

# Swallowable gastric balloon capsule for weight loss

Interventional procedures guidance

Published: 18 November 2020

[www.nice.org.uk/guidance/ipg684](https://www.nice.org.uk/guidance/ipg684)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# 1 Recommendations

- 1.1 Evidence on the safety of the swallowable gastric balloon capsule for weight loss shows infrequent but potentially serious adverse events:
- For people who need to lose weight in the short term for medical reasons, the evidence of efficacy is adequate to support the use of this procedure provided that special arrangements are in place for clinical governance, consent and audit. Find out what special arrangements mean on the NICE interventional procedures guidance page.
  - For people who are aiming for long-term weight loss, the evidence on efficacy is inadequate in quantity and quality, so the procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to use a swallowable gastric balloon capsule for weight loss should:
- Inform the clinical governance leads in their healthcare organisation.
  - Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
  - Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
  - Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's audit tool (for use at local discretion).

- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Further research could be in the form of randomised controlled trials comparing the procedure with current standard therapies, or an observational cohort study, including using registry data. Studies should include details of patient selection such as body mass index and other treatments such as diet and lifestyle changes. They should also report:
- short- and long-term weight loss
  - quality of life
  - metabolic parameters
  - the need for later surgery.

## 2 The condition, current treatments and procedure

### The condition

- 2.1 Overweight is defined as a body mass index (BMI) of 25 kg/m<sup>2</sup> to 29.9 kg/m<sup>2</sup> and obesity as a BMI of 30 kg/m<sup>2</sup> or more. Overweight and obesity increase people's risk of type 2 diabetes, coronary heart disease and hypertension. Weight loss reduces these risks and improves life expectancy.

### Current treatments

- 2.2 Obesity is managed by dietary advice, physical activity and exercise, lifestyle and behavioural changes, and medication. Bariatric surgery is considered for people:
- whose BMI is over 40 kg/m<sup>2</sup>, or over 35 kg/m<sup>2</sup> if they have other significant comorbidities, and

- who have not been able to reach or maintain a clinically beneficial weight using non-surgical measures.

Surgical procedures include gastric banding, sleeve gastrectomy, or Roux-en-Y gastric bypass or other diversion procedures.

- 2.3 People unable to lose weight by non-surgical measures who do not want invasive surgery can have less invasive bariatric procedures. Examples are endoscopic intragastric balloons, gastrointestinal bypass sleeves, endoscopic sleeve gastroplasty and endoluminal restrictive surgical techniques.

## The procedure

- 2.4 A swallowable gastric balloon capsule for weight loss must be used with a nutrition and behaviour modification programme supervised by a suitably qualified and registered healthcare professional.
- 2.5 The procedure is usually done in an outpatient setting without endoscopy or sedation. The patient swallows a capsule containing the deflated balloon, which is attached to a fine delivery catheter, with water. If they have difficulty swallowing the capsule, a stylet can be fed through the catheter to stiffen it. This allows the doctor to help push the catheter during swallowing. After the capsule reaches the stomach, this stylet is removed. The position in the stomach is confirmed by X-ray using guide marks on the catheter. The capsule disintegrates and the balloon is inflated with a fixed amount of fluid (for example, distilled water and citric acid) through the connected catheter. After the balloon is inflated, the catheter is detached by pulling it firmly from the patient's mouth. Imaging is done to recheck position and inflation. After a short wait to make sure the patient can tolerate the balloon, they are discharged with medication including anti-emetics, antispasmodics and proton pump inhibitors. About 4 months later, a resorbable material element of the balloon degrades, which then allows a release valve to open and expel the fluid into the stomach gradually. The deflated balloon then passes through the gastrointestinal tract to be excreted through the bowel.

## 3 Committee considerations

### The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 1 meta-analysis, 8 case series and 1 case report. It is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: weight loss in the short term, maintenance of weight loss in the long term, and improved comorbidities and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: gastrointestinal obstruction, perforation, early balloon deflation and expulsion.
- 3.4 Three commentaries from patients who have had this procedure were discussed by the committee.

### Committee comments

- 3.5 The procedure may be useful for people who need to lose weight rapidly before surgery or other procedures.
- 3.6 The committee noted that nausea and vomiting were associated with this procedure, as with other intragastric balloon procedures.
- 3.7 The committee was informed that the technology is evolving.

ISBN: 978-1-4731-3891-9

# Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).