008 (2009) <sup>22</sup>	Offer SMBG to a person newly diagnosed with type 2 DM only as an integral part of his/her self-education. The purpose and interpretation of SMBG should be agreed and acted upon.
SIGN, Scotland	National Clinical Guideline 116, 2010 <sup>3</sup>	Does not recommend routine use in non-insulin treated patients with type 2 DM (with the exception of sulphonylureas) but states that testing may be considered during conditions of: acute illness, increased risk of hypoglycaemia, significant change in drug therapy, fasting (e.g. during Ramadan), or if pregnant or planning pregnancy Motivated patients who are using sulphonylureas may benefit from SMBG to reduce risk of hypoglycaemia.

CERC, Canada	COMPUS Expert Review Committee * recommendation, 2010 <sup>10</sup>	<p><b><u>Adult patients with type 2 diabetes - who use insulin</u></b>  Recommends that the optimal daily frequency of SMBG be individualized. Suggests that the maximum weekly frequency of SMBG is 14 tests per week for most of these patients.</p> <p><b><u>Most adult patients with type 2 diabetes on oral anti-diabetic drugs (without insulin) or no drug therapy</u></b>  The routine use of blood glucose test strips for SMBG is not recommended. **</p>
NHMRC, Australia	NHMRC Diabetes guideline 2009 <sup>23</sup>	Glycated haemoglobin (HbA1c) measurement should be used to assess long term blood glucose control. They also recommend that SMBG should be considered in all people with type 2 diabetes but the decision to perform SMBG, and the frequency and timing of testing, should be individualised.
Bpac <sup>NZ</sup> , New Zealand	Self-monitoring of blood glucose: an update, 2008 <sup>11</sup>	<p>For people with non-insulin treated type 2 diabetes, SMBG appears to have little or no effect on glycaemic control.</p> <p>SMBG is associated with higher costs and lower quality of life.</p> <p>HbA1c remains the most useful tool for assessing glycaemic control in people with non-insulin treated type 2 diabetes.</p>
ICGP Quality in Practice Committee, Ireland	A practical guide to integrated type 2 diabetes care, 2008 <sup>24</sup>	Highlight the NICE recommendations that self-monitoring should not be considered as a stand-alone intervention but used in conjunction with appropriate therapy as part of integrated self-care.
International Diabetes Federation	Guideline on self-monitoring of blood glucose in non-insulin treated type 2 diabetes, 2009 <sup>25</sup>	<p>SMBG should only be used when individuals have the knowledge, skills and willingness to incorporate monitoring and therapy adjustment into their diabetes care plan.</p> <p>SMBG protocols should be individualized for individual patients and should be discouraged when it is not linked to diabetes self-management education and training.</p>

\* The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) was set up to optimise drug-related health outcomes and cost-effective use of drugs in Canada.

\*\* In addition to these recommendations, CERC specified that SMBG should not be applied in isolation; rather, it should be a component of a broader diabetes self-management strategy. Patients for whom SMBG is recommended require education and regular feedback so that blood glucose results are interpreted and applied appropriately.

## Recommendations regarding frequency of blood glucose testing in type 2 diabetes

Based on the review of international evidence, guidelines and clinical trial results, the new recommendations (Table 4) allow for a sufficient level of blood glucose testing in all patients while also reducing waste and inappropriate testing. Patients should understand why they are testing their blood glucose and know what to do with the results. Patients should also be urged to record their results for consultation with their healthcare professional as part of their management. Regular HbA1c should also be carried out at least every 6 months and every three months in patients whose therapy has changed or who are not meeting glycaemic targets. This is recommended in current Irish guidance.<sup>24</sup> In November 2015 the National Clinical Programme for Diabetes launched their recommendations on Blood Glucose testing in Type 2 diabetes which are in line with the MMP recommendations.<sup>26</sup>

**Table 4: Blood glucose testing recommendations for type 2 diabetes**

<i>Patients with type 2 diabetes</i>	<i>Testing requirements</i>
Patients on <b>insulin therapy</b> (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)
Patients on a <b>sulphonylurea or meglitinide</b> alone or in combination with metformin, thiazolidinedione, DPP-4 inhibitor, GLP-1 analogue, SGLT2 inhibitor	Patients may test one or two times a day, before food or if they feel hypoglycaemic.*
Patients on oral drugs other than sulphonylurea or meglitinides ( <b>i.e. metformin and/or a thiazolidinedione, DPP-4 inhibitor, GLP-1 analogue, SGLT2 inhibitor</b> )	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.

