National Institute for Health and Care Excellence

IP1970 Endoscopic sleeve gastroplasty for obesity

IPAC date: 14 December 2023

Com. no.	Consultee name and organisation	Sec. no.	Comments (sic)	Response
1	Consultee 1 Company Apollo Endosurgery (Boston Scientific)	Draft recommendations 1.1	Thank you for the opportunity to comment on the interventional procedures consultation document for endoscopic sleeve gastroplasty (ESG) for obesity. Apollo Endosurgery an indirect wholly owned subsidiary of Boston Scientific Corporation (from this point referred to as Apollo/Boston Scientific) supports the draft recommendations for standard arrangements for ESG for obesity and believe the guidance will provide patients and physicians with an additional treatment option to manage the growing unmet need for treatment of obesity in the United Kingdom. Indeed a recent UK observational cohort study by Coulman et al. 2023 , including almost 2 million patients has highlighted that only 1% of patients with severe and complex obesity underwent Bariatric Surgery underpinning the need for additional treatment options for people living with obesity. (Coulman KD, Margelyte R, Jones T, Blazeby JM, Macleod J, Owen-Smith A, et al. (2023) Access to publicly funded weight management services in England using routine data from primary and secondary care (2007– 2020): An observational cohort study. PLoS Med 20(9): e1004282. https://doi.org/10.1371/journal. pmed.1004282 Received: April 24, 2023)	Thank you for your comments. Consultee agrees with the recommendations and brings to our notice a cohort study (Coulman 2023) that supports the need for additional treatment options for obesity.

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2	Consultee 3 British Obesity and Metabolic Surgery Society	1	BOMSS thanks NICE for their recommendations on the interventional procedures consultation document for endoscopic sleeve gastroplasty (ESG) for obesity. BOMSS supports the draft recommendations with the following comments.	Thank you for your comments. Consultee agrees with the recommendations.
3	Consultee 2 British Dietetic Association - Obesity Specialist Committee	Draft recommendations 1.2	Agree with these draft recommendations. Recommend addition of considering not only patient selection and work up but also follow-up post-procedure. Within this the importance of ensuring that this is delivered within an MDT setting should be highlighted. (see summary in ASMBS ESG obesity guidance: Docimo S Jr, Aylward L, Albaugh VL, Afaneh C, El Djouzi S, Ali M, Altieri MS, Carter J; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. Endoscopic sleeve gastroplasty and its role in the treatment of obesity: a systematic review. Surg Obes Relat Dis. 2023 Nov;19(11):1205-1218. doi: 10.1016/j.soard.2023.08.020. Epub 2023 Sep 16. PMID: 37813705.) and monitoring (for example see CG189 section 1.10.17). Important to highlight, as was done in the studies informing this, that this procedure is done alongside the lifestyle modification. Re: monitoring, would additionally include nutritional monitoring. Whilst theoretically this procedure should not have the same risks of nutritional deficiencies associated with bariatric procedures, the data is also not well reported. Cases of malnutrition/nutritional deficiencies post ESG are reported in the literature (see MERIT and Brazilian guidelines).	Thank you for your comments. The study (Docimo S Jr 2023) referred by the consultee has been added to the appendix in the overview of evidence. IPAC considered whether to reference section 1.10.6 in CG189 about MDT in managing obesity and amended 1.2 as follows: *'Patient selection, assessment, delivery and monitoring should be done by a multidisciplinary team within a specialist weight service experienced in managing obesity as stated in 1.10.6 in CG189'.* IPAC also considered comments about 'nutritional monitoring' and amended 1.4. 'Brazilian consensus on endoscopic sleeve gastroplasty' has been added to the appendix in the overview. Neto MG, Silva LB, de Quadros LG, et al. (2021) Brazilian Endoscopic Sleeve Gastroplasty Collaborative.

