INESSS
LE SAVOIR PREND FORME

Evidence brief on the measures related to the reimbursement of blood glucose test strips

English summary

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This is the English summary of the guidance entitled Avis sur les mesures relatives au remboursement des bandelettes published in July 2016.

The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

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SUMMARY

Introduction

Diabetes mellitus is a chronic disease characterized by hyperglycemia, which occurs when the body is unable to produce sufficient insulin, whether or not in the presence of insulin resistance. According to the estimates published by the Canadian Diabetes Association (CDA), around 3.4 million Canadians lived with diabetes in 2015. Of the different existing forms, type 2 diabetes is by far the most widespread. Self-monitoring of blood glucose (SMBG) is one of the approaches offered to help people with diabetes control their blood glucose (BG) levels. The use of BG test strips and a meter helps to measure capillary glycemia and to make any necessary lifestyle or medication adjustments. In 2015, expenditures tied to the class of BG test strips totalled nearly $104 million and concerned around 285,000 people covered by Québec's public prescription drug insurance plan (PPDIP). Based on the measures introduced in the other Canadian provinces, about 30% of users covered by the PPDIP and not treated with insulin seem to make non-optimal use of them, which leads to costs for the health and social services system, without health benefits for users. The other Canadian provinces, except for Québec, have introduced measures governing the reimbursement of BG test strips to encourage their optimal use and to limit costs. For this reason, the Minister of Health and Social Services mandated INESSS to produce a brief, essential to making a decision about introducing measures for reimbursing BG test strips based on the best available evidence and knowledge.

Methods

To perform this mandate, INESSS compiled scientific, contextual and experiential data on the technological aspects, the clinical elements and the measures introduced elsewhere in Canada and in other countries, along with data on the use of BG test strips through various approaches. In short, concerning the technological aspects, the manufacturers of BG test strips covered by the PPDIP were invited to submit all relevant documents, especially those addressing technological features and technological innovations. INESSS used the Google search engine to locate the websites of the different manufacturers in order to complete any missing information, in addition to examining user manuals for BG meters and scientific articles on the new technologies. The briefs to the Minister drafted by INESSS during the process of developing recommendations on adding BG test strips to the List of Medications were also examined. One author researched and extracted the data. The authors also performed a targeted literature review on the clinical aspects, which included two sections: comparative effectiveness and recommended best practices on the frequency of SMBG. Regarding comparative effectiveness, the researchers updated a rapid response report published in 2013 by the Canadian Agency for Drugs and Technologies in Health (CADTH). For the second section dealing with recommendations on the frequency of SMBG among the different populations living with diabetes, the researchers examined the clinical practice guidelines selected following the systematic approach used in the work related to the optimal use guides on SMBG published by INESSS in 2013. Only documents from Canada (Canadian Diabetes Association [CDA], CADTH and INESSS), the Haute Autorité de Santé (HAS) in France, and the National Institute for Health and Care Excellence (NICE) in the United Kingdom, were selected. A search was then performed to identify all the updates to these documents published since 2013. INESSS also performed a supplementary search using the Google search engine to identify the standards, regulations and guidelines in the aviation and road transportation sectors. Two authors participated in the

document search and selection. Only one extracted the data, which were validated by the other. INESSS then performed a literature review concerning the experiences of other countries by using the Google search engine to identify all the reports, studies, and orders-in-council published in French or English since 2011 related to the reimbursement policies on BG test strips in Canada and in comparable countries, that is, Australia, France, New Zealand and the United Kingdom. This search also extended to the government websites of the health agencies and departments of the different Canadian provinces, the health technology assessment agencies of other countries and the websites of public health policy research centres. One author researched and extracted the data.

INESSS also conducted a cross-sectional study to document the use of BG test strips among the people covered by Québec's PPDIP in 2015. The extracted data helped identify the number of users, the number of test strips prescribed, the number of test strips billed, their cost, and the average number of test strips used per day, based on the categories of anti-diabetes treatments. Data on the quantities of the different test strips reimbursed by the PPDIP in 2015 were also compiled from the RAMQ's billing statistics.