\* Additional testing may be warranted in patients on a sulphonylurea or meglitinide as recommended in the 2014 Medical Fitness to Drive Guidelines (Group 1 and 2 Drivers).<sup>27</sup> These patients must be under regular medical review (available on [www.rsa.ie](http://www.rsa.ie)).

It is also acknowledged that SMBG may be required in some situations such as:

- 1) acute illness
- 2) therapy changes
- 3) lifestyle changes
- 4) pregnant or trying to become pregnant
- 5) occupational safety requirement

Recommendations on SMBG with non-insulin therapies may take into consideration the degree of risk of hypoglycaemia associated with different treatment choices<sup>28</sup> (Table 5).

**Table 5: Examples of non-insulin medication and risk of causing hypoglycaemia**

Medication with <b>HIGHER</b> risk of causing hypoglycemia	Medication with <b>LOW</b> risk of causing hypoglycemia
<ul style="list-style-type: none"> <li>➤ Sulphonylureas (e.g.gliclazide)</li> <li>➤ Meglitinides (e.g.repaglinide)</li> </ul>	<ul style="list-style-type: none"> <li>➤ Metformin</li> <li>➤ Acarbose</li> <li>➤ Thiazolidinediones (e.g. pioglitazone)</li> <li>➤ DPP-4 inhibitors (e.g.sitagliptin, saxagliptin)</li> <li>➤ GLP-1 analogues (e.g.liraglutide, exenatide)</li> <li>➤ SGLT2 inhibitors (e.g. canagliflozin, dapagliflozin)</li> </ul>

For patients with non-insulin type 2 diabetes who are treated with sulphonylureas or meglitinides the Road Safety Authority has produced recommendations based on Group 1 (i.e. car, motorcycle, tractor) or Group 2 (i.e. truck and bus with or without trailer) categories. Vehicles in Group 2 are regarded as higher-risk vehicles which require a higher standard of physical and mental fitness on the part of the driver ([www.rsa.ie](http://www.rsa.ie)). Additional testing may be warranted and these patients must be under regular medical review.<sup>27</sup>

## Recommendations for reimbursement of BGTS for type 2 diabetes on GMS, LTI and DPS schemes

**Table 6: Recommendation for reimbursement of test strips for type 2 diabetes**

<i><b>Patient group</b></i>	<i><b>Testing recommendation</b></i>	<i><b>Limit on yearly dispensing</b></i>
Patients receiving insulin	<b>4 times daily</b> and when required	<b>No limit recommended</b>  Test according to specialist recommendations
Patients receiving non-insulin anti-diabetic drugs	Patients receiving sulphonylurea or meglitinide drugs: May test <b>1-2 times daily</b> or if feeling hypoglycaemic.	<b>1200 test strips per year</b> Two boxes (100 test strips) per month will be reimbursed
	Patients on oral drugs other than sulphonylurea or meglitinides ( <b>i.e. metformin and/or a thiazolidinedione, DPP-4 inhibitor, GLP-1 analogue, SGLT2 inhibitor</b> ): May test <b>3 times per week</b> if needed	<b>600 test strips per year</b> One box (50 test strips) per month will be reimbursed
Diet alone	<b>Not required</b>	<b>100 test strips per year</b> One pack per 6 months to allow for periodic testing where recommended

