

## National Institute for Health and Care Excellence

### IP1340– Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating severe obesity Consultation Comments table

IPAC date: 8 September 2016

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Professional organisation Royal College of Physicians (RCP)	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with experts from UCLH Centre for Weight loss, Metabolic and Endocrine Surgery and would like to make the following comments.	Please respond to all comments.  Thank you for your comments.
2	Consultee 1 Professional organisation Royal College of Physicians (RCP)	4.1	The use of %EWL is to be discouraged. It is a term that is used uniquely by surgeons. At the least absolute or % weight loss should be given.	Thank you for your comment. % excess weight loss was reported as the primary outcome measure in the included studies. The use of %EWL in the guidance is as reported in the published papers.  Absolute weight loss measure was not used in the reviewed studies.

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3	Consultee 1 Professional organisation Royal College of Physicians (RCP)	lay description	‘The aim is to reduce the size of the stomach to restrict the amount of food a patient can eat, and to make the gut smaller so that less food is absorbed.’ Our experts believe that this is an outdated view as to the mechanism by which the procedure works and note that there is no evidence for restriction. The malabsorption may or may not be necessary for weight loss that probably relates to endocrine/metabolic/microbiota changes induced by the surgery.	Please respond to all comments  Thank you for your comment. This section of the guidance is intended to be a short and simple summary of the procedure for lay members and has been amended.  <i>Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy is a type of weight loss surgery used to treat people with morbid obesity (also known as bariatric surgery). The left side of the stomach is removed (sleeve gastrectomy), and the exit point of the stomach is cut and re-joined to the gut further down. <b>The aim is to reduce the size of the stomach and the length of the intestine to reduce the amount of food absorbed.</b></i>

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4	Consultee 1 Professional organisation Royal College of Physicians (RCP)	1	Four experts believe that follow-up of patients is extremely poor. This may be due to a variety of factors (patient, commissioning, centres) but since the procedure produces significant malabsorption our experts would like to see it confined to centres who can demonstrate their ability to achieve very high levels of FU (? >90%) in their general bariatric surgical practice, and that specialist follow-up must be commissioned rather than the standard maximum of 2 years.	Please respond to all comments  Thank you for your comment. Section 1.5 of the guidance states that the treatment should be done in centres with expertise in the treatment of morbid obesity and 1.6 encourages further research particularly examining long-term outcomes. IP guidance does not usually specify the performance of centres (such as achieving high follow-up rates), and does not make commissioning recommendations.
5	Consultee 1 Professional organisation Royal College of Physicians (RCP)	General	The RCT from the Madrid Centre <a href="https://clinicaltrials.gov/ct2/show/NCT01463904?term=SADI&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT01463904?term=SADI&amp;rank=1</a> started in 2011 but has failed to report updates or results. This calls into question the validity of data from this group.	Thank you for your comment. The Committee is aware of this ongoing RCT (NCT01463904) and has noted in the overview that the status of the study is unknown. Safety and efficacy evidence reported in the guidance from this group (Sanchez-Pernaute et al) are from peer reviewed publications.

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6	Consultee 1 Professional organisation Royal College of Physicians (RCP)	General	SADI is most often being considered as a revision procedure after 'failed' sleeve gastrectomy. This requires a different evidence base. Again the Madrid group roistered a trial ( <a href="https://clinicaltrials.gov/ct2/show/NCT01685177?term=SADI&amp;rank=2">https://clinicaltrials.gov/ct2/show/NCT01685177?term=SADI&amp;rank=2</a> ) in 2012, that is not updated nor results published	Please respond to all comments  Thank you for your comment. SADI after failed sleeve gastrectomy is outside the scope of this guidance. Therefore evidence related to this was not considered.

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7	Consultee 1 Professional organisation Royal College of Physicians (RCP)	General	McMaster has recently registered an RCT comparing Switch with SADI.	<p>Please respond to all comments</p> <p>Thank you for your comment. The team have identified 2 new studies registered on the clinical trials website related to this procedure. These have been added to the overview.</p> <ul style="list-style-type: none"> <li>• <u>NCT02692469</u>: Laparoscopic single-anastomosis duodenal-jejunal bypass with sleeve gastrectomy vs laparoscopic duodenal switch (DS VS SADI)-estimated enrolment=140; estimated completion date 2026.</li> <li>• <u>NCT02792166</u>: Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S): a prospective cohort study- estimated enrolment=40; estimated completion date 2024.</li> </ul>

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8	Consultee 1 Professional organisation Royal College of Physicians (RCP)	General	Regarding Appendix B, our experts question whether the Endobarrier is still available as it was thought to have been suspended.	Please respond to all comments Appendix B is a list of related NICE guidance. This includes: IPG 471 Implantation of a duodenal–jejunal bypass sleeve for managing obesity <a href="http://www.nice.org.uk/guidance/IPG471">http://www.nice.org.uk/guidance/IPG471</a> and IPG 518 Implantation of a duodenal–jejunal bypass liner for managing type 2 diabetes <a href="http://www.nice.org.uk/guidance/IPG518">http://www.nice.org.uk/guidance/IPG518</a>
9	Consultee 1 Professional organisation Royal College of Physicians (RCP)	General	An economic evaluation is essential.	Thank you for your comment. Cost-effectiveness is not part of the remit of the IP Programme.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*