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				Brazilian Consensus on Endoscopic Sleeve Gastroplasty. Obes Surg. 31(1):70-78.
4	Consultee 1 – Company Apollo Endosurgery (Boston Scientific)	Draft recommendations 1.2	Apollo/Boston Scientific thanks the committee for this recommendation and emphasise the importance of training and experience in performing ESG. Currently Apollo/Boston Scientific supports clinicians in a number of different ways offering bespoke training modules and courses tailored to the requirements of the individual. All clinicians performing ESG are initially advised to complete 'wet-lab' basic training using porcine models. The training can be offered at our premises in Knaresborough, North Yorkshire; or at an NHS hospital training facilities where available. - Approximately 30 NHS clinicians were trained for the ESG procedure in the 'wet-lab' setting in 2022. - In addition to this Apollo/Boston Scientific offers advanced training programmes in Hamburg, Germany and routinely deliver 'hands-on' training with porcine models at several International Congresses i.e. European Society of Gastrointestinal Endoscopy, King's Live Endoscopy, Digestive Diseases Week. - Proctorships and preceptorships are also available at the beginning of the learning curve of surgeon. These are organised and supported fully by Apollo/Boston Scientific. - On-going clinical ESG case support and training from experienced Apollo/Boston Scientific representatives is provided for as long is deemed necessary. Apollo/Boston Scientific is also committed to providing maximal engagement to the ESG procedure to surgical and endoscopy trainees within the NHS. Established training programmes for	Thank you for your comments.

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			ESG have been endorsed by the British Obesity and Metabolic Surgery Society (BOMSS) University Southampton Endo-Bariatric Couse. We are actively engaged with the lead trainees of British Obesity & Metabolic Surgery Society (BOMSS) and Association of Upper GI Surgeons (AUGIS, Roux Group) to further develop robust training pathways focusing on the ESG procedure.	
5	Consultee 2 British Dietetic Association - Obesity Specialist Committee	Draft recommendations 1.2	Could there be a cross reference to CG189 as this makes clear what is meant by a multidisciplinary team experienced in managing obesity. 1.10.6Ensure the multidisciplinary team within a specialist weight management service includes or has access to health and social care professionals who have expertise in conducting medical, nutritional, psychological and surgical assessments in people living with obesity and are able to assess whether surgery is suitable. [2023]	Thank you for your comments. See response to comment 3.
6	Consultee 2 British Dietetic Association - Obesity Specialist Committee	Draft recommendations 1.2	Importance of Offering ESG in a Multidisciplinary Setting (Reference: Endoscopic sleeve gastroplasty and its role in the treatment of obesity: a systematic review. Docimo Jr November 2023 link https://www.soard.org/article/S1550-7289(23)00698-6/fulltext?dgcid=raven_jbs_etoc_email)	Thank you for your comments. This study (Docimo S Jr 2023) has been added to the appendix in the overview of evidence.
7	Consultee 2 British Dietetic Association - Obesity Specialist Committee	Draft recommendations 1.2	Re: patient selection, as is outlined in the NICE obesity guidelines regarding bariatric surgery, would be beneficial to include information on the skill set required by the MDT experienced in managing obesity (see CG189 section 1.10.14)	Thank you for your comment. See response to comment 3.
8	Consultee 5 Association for the Study of Obesity	Draft recommendations 1.2	We suggest that this is linked to CG189 1.10.6 Ensure the multidisciplinary team within a specialist weight management service includes or has access to health and social care professionals who have expertise in conducting medical, nutritional, psychological and surgical assessments in people living with obesity and are able to assess whether surgery is suitable. [2023]. The lead clinician doing endoscopic sleeve	Thank you for your comment. Please see response to comment 3.

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			gastrectomy may not a bariatric surgeon and a member of the multidisciplinary specialist weight management team.	
9	Consultee 2 British Dietetic Association - Obesity Specialist Committee	Draft recommendations 1.3	should say surgeon/endoscopist	Thank you for your comment. IPAC discussed this comment but decided not to be specific about which specialist should do the procedure. 1.3 was slightly amended as follows: *'This procedure should only be done in specialist weight management centres by a clinician with specific training and experience in the procedure'.*
10	Consultee 3 British Obesity and Metabolic Surgery Society	Draft Recommendations 1.3	BOMSS agrees with the committee and emphasises the importance of training, proctorship and preceptorship allowing introduction into wider NHS clinical practice.	Thank you for your comments. IPAC added a committee comment about the importance of training for wider introduction into NHS practice (see section 3.11).
11	Consultee 5 Association for the Study of Obesity	Draft recommendations 1.3	Other members of the multidisciplinary team also need training in this procedure and a good understanding so that they can help assess whether this is the most appropriate procedure, help share objective information with the patient, and also support the patient afterwards.	Thank you for your comment. See response to comment 9. IPAC added a committee comment about the importance of MDT training for wider introduction into NHS practice (see section 3.11).
12	Consultee 1 – Company Apollo Endosurgery (Boston Scientific)	Draft recommendations 1.4	Apollo/Boston Scientific support this recommendation and note that existing fields within the National Bariatric Surgery Registry for 'Endoscopic Plication' may help expedite the inclusion of ESG procedures.	Thank you for your comment.