## Key Messages

- There is limited evidence of the benefit of SMBG in non-insulin dependent type 2 diabetes and evidence has shown reduced quality of life in such patients who test regularly.
- Patients should be advised to only test their blood glucose as part of an integrated programme where results guide future management.
- HbA1c is a recommended measure of glycaemic control in patients with diabetes on non-insulin treatments or managing their condition through diet and lifestyle interventions only.
- Patients should be encouraged to know their level and know their target for HbA1c results
- Some oral agents which may increase the risk of hypoglycaemia (e.g. sulphonylureas and meglitinides) may require more SMBG than other treatments.
- Patients should be encouraged to understand the reason for blood glucose testing and should know what to do with results.
- If patients require a higher volume of test strips for a particular reason and time period (e.g. if pregnant) the additional allocation can be applied for on-line to the PCRS by the prescriber (available on [www.pcrs.ie](http://www.pcrs.ie) at online services).

## Tools for implementation

- ✓ Question & Answer sheets have been prepared for both healthcare professionals and patients outlining the basis for the new recommendations and are available in appendices 1 and 2 of this document.
- ✓ The National Clinical Programme for Diabetes recommendations on Blood Glucose testing in Type 2 diabetes available on:  
<http://www.hse.ie/eng/about/Who/clinical/natclinprog/diabetesprogramme/glucosetesting.pdf>.

## References

1. www.HSE.ie (<http://www.hse.ie/portal/eng/health/az/D/Diabetes/>).
2. Medicines Management Programme (MMP) internal communication, July 2014
3. SIGN. Management of diabetes. A national clinical guideline, 116. Scottish Intercollegiate Guidelines Network; 2010.
4. Malanda UL, Welschen LMC, Riphagen II, Dekker JM, Nijpels G, Bot SDM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. Cochrane Database Syst Rev. 2012;1:CD005060.
5. Farmer AJ, Perera R, Ward A, Heneghan C, Oke J, Barnett AH, et al. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. BMJ. 2012;344:e486.
6. Cameron C, Coyle D, Ur E, Klarenbach S. Cost-effectiveness of self-monitoring of blood glucose in patients with type 2 diabetes mellitus managed without insulin. CMAJ Can Med Assoc J J Assoc Medicale Can. 2010;182(1):28–34.
7. O’Kane MJ, Bunting B, Copeland M, Coates VE, ESMON study group. Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial. BMJ. 2008;336(7654):1174–1177.
8. Farmer AJ, Wade AN, French DP, Simon J, Yudkin P, Gray A, et al. Blood glucose self-monitoring in type 2 diabetes: a randomised controlled trial. Health Technol Assess Winch Engl. 2009;(15):iii–iv, ix–xi, 1–50.
9. Peel E, Douglas M, Lawton J. Self Monitoring of Blood Glucose in Type 2 Diabetes: Longitudinal Qualitative Study of Patients’ Perspectives. BMJ. 2007;335(7618):493-496
10. Canadian Agency for Drugs and Technologies in Health (CADTH). Optimal therapy recommendations for the prescribing and use of blood glucose test strips. CADTH Technol Overv. 2010;1(2):e0109.
11. Self monitoring of blood glucose for people with non-insulin treated type 2 diabetes: An update, 2008 BPJ Issue 14 bpacnz available on: <http://www.bpac.org.nz/>