This body of data made it possible to analyze the budget impact that would result from adopting the scenarios based on applying a maximum payable price (MPP), a maximum number of test strips reimbursed per year, or the combination of the two. Concerning the application of an MPP, the researchers analyzed scenarios with MPP levels ranging from $0.40 to $0.74 per test strip. They then assessed three scenarios for applying a maximum number of test strips reimbursed per year, based on the level of hypoglycemic risk associated with the anti-diabetes treatments in use. Users were categorized by the maximum number of test strips allowed per day, based on the limits in effect in Ontario and British Columbia. The first scenario was limited to maximum numbers per day, with no additions. For the second scenario, the researchers performed sensitivity analyses to assess the effect of using an exception code authorizing the use of 100 additional test strips per year for a specific clinical reason by all users, except those on insulin. In the third scenario, sensitivity analyses were also performed to assess the effect of this code based on the actual percentages of exceptions derived from British Columbia's experience in 2015. INESSS documented the number of users, prescribers and community pharmacies concerned and the budget impact of the different scenarios.

The researchers then put this body of data into the context of Québec's clinical practice by holding consultations with various stakeholders, including clinicians from different fields with expertise in diabetes, INESSS's Comité scientifique de l'évaluation aux fins d'inscription (CSEMI), the governance committee put in place by the MSSS's Direction des affaires pharmaceutiques et des médicaments (DAPM), and the RAMQ. These discussions contributed, in particular, to incorporating experiential knowledge and to raising several issues to be taken into account in developing recommendations and implementing reimbursement measures.

Results

Technological aspects

There are technological differences between the blood glucose meters available on the market in Québec. Certain features address the needs of people with diabetes who have specific clinical conditions that require, for example, a small amount of blood for the test and a device that is easy to use and to read. The expiry date of the test strips after opening the vial or cassette is another important feature to consider based on the recommended frequency of SMBG. Given the burden of diabetes, the features considered practical, according to the experts consulted, are (1) the possibility for a device to function with an insulin pump; and (2) the possibility of measuring ketones and glucose with the same device for patients with type 1 diabetes. Furthermore, the possibility for a device to transmit data directly to a computer may be a practical feature for the healthcare professionals who monitor people with diabetes, but this need did not meet with consensus in the expert group or in the discussions with other stakeholders, given the different models of healthcare organization.

Clinical aspects

Despite the differences in accuracy of the blood glucose meters available in Québec, these differences do not have any particular clinical incidence, according to the experts consulted. Compliance with ISO 15197 standards ensures that the meters are capable of detecting hypoglycemia. The recommendations on the frequency of SMBG put forth in all the documents reviewed, particularly those from the CDA, indicate that pregnant women with gestational diabetes, women with type 1 or type 2 diabetes planning a pregnancy, and people with diabetes treated with insulin are those most likely to use a large number of test strips. The same applies to people with diabetes employed in the aviation or road transportation sectors and whose hypoglycemic episodes could jeopardize their own safety, their colleagues' safety or public safety. People with type 2 diabetes who reach their glycemic targets or who receive treatment not associated with hypoglycemia should not monitor their blood glucose every day; whereas people taking a medication liable to induce hypoglycemic events should monitor their blood glucose based on their hypoglycemic symptoms. Moreover, according to the CDA, the latter category of people may need to perform additional blood glucose monitoring when driving a vehicle. According to the experience of the experts consulted, patients with diabetes tend to use more test strips than the quantity recommended in clinical practice guidelines. Much of this testing is therefore not essential and patients do many of these tests by force of habit, without their necessarily being clinically relevant. Data on the use of test strips for SMBG in 2015 point in the same direction.

