5.27 GLUCOSE INDICATOR BLOOD

Glucose indicator blood strip: diagnostic, 50 and 100,

2in1 Smart Blood Glucose measuring test strips,

Merchantshub Networks (AustPacific) Pty Ltd

# Purpose of Application

* 1. The minor submission requested the listing of a new form of blood glucose test strips in two pack sizes (50 strips and 100 strips).

# Requested listing

* 1. While the submission did not propose the wording for a restriction for 2in1 Smart Blood Glucose Test Strips (BGTS), listing was requested under the same conditions as those that apply to blood glucose test strips that are currently PBS-listed.

# PBAC consideration of the evidence

## Sponsor hearing

* 1. There was no hearing for this item as it was a minor submission.

## Consumer comments

* 1. The PBAC noted that no consumer comments were received for this item.
  2. The PBAC recalled the Post-Market Review of Products used in the management of Diabetes. The PBAC noted the proposed restrictions for BGTS to replace the current listings, in line with the Committee’s previous advice from the August 2013 meeting.

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| **Category /**  **Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **Episodicity:** | N/A |
| **Severity:** | N/A |
| **Condition:** | Blood glucose monitoring |
| **PBS Indication:** | Blood glucose monitoring |
| **Treatment phase:** | N/A |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | Patient must have diabetes,  AND  Patient must be on insulin therapy. |
| **Administrative Advice** | No increase in the maximum quantity or number of units may be authorised. |
| **Administrative Advice** | No increase in the maximum number of repeats may be authorised. |

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| **Category /**  **Program** | GENERAL – General Schedule (Code GE) |
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| **Episodicity:** | N/A |
| **Severity:** | N/A |
| **Condition:** | Blood glucose monitoring |
| **PBS Indication:** | Blood glucose monitoring |
| **Treatment phase:** | N/A |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | Patient must not be on insulin therapy,  AND  Patient must have gestational diabetes; OR  Patient must have an inter-current illness that may adversely affect blood glucose control; OR  Patient must be undergoing treatment with a concomitant medicine that may adversely affect blood glucose control. |
| **Administrative Advice** | No increase in the maximum quantity or number of units may be authorised. |
| **Administrative Advice** | No increase in the maximum number of repeats may be authorised. |

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| **Episodicity:** | N/A |
| **Severity:** | N/A |
| **Condition:** | Blood glucose monitoring |
| **PBS Indication:** | Blood glucose monitoring |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | The condition must be diabetes which is inadequately controlled; OR  The condition must be diabetes which requires monitoring for up to 12 months from initiation,  AND  Patient must not be on insulin therapy. |
| **Administrative Advice** | No increase in the maximum quantity or number of units may be authorised. |
| **Administrative Advice** | No increase in the maximum number of repeats may be authorised. |

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| **Category /**  **Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **Episodicity:** | N/A |
| **Severity:** | N/A |
| **Condition:** | Blood glucose monitoring |
| **PBS Indication:** | Blood glucose monitoring |
| **Treatment phase:** | Initial |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | Patient must have diabetes,  AND  Patient must not be on insulin therapy,  AND  The treatment must have been initiated within the previous three months; OR  The treatment must have required a change to existing diabetes management within the previous three months. |
| **Administrative Advice** | No increase in the maximum quantity or number of units may be authorised. |
| **Administrative Advice** | No increase in the maximum number of repeats may be authorised. |
| **Category /**  **Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **Episodicity:** |  |
| **Severity:** |  |
| **Condition:** | Blood glucose monitoring |
| **PBS Indication:** | Blood glucose monitoring |
| **Treatment phase:** | Continuing |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | Patient must have diabetes,  AND  Patient must be on insulin therapy,  AND  Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |
| **Administrative Advice** | No increase in the maximum quantity or number of units may be authorised. |
| **Administrative Advice** | No increase in the maximum number of repeats may be authorised. |

* 1. The PBAC recalled their discussion at the April 2015 meeting of BGTS in the context of removing (delisting) over the counter (OTC) medicines.

# PBAC Outcome

* 1. The PBAC recommend listing under the same conditions as currently PBS‑listed blood glucose test strips.

## Outcome:

Recommended

# Recommended listing

Add new items, restriction as for other currently PBS listed blood glucose test strips

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| Name, Restriction,  Manner of administration and form | | Max.  Qty (Packs) | Max.  Qty (Units) | No. of  Rpts | Proprietary Name and Manufacturer | |
| GLUCOSE INDICATOR BLOOD  glucose indicator blood strip: diagnostic, 50 diagnostic strips | | 2 | 2 | 5 | 2in1 Smart Blood Glucose | Merchantshub Networks Austpacifc Pty Ltd |
| glucose indicator blood strip: diagnostic, 100 diagnostic strips | | 1 | 1 | 5 | 2in1 Smart Blood Glucose | Merchantshub Networks Austpacifc Pty Ltd |
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| **Category /**  **Program** | GENERAL – General Schedule (Code GE) | | | | | |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives | | | | | |

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| --- | --- | --- | --- | --- | --- | --- |
| Name, Restriction,  Manner of administration and form | | Max.  Qty (Packs) | Max.  Qty (Units) | No. of  Rpts | Proprietary Name and Manufacturer | |
| GLUCOSE INDICATOR BLOOD  glucose indicator blood strip: diagnostic, 50 diagnostic strips | | 2 | 2 | 11 | 2in1 Smart Blood Glucose | Merchantshub Networks Austpacifc Pty Ltd |
| glucose indicator blood strip: diagnostic, 100 diagnostic strips | | 1 | 1 | 11 | 2in1 Smart Blood Glucose | Merchantshub Networks Austpacifc Pty Ltd |
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| **Category /**  **Program** | GENERAL – General Schedule (Code GE) | | | | | |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives | | | | | |
| **Condition:** | Blood glucose monitoring | | | | | |
| **PBS Indication:** | Blood glucose monitoring | | | | | |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined | | | | | |
| **Clinical criteria:** | Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. | | | | | |
| **Administrative Advice**  **(not included in LI)** | No increase in the maximum quantity or number of units may be authorised.  No increase in the maximum number of repeats may be authorised. | | | | | |

# Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

# Sponsor’s Comment

The sponsor had no comment.