12. Usher C, O'Leary A, Mulhall C, Barry M. The cost impact of modifying patterns of self-monitoring of blood glucose in an Irish type 2 diabetes cohort. *Value in Health* 2012;15(7):A360
13. COMPUS. Systematic Review of use of Blood Glucose Test Strips for the Management of Diabetes Mellitus. 2009 Volume 3, Issue 2. Available on:  
[http://www.cadth.ca/media/pdf/BGTS\\_SR\\_Report\\_of\\_Clinical\\_Outcomes.pdf](http://www.cadth.ca/media/pdf/BGTS_SR_Report_of_Clinical_Outcomes.pdf)
14. Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, et al. A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the STeP study. *Diabetes Technol Ther.* 2011 (8):797–802.
15. Franciosi M, Lucisano G, Pellegrini F, Cantarello A, Consoli A, Cucco L, et al. ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial. *Diabet Med J* 2011;28(7):789–796.
16. Kleefstra N, Hortensius J, Logtenberg SJJ, Slingerland RJ, Groenier KH, Houweling ST, et al. Self-monitoring of blood glucose in tablet-treated type 2 diabetic patients (ZODIAC). *Neth J Med.* 2010;68(1):311–316.
17. Barnett AH, Krentz AJ, Strojek K, Sieradzki J, Azizi F, Embong M, et al. The efficacy of self-monitoring of blood glucose in the management of patients with type 2 diabetes treated with a gliclazide modified release-based regimen. A multicentre, randomized, parallel-group, 6-month evaluation (DINAMIC 1 study). *Diabetes Obes Metab.* 2008;10(12):1239–1247.
18. Simon J, Gray A, Clarke , Wade A, Neil A, Farmer A (2008) Cost effectiveness of self monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial. *BMJ*, 336(7654):1177-1180.
19. Clar C, Barnard K, Cummins E, Royle P, Waugh N. Self-monitoring of blood glucose in type 2 diabetes: systematic review. *Health Technol Assess.* 2010;14:1-140
20. UBC Centre for Health Services and Policy Research, Utilisation Patterns and Reimbursement Options for Diabetes Test Strips in British Columbia, June 2014 available on:

[http://www.chspr.ubc.ca/sites/default/files/publication\\_files/Test%20Strips%20in%20BC%202014\\_0.pdf](http://www.chspr.ubc.ca/sites/default/files/publication_files/Test%20Strips%20in%20BC%202014_0.pdf) (accessed on 22/07/14)

21. Post market review: Pharmaceutical Benefits Scheme Products Used in the Treatment of Diabetes. Department of Health and Ageing; University of South Australia; Dec 2012. Available on: <http://www.pbs.gov.au/reviews/diabetes-files/blood-glucose-test-strips-draft-report.pdf> (accessed 28/07/14)
22. National Collaborating Centre for Chronic Conditions (UK). Type 2 Diabetes: National Clinical Guideline for Management in Primary and Secondary Care (Update) [Internet]. London: Royal College of Physicians (UK); 2008 [cited 2014 May 26]. Available on: <http://www.ncbi.nlm.nih.gov/books/NBK53885/>
23. National Evidence Based Guideline for Blood Glucose Control in type 2 diabetes. NHMRC Diabetes guideline 2009 available on: <http://www.australiandiabetescouncil.com/resources/nhmrc-diabetes-guidelines>
24. Harkins, V, ICGP Quality in Practice Committee. A practical guide to integrated type 2 diabetes care. Available at [http://www.hse.ie/eng/services/Publications/topics/Diabetes/A\\_Practical\\_Guide\\_to\\_Integrated\\_Type\\_II\\_Diabetes\\_Care.pdf](http://www.hse.ie/eng/services/Publications/topics/Diabetes/A_Practical_Guide_to_Integrated_Type_II_Diabetes_Care.pdf). 2008.
25. International Diabetes Federation: Guideline on self-monitoring of blood glucose in non-insulin treated type 2 diabetes (2009) available on: [http://www.idf.org/webdata/docs/SMBG\\_EN2.pdf](http://www.idf.org/webdata/docs/SMBG_EN2.pdf) (accessed on 19/05/14)
26. National Clinical Programme for Diabetes. Guide to Blood Glucose Testing in Type 2 Diabetes 2015 available on: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/diabetesprogramme/glucosetesting.pdf>
27. Sláinte agus Tiomáint. Medical Fitness to Drive Guidelines (Group 1 and 2 Drivers) April 2014, Road Safety Authority available on [www.rsa.ie](http://www.rsa.ie)
28. Miller D, Berard L, Cheng A et al. Self-Monitoring of Blood Glucose in People with Type 2 Diabetes: Canadian Diabetes Association Briefing Document for Healthcare Providers, Commentary, available on: <http://www.diabetes.ca/getmedia/ab93def3-6da4-4b1e-92af-8e026635de11/self-monitoring-of-blood-glucose-briefing-english.pdf.aspx>