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13	Consultee 3 British Obesity and Metabolic Surgery Society	Draft recommendations 1.4	BOMSS support this recommendation and suggest that it should be mandatory to place all NHS ESG cases in the NBSR.	Thank you for your comment.
14	Consultee 5 Association for the Study of Obesity	Draft recommendations 1.4	There is very little information available about the impact on nutrition and micronutrients. Nutritional data also needs to be collected.	Thank you for your comment. Section 1.4 recommends data submission to NBSR and this may also include data on nutritional status. IPAC amended 3.10 as follows: *The committee noted that more detailed data collection on the exact type of procedure technique used and nutritional status would be useful for the National Bariatric Surgery Registry.*
15	Consultee 2 British Dietetic Association - Obesity Specialist Committee	Current treatments 2.3	Recommend review wording in line with NICE guidelines. Not only those of Asian decent who guidance recommend are considered if have recent onset type 2 diabetes	Thank you for your comment. IPAC amended section 2.3 as follows: '*The NICE guideline on obesity recommends a multicomponent approach involving dietary advice, exercise, lifestyle changes and medication. Bariatric surgery is recommended as a treatment option in some people who have a BMI of 40 kg/m2 or more (class 3 obesity), or between 35 kg/m2 and 39.9 kg/m2 (class 2 obesity) and other significant disease (such as type 2 diabetes) and have not lost enough weight using other methods. It is also considered at a lower BMI threshold than in other*

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				populations for people of Asian, Chinese, Middle Eastern, Black African-Caribbean family background as these groups are prone to central adiposity and cardiometabolic risk occurs at lower BMI'.
16	Consultee 2 British Dietetic Association - Obesity Specialist Committee	Current treatments 2.4	by specialist dietitians	Thank you for your comment. IPAC amended the last sentence in 2.4 as follows: *'People are also advised to modify their eating behaviour by adhering to an explicit postoperative diet advised by specialist dieticians'.*
17	Consultee 3 British Obesity and Metabolic Surgery Society	The procedure 2.5	BOMSS recognises ESG reduces gastric volume but notes the mechanism of action is to create an early sensation of fullness helping the patient reduce portion size. It can also delay emptying of the stomach allowing the patient to feel fuller for longer.	Thank you for your comment. IPAC amended section 2.5 as follows: *Endoscopic sleeve gastroplasty is a minimally invasive transoral endoscopic procedure that reduces the volume of the stomach and may delay gastric emptying. It creates a sensation of fullness and reduces the amount of food that can be eaten at one time.*
18	Consultee 1 – Company Apollo Endosurgery (Boston Scientific)	The procedure 2.6	Apollo/Boston Scientific note the committees comments on the use of a double channel scope and would like to clarify that ESG procedures with a single gastroscope can be conducted using the OverStitch Sx™ device, whilst the OverStitch™ Gen 2 device facilitates use of the procedure with a double channel gastroscope. Currently, the majority of ESG cases in the UK are conducted using the OverStitch Sx™ device and single channel scopes.	Thank you for your comments. IPAC amended 2.6 as follows: 2.6 *'The procedure is done under general anaesthesia. It may be done as a day case, but most people are kept under observation overnight and discharged the next day. A single or a*

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			To the best of our knowledge, only the OverStitch Sx™ device and the OverStitch™ Gen 2 device facilitates ESG as described in this guideline.	*double channel scope with a procedure-specific endoscopic device attached is passed through the mouth (transorally)'*.
19	Consultee 3 British Obesity and Metabolic Surgery Society	The procedure 2.6	The ESG procedure can be conducted using both single (using the OverStitch Sx™ device) and double channel (OverStitch™ Gen 2 device) scopes. The suturing extends from proximal antrum into the fundus not to the Gastro-oesophageal junction.	Thank you for your comment. IPAC amended section 2.6 as follows: 2.6 '*The procedure is done under general anaesthesia. It may be done as a day case, but most people are kept under observation overnight and discharged the next day. A single or double channel scope with a procedure-specific endoscopic device attached is passed through the mouth (transorally). A series of endoluminal full-thickness suture plications (in a U, Z, square, triangle or rectangle pattern) are done along the greater curvature of the stomach (through the gastric wall, extending from the pre-pyloric antrum to the fundus). This involves folding the stomach in on itself and stitching it together, creating a restrictive endoscopic sleeve to reduce the stomach volume by about 70% to 80%. There is no resection of the stomach and the procedure may be reversible in early stages*.'
20	Consultee 2	The procedure 2.6	There need to be additional statements about the postoperative support including ongoing specialist dietetic support. See CG189 1.10.10.	Thank you for your comments. Section 2.6 is a brief description of the procedure.

