

Feedback Survey

Application 1386 – Gastric Contractility Modulation (GCM) therapy for patients with Type 2 Diabetes with Obesity.

The Department of Health is seeking your feedback on the draft protocol for Application 139486 – Gastric Contractility Modulation (GCM) therapy for patients with Type 2 Diabetes with Obesity. Please note, this protocol is yet to be considered by the Protocol Advisory Sub-committee (PASC), a sub-committee of the Medical Services Advisory Committee.

Please reply to the HTA Team

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Email: HTA@health.gov.au

Your feedback is required by **15 November 2014** to enable PASC to consider, when it reviews this protocol, at its meeting of 11-12 December 2014.

PERSONAL AND ORGANISATIONAL INFORMATION

1. What is your name? _____
2. Is the feedback being provided on an individual basis or by a collective group?
 - Individual
 - Collective group. Specify name of group (if applicable) _____
3. What is the name of the organisation you work for (if applicable)? _____
4. What is your e-mail address? _____
5. Are you a:
 - a. General practitioner
 - b. Specialist
 - c. Researcher
 - d. Consumer
 - e. Care giver
 - f. Other (please specify) _____

MEDICAL CONDITION (DISEASE)

Type 2 diabetes mellitus (T2DM) is the most common form of diabetes in Australia, accounting for contributing more than 85% to the total number of people with diabetes in Australia. Type 2 diabetes is a chronic and progressive medical condition that results from two major metabolic dysfunctions: insulin resistance and then pancreatic islet cell dysfunction causing a relative insulin deficiency. In the individual, these occur due to modifiable lifestyle-related risk factors interacting with genetic risk factors.

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PROPOSED INTERVENTION

This application requests the MBS listing of Gastric Contractility Modulation (GCM) therapy for the treatment of Type 2 Diabetes Mellitus (T2DM) patients with obesity, who are inadequately controlled on standard oral glucose lowering (anti-diabetic) therapy, aged ≥ 18 years, have normal triglyceride levels (fasting plasma triglycerides $\leq 1.7\text{mmol/l}^1$) and HbA1c $\geq 7.5\%$.

CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

- 1) Describe your experience with the medical condition (disease) and/or proposed intervention relating to the draft protocol?

- 2) What do you see as the benefits of this proposed intervention for the person involved and/or their family and carers?

- 3) What do you see as the disadvantages of this proposed intervention for the person involved and/or their family and carers?

- 4) How do you think a person's life and that of their family and/or carers can be improved by this proposed intervention?

- 5) What other benefits can you see from having this proposed intervention publicly funded on the Medical Benefits Schedule (MBS)?

INDICATION(S) FOR THE PROPOSED INTERVENTION AND CLINICAL CLAIM

Flowchart of existing (page 16) and potential management (page 17) with the proposed intervention for this medical condition.

- 6) Do you agree or disagree with the eligible population for the proposed intervention as specified in the proposed management flowcharts?
 - Strongly agree
 - Agree
 - Disagree
 - Strongly disagree

¹ The definition of normal triglycerides used for this application is consistent with the GCM therapy clinical trial data. In some cases, normal triglycerides are defined as fasting plasma triglycerides $< 2.0\text{mmol/l}$ (Australian Health Survey: Biomedical Results for Chronic Disease, 2011-2012. Cat number 4364.0.55.005)

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Why or why not?

7) Do you agree or disagree with the comparators, page 12 and 13 of the protocol, for the proposed intervention as specified in the current management flowchart?

- Strongly agree
- Agree
- Disagree
- Strongly disagree

Why or why not?

8) Do you agree or disagree with the clinical claim (outcomes), page 13 of the protocol made for the proposed intervention?

- Strongly agree
- Agree
- Disagree
- Strongly disagree

Why or why not?

9) Have all associated interventions been adequately captured in the flowchart, see page 19 of the protocol?

- Yes
- No

If not, please move any misplaced interventions, remove any superfluous intervention, or suggest any missing interventions to indicate how they should be captured on the flowcharts. Please explain the rationale behind each of your modifications.

ADDITIONAL COMMENTS

10) Do you have any additional comments on the proposed intervention and/or medical condition (disease) relating to the proposed intervention?

11) And finally, do you have any comments on this feedback form and process? Please provide comments or suggestions on how this process could be improved.

Feedback Survey

Thank you again for taking the time to provide your valuable feedback.

If you experience any problems completing this on-line survey please contact the HTA Team

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