## Appendix 1

# Type 2 Diabetes Test Strips Reimbursement: Questions and Answers for Healthcare Professionals

**Note: This restriction does not apply to type 1 diabetes or type 2 diabetes on insulin**

## 1. Why is the HSE introducing changes to the reimbursement of Blood Glucose Test Strips?

The National Clinical Programme for Diabetes has developed guidance on blood glucose testing for people with type 2 diabetes. Research has indicated that blood glucose test strips (BGTS) have a limited benefit for many patients who **do not** take insulin to manage their diabetes. In line with this, the HSE Medicines Management Programme (MMP) has recommended changes to the number of BGTS provided for people with type 2 diabetes while ensuring those who need test strips to help manage their diabetes will continue to have access to them. These are aligned with international best practice recommendations on appropriate blood glucose testing practices required for optimal patient outcomes.

## 2. When will changes in reimbursement of BGTS be in effect?

The changes for BGTS reimbursement are effective on or after the 1<sup>st</sup> April 2016.

## 3. How many diabetes test strips are recipients eligible to receive under this initiative?

Following the review by the MMP into international recommendations and guidelines on appropriate blood glucose testing frequencies it is recommended that reimbursement of Blood Glucose Test Strips for patients with Type 2 Diabetes Mellitus be revised as follows:

- Patients on insulin have no restriction.
- Patients managed on sulphonylurea or meglitinide drugs will be reimbursed for 2 boxes of test strips per month i.e. 1,200 test strips/annum.
- Patients managed on oral hypoglycaemic drugs other than sulphonylurea or meglitinide drugs will be reimbursed for 1 box of test strips per month i.e. 600 test strips/annum.
- Patients managed through diet alone will be reimbursed for 2 boxes of test strips per annum i.e. 100 test strips/annum.

<b>Patient group</b>	<b>Testing recommendation</b>	<b>Limit on yearly dispensing</b>
Patients receiving insulin	<b>4 times daily</b> and when required	<b>No limit recommended</b> Test according to specialist recommendations
Patients receiving non-insulin anti-diabetic drugs	Patients receiving sulphonylurea (e.g. gliclazide) or meglitinide (e.g. repaglinide) drugs: May test <b>1-2 times daily</b> or if feeling hypoglycaemic.	<b>1200 test strips per year</b> Two boxes (100 test strips) per month will be reimbursed
	Patients on anti-diabetic drugs other than sulphonylurea or meglitinides ( <b>i.e. metformin and/or a thiazolidinedione, DPP-4 inhibitor, GLP-1 analogue, SGLT2 inhibitor</b> )*: May test <b>3 times per week</b> if needed	<b>600 test strips per year</b> One box (50 test strips) per month will be reimbursed
Diet alone	<b>Not required</b>	<b>100 test strips per year</b> One pack per 6 months to allow for periodic testing where recommended

- \* **Thiazolidinedione (e.g. pioglitazone)**
- DPP-4 inhibitor (e.g. sitagliptin, saxagliptin)**
- GLP-1 analogue (e.g. liraglutide, exenatide)**
- SGLT2 inhibitor (e.g. canagliflozin, dapagliflozin)**

#### **4. How should simultaneous claims for test strips and insulin/anti-diabetic medication be processed?**

It is important that insulin and anti-diabetic medication are claimed in the same month as blood glucose test strips to ensure the correct allocation is reimbursed. This ensures that the most current drug profile is included in the historical treatment review and patients are allocated the proper number of test strips.

## 5. What insulin or anti-diabetic medications will the PCRS use to determine treatment categories for recipients?

A distinction has been made between anti-diabetic medication which may or may not have an increased risk of causing hypoglycaemia. Extra supply is allocated for patients on sulphonylureas or meglitinides as more frequent testing may be required.