Experience in the rest of Canada and in other comparable countries

As opposed to the other Canadian provinces, Québec is the only one not to have implemented measures governing the reimbursement of test strips to encourage their optimal use and to limit costs. However, only one province applies both a maximum payable price (MPP) and a maximum quota of test strips reimbursed per year (Ontario, with an MPP set at $0.729), most other provinces having opted only for the second scenario. In Ontario and British Columbia, the maximum number of test strips reimbursed per year is based on anti-diabetes treatments. For exceptional clinical circumstances, these two provinces allow users to exceed the authorized number of 100 additional test strips. In addition, British Columbia allows endocrinologists to submit a written request to PharmaCare for authorization on a case-by-case basis for the

reimbursement of 100 additional test strips in exceptional clinical circumstances where the annual quantity limit and the addition of 100 test strips per year do not meet the patient's needs. According to the stakeholders consulted, adjusting the number of test strips allowed per year based on the medication used is a good approach because it ties in with the clinical evidence on the frequency of SMBG.

Budget impacts

The cost savings generated from implementing the measure limiting the number of test strips reimbursed over a 365-day period range from $14.6 to $19.9 million, depending on the scenario; whereas the savings expected with the MPP measure total less than $2,000 for an MPP of $0.74 and extend beyond $28 million for an MPP of $0.40. With the combined application of an MPP and a maximum number of test strips reimbursed over a 365-day period, the government could reduce health expenditures from $14.6 to $39.9 million annually and recurrently, based on the level of MPP selected by the Minister of Health and Social Services, and could do so without hindering SMBG best practices. On the other hand, even though applying an MPP is a good approach to reducing costs, decision makers should take into account several issues related to the technological features of the different devices available, the organization of care and services in Québec, and manufacturers' ability to provide technology in order to prevent significant harms to the health of people with diabetes who use test strips, and also to limit the impacts on clinicians.

Conclusions

To ensure that the recommendations issued by INESSS are well received by the different stakeholders, communication and implementation initiatives should be undertaken, bearing in mind the different issues raised. Joint actions and collaboration among the different stakeholders will ensure that the recommendations for clinicians will be accepted and adopted.

With the combined application of an MPP and a maximum number of test strips reimbursed over a 365-day period, the government will save several millions of dollars that could be re-invested in part in all areas affected by the problem of diabetes, whether the organization of care and services, the reimbursement of anti-diabetes medications or technologies, or the funding of granting agencies that support research and development in this field.

Recommendations

Following this study, INESSS concludes that implementing measures governing the reimbursement of test strips is warranted both clinically and economically.

INESSS therefore recommends that the Minister of Health and Social Services should:

1. Favour a measure without a code by applying a maximum number of test strips reimbursed per 365-day period, adjusted to the risk of hypoglycemia (i.e., the anti-diabetes treatment in use).

2. Allow people with diabetes presenting with exceptional clinical circumstances or people with pancreatic disorders leading to an abnormal insulin production (e.g., insulinoma and nesidioblastosis) to have access to 100 additional test strips per period. This approach will require assigning a code that pharmacists must enter into their software before submitting a claim for payment via the interactive communication system for pharmacies (système de communication interactive en pharmacie - CIP). This code could be applied when clinical

circumstances permitting exceptions arise. This request would not be admissible for people allotted a maximum of 3000 test strips per year.

3. Allow pregnant women with diabetes whether or not treated with insulin to receive 3000 test strips per 365-day period. This approach would require assigning a code and would be managed by the pharmacy.

4. Allow the use of a code as a last resort entered by the pharmacist in response to a request supported by a healthcare professional monitoring the user in the exceptional cases where the addition of 100 test strips would not be sufficient to meet the needs of a person who has diabetes or a pancreatic disorder leading to abnormal insulin production (e.g., insulinoma or nesidioblastosis) for the 365-day period. Each claim entered with this code should allow a maximum of 100 additional test strips. The claims entered with this code of "last resort" should be made according to the user's exceptional needs. For this reason, there should be no limits to the number of claims per period. In addition, contrary to the code allowing access to 100 additional test strips per period among the seven special conditions (recommendation 2), a request for additional test strips would be admissible for people allotted a maximum of 3000 test strips per year.

5. Specify the MPP to be applied and ask manufacturers to lower their guaranteed selling price (GSP), while still offering free glucose meters.

6. Introduce an MPP whereby at least one model of test strip associated with a glucose meter has the technological features leading to clinical benefits for certain patients in the event that manufacturers do not lower their GSP.