Patients managing diabetes with anti-diabetic medication with <b>HIGHER</b> risk of causing hypoglycaemia	Patients managing diabetes using anti-diabetic medication with <b>LOW</b> risk of causing hypoglycaemia
<ul style="list-style-type: none"> <li>➤ Sulphonylureas (e.g. gliclazide)</li> <li>➤ Meglitinides (e.g. repaglinide)</li> </ul>	<ul style="list-style-type: none"> <li>➤ Metformin</li> <li>➤ Acarbose</li> <li>➤ Thiazolidinediones (e.g. pioglitazone)</li> <li>➤ DPP-4 inhibitors (e.g. saxagliptin)</li> <li>➤ GLP-1 agonists (e.g. liraglutide, exenatide)</li> <li>➤ SGLT2 inhibitors (e.g. canagliflozin, dapagliflozin)</li> </ul>

## 6. What should I do if a recipient requires more test strips than the revised reimbursement limits?

If patients have a requirement for more test strips due to a particular medical condition or circumstance (exceptional arrangements) the prescriber may apply online to the PCRS stating the reasons for the extra allowance request. The online application may be accessed via [www.pcrs.ie](http://www.pcrs.ie) (online services). Where such a request is received it will be approved. To register specific patients for exceptional arrangements, please provide the following details online:

1. GMS number, LTI number or Drugs Payment Scheme Number (where a patient is recently diagnosed or does not qualify for an LTI Book)
2. The category of diabetes treatment currently prescribed for the patient which will automatically populate the recommended quantity of test strips for that category
3. The reason for additional quantities (pregnancy, job safety etc)
4. The number of test strips you wish the patient to access on a monthly basis.

## 7. How will a pharmacist know if a patient is registered for exceptional arrangements?

The pharmacist can check that a patient has been registered by accessing the secure portal on the Systems Checker where the patients' approval status will be provided.

## **8. How much is currently spent on blood glucose test strips through the LTI, DPS and GMS?**

In 2014, the total HSE expenditure (ingredient cost plus fees) on blood glucose test strips was €46.8 million. This initiative hopes to reduce over-use of test strips by funding their supply based on best practice guidelines while ensuring that those who need test strips to help manage their diabetes will continue to have access to them.

## **9. Pregnancy**

If insulin is not prescribed in a pregnant woman with type 2 diabetes, but blood glucose testing is indicated, it is important that the prescriber registers their patient through the online system for a blood glucose test strip allowance.

## **10. Where can I get information for my patients in relation to best practice for self-monitoring of blood glucose?**

You can order the Diabetes Programme patient information leaflets on [www.healthpromotion.ie](http://www.healthpromotion.ie). For further information and for frequently asked questions (FAQs) for patients and the full evaluation report you can visit [www.hse.ie/yourmedicines](http://www.hse.ie/yourmedicines).

## Type 2 Diabetes Test Strips: Questions and Answers for Patients

**Note: This does not apply to people with type 1 diabetes or type 2 diabetes on insulin**

### 1. Why are changes being introduced to blood glucose test strips for Type 2 diabetes?

The National Clinical Programme for Diabetes has provided updated guidance on self testing for people with type 2 diabetes. Research has indicated that blood glucose testing has a limited benefit for many patients who **do not** take insulin to manage their diabetes. Based on best evidence, the HSE is introducing changes to the number of blood glucose test strips it will provide for people with type 2 diabetes while ensuring those who need test strips to help manage their diabetes will continue to have access to them. The new changes are based on recommendations from a review by the Medicines Management Programme (MMP). This review looked at international evidence and best practice guidelines along with national usage (available on [www.HSE.ie/yourmedicines](http://www.HSE.ie/yourmedicines)).

This initiative will reduce wastage of test strips by providing them based on best practice guidelines while ensuring that those who need test strips to help manage their diabetes will continue to have access to them.

### 2. When will the changes come into effect?

These changes will be effective from 1<sup>st</sup> April 2016.