Further, INESSS recommends that the Minister of Health and Social Services should:

7. Consider introducing the administrative measures in two stages if the discussions with the manufacturers extend over time, to avoid patients' unnecessarily changing their BG test strips and meters if the GSPs are reduced.

8. Allow patients to pay only the difference between the sales price and the MPP when they want to continue with their blood glucose meters using test strips that cost more than the MPP.

9. Delay for at least two months the application of a maximum number of test strips reimbursed after this measure is announced, while avoiding the summer period and the holiday season, in order to allow the RAMQ to develop the software, to implement a communication plan designed to reach the insurers and to support the pharmacists, physicians and other healthcare professionals affected by these changes; give the public and healthcare professionals the time to fully understand this new measure and to be able to discuss it together, if necessary; communicate with private insurers to inform them of the new measure in effect concerning test strips.

10. Announce the introduction of the application of an MPP, delaying its implementation for at least six months, while avoiding the summer period and the holiday season, in the event that manufacturers do not reduce their GSPs, in order to give the public and healthcare professionals the time to fully understand this new measure and to make an informed decision about it before it comes into effect; allow healthcare professionals the necessary time to adapt the information they give to patients in the event of a change in device; allow health professionals the time to be trained on the new blood glucose meters; allow

institutions, teaching clinics and community pharmacies to change their inventories of blood glucose meters and test strips.

In addition, INESSS recommends that the Régie de l'assurance maladie du Québec should:

11. Regularly update the list of anti-diabetes medications, regardless of the mode of reimbursement for the medications entered on the Lists, as well as those not entered therein but reimbursed through the measure for patients with exceptional status.
12. Update the computer system so that pharmacists can be informed of the number of test strips remaining for the period.
13. Calculate and apply the GSP to the packaging format, regardless of the transmission by unit in the present brief.
14. Include, in the newsletters for the healthcare professionals affected by these changes, information and a link to the INESSS website to allow them to understand the rationale for these changes, to promote the application of the reimbursement measures, and to translate them into language easily understood by test-strip users.
15. Add information on the RAMQ website to explain the procedure to follow according to users' specific conditions (who, by whom, where, when, how, why).

Furthermore, INESSS recommends that test-strip manufacturers should:

16. Restore the price of the packaging formats listed to formats of 50 or 100 test strips in order to conform with the measures on the maximum numbers of test strips reimbursed over a 365-day period.
17. Ensure that the unit price is the same, regardless of the packaging format.
18. Offer smaller formats (e.g., 25 test strips) or individual packages in order to adjust the formats to the maximum number of test strips reimbursed per 365-day period, according to the expiry dates after opening the vial or cassette.
19. Continue to offer free blood glucose meters in order to limit the impacts on patients.

It is recommended that clinicians should:

20. Inform patients of the recommendations regarding the frequency of SMBG, in accordance with their clinical characteristics and occupational situations. This information may be transmitted orally and accompanied with a card indicating the frequency of SMBG, according to the categories of antidiabetes-medications prescribed and the clinical circumstances.
21. Encourage users to use a single blood glucose meter and the same types of test strips.
22. Update the local group prescriptions used wherever nurses or pharmacists are allowed to initiate or renew test-strip prescriptions, taking into account the new reimbursement measures that will be implemented and that are consistent with the optimal use of test strips.

Lastly, INESSS specially recommends that community pharmacists should:

23. Record the prescribed antidiabetes medications in the user's prescription file before entering the test strips, where possible, so that the RAMQ's historical database can be kept as up-to-date as possible.

24. Check the remaining quantities of test strips at each renewal and discuss with the client when their use does not seem optimal and when there is a risk of exceeding the maximum number of test strips reimbursed before the end of the reference period.

Once the Minister makes a decision, INESSS intends to develop knowledge transfer tools to support clinicians and to encourage shared decision making with patients. However, during the update of the province-wide group prescriptions related to diabetes, the new measures will be taken into consideration. Finally, INESSS expects to monitor the implementation for 12 months after the new reimbursement measures come into effect.