### 3. What are the new allowances for test strips in type 2 diabetes?

<i>Patient group</i>	<i>Testing recommendation</i>	<i>yearly dispensing amounts</i>
Patients receiving insulin	<b>4 times daily</b> and when required	<b>No limit recommended</b> Test according to specialist recommendations
Patients receiving non-insulin anti-diabetic drugs	Patients receiving sulphonylurea (e.g. gliclazide) or meglitinide (e.g. repaglinide) drugs : May test <b>1-2 times daily</b> or if feeling hypoglycaemic.	<b>1200 test strips per year</b> Two boxes (100 test strips) per month will be reimbursed
	Patients on anti-diabetic drugs other than sulphonylurea or meglitinides ( <b>i.e. metformin and/or a thiazolidinedione, DPP-4 inhibitor , GLP-1 analogue, SGLT2 inhibitor</b> )*: May test <b>3 times per week</b> if needed	<b>600 test strips per year</b> One box (50 test strips) per month will be reimbursed
Diet alone	<b>Not required</b>	<b>100 test strips per year</b> One pack per 6 months to allow for periodic testing where recommended

\* Thiazolidinedione (e.g. pioglitazone), DPP-4 inhibitor (e.g. sitagliptin, saxagliptin), GLP-1 analogue (e.g. liraglutide, exenatide), SGLT2 inhibitor (e.g. canagliflozin, dapagliflozin)

### 4. How do I know how many test strips I qualify for?

The test strip allowance is based on the medicines that you are taking (see question 3). Through your pharmacy, the Primary Care Reimbursement Service (PCRS) will track the number of blood glucose test strips that you are eligible to receive in a 365-day period based on your diabetes treatments.

If you use more test strips than the expected amount in one year, it is suggested that you speak to your doctor to ensure you are testing properly.

### 5. What will I do if I need more test strips?

While the new amounts allow for more regular testing than is generally recommended, it is understood that there still may be *exceptional clinical circumstances* where you may require even more frequent testing.

If it is determined that you need more test strips, your doctor (GP or in your diabetes clinic) can apply on-line for an exemption on your behalf to the PCRS. He/she must indicate the reason(s) for the additional monitoring along with the additional test strip requirement. Where such a request is received it will be approved.

## 6. I have type 2 diabetes controlled by diet and lifestyle changes and I don't currently test my blood glucose levels. Should I start now?

No, not every patient with type 2 diabetes is required to test their blood glucose levels and many patients won't benefit from it. Healthy eating and modifying your lifestyle is a very useful way to control your blood sugars and diabetes. If you would like to track your blood glucose levels going forward schedule regular HbA1c tests with your doctor (every 4 to 6 months). This can help in the management of your diabetes.

Also, you may find that you don't need your full allowance of test strips. We ask that you only fill a prescription for test strips as you need them as this will reduce waste and unnecessary supply.

## 7. What other steps should I be taking to manage my diabetes?

Many people think that self-testing their blood sugar is the main way to manage their diabetes, but there is much more to managing diabetes. Healthcare providers use a lab test called an HbA1C test to keep track of your blood sugar. The HbA1C test is a blood test that is done up to four times per year. The results of this test give your doctor an overall picture of how well controlled your blood sugar is. Keeping track of your HbA1C results is a very useful tool you can use to manage your diabetes.

There is also a lot that you can do to stay healthy and prevent complications:

- ✓ Eat healthy meals and avoid junk food.
- ✓ Be active: Walking regularly is a good start.
- ✓ Take all your medications according to your doctor and pharmacists instructions.
- ✓ Make sure your blood pressure and cholesterol levels are in a healthy range.
- ✓ Go for regular eye check-ups.
- ✓ Regularly check your feet for any sores.
- ✓ Manage your stress well.
- ✓ See your health care providers regularly and talk about your HbA1C results.

Please remember that these amounts **DO NOT APPLY** to patients with **type 1 diabetes** or to **type 2 diabetes who are treated with insulin**.

## 8. Where can I get information in relation to best practice for self-monitoring of blood glucose?

The National Clinical Programme for Diabetes has produced an information booklet on appropriate testing with type 2 diabetes. This can be found on [www.hse.ie/diabetes](http://www.hse.ie/diabetes) and is available to order by your doctor or yourself on [www.healthpromotion.ie](http://www.healthpromotion.ie). Further information can be found on [www.hse.ie/yourmedicines](http://www.hse.ie/yourmedicines).