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	British Dietetic Association - Obesity Specialist Committee		The impact on nutrition and micronutrients are not known. Vitamin and mineral supplements are recommended, and people need both preoperative and postoperative nutritional blood tests. Given the lack of information available, it is essential that nutritional data is collected and reported.	Section 1.2 and 1.3 recommends patient selection, assessment, delivery and monitoring by a multidisciplinary team within a specialist weight management service experienced in managing obesity as stated in CG189. This includes postoperative support as well. Section 1.4 recommends data submission to NBSR and this may also include data on nutritional status. IPAC amended 3.10 as follows: *The committee noted that more detailed data collection on the exact type of procedure technique used and nutritional status would be useful for the National Bariatric Surgery Registry.*
21	Consultee 5 Association for the Study of Obesity	The procedure 2.6	Patients will need dietetic support with diet progression and aftercare. CG189 1.10.10. The requirements for nutritional supplementation are unknown for this procedure, however, the need for supplementation is recognised along with monitoring macronutrient and micronutrient status.	Thank you for your comment. See response to comment 20.
22	Consultee 2 British Dietetic Association - Obesity Specialist Committee	The evidence 3.3	Unfortunately, there is a lack of information on the impact on nutrition, and therefore this important area is missing. It is important to emphasise the role of the dietitian in supporting the patient undergoing this procedure to ensure nutritional adequacy.	Thank you for your comment. See response to comment 20.
23	Consultee 5	The evidence 3.3.	There is very little information available on the impact on nutritional status. Given that many people living with obesity	Thank you for your comment. See response to comment 20.

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	Association for the Study of Obesity		have nutritional deficiencies, it is important that nutrition is also considered.	
24	Consultee 1 – Company Apollo Endosurgery (Boston Scientific)		Apollo/Boston Scientific commend the excellent evidence review that informs this guidance. We wish to draw attention to several key studies likely published after the initial search dates as these provide additional details for the resolution of comorbidites and efficacy particularly in patients with Class III Obesity. The first is a US study reporting 3-year results in 404 consecutively enrolled patients with class III obesity who underwent ESG. The mean BMI for the cohort was 44.8 (+ 4.7) prior to the procedure. At 36 months, the % Total Body Weight Loss (TBWL) was 20.3 (+9.5%) and patient follow up rates for this cohort exceeded 88% at 36 months. Mean Body Mass Index (BMI) decreased from 44.8 kg/m2 at baseline to 35.6 +5.5 kg/m2 after 36 months, and by the 6 month mark the majority of patients exited their Class III status. Moreover, patients demonstrated a reduction in co-morbidites. (Maselli DB,et al . Endoscopic sleeve gastroplasty in class III obesity: Efficacy, safety, and durability outcomes in 404 consecutive patients. World J Gastrointest Endosc. 2023 Jun 16;15(6):469-479). The second French study (identifed as an abstract) included 227 patients with a mean initial BMI of 42.7 ± 7.8 kg/m2. Statistically significant reduction rates at 6 and 12 months were observed for TBWL and resolution of Type 2 Diabetes Mellitus (30.8 and 32.7%), Arterial Hypertension (18.4 and 22.1%), GERD (28 and 25.7%), Obstructive Sleep Apnoea (15.8 and 25.5%) and dyslipidaemia (69.2 and 77.2%) (P < 0.001). The authors' conclusion states that not only is ESG a well-tolerated and safe surgical procedure that is effective in terms of weight	Thank you for your comments and brining to our notice additional recently published peer-reviewed evidence. These 2 studies (Maselli 2023, Alexandre 2023) have been added to the appendix in the overview.

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			loss, there is also significant reduction of obesity-related co-morbidities at six months and one year which supports the adoption of ESG in a broader clinical scale as an effective treatment for morbid obesity. (Alexandre F, Lapergola A, Vannucci M, Pizzicannella M, D'Urso A, Saviano A, Mutter D, Vix M, Perretta S. Endoscopic management of obesity: Impact of endoscopic sleeve gastroplasty on weight loss and co-morbidities at six months and one year. J Visc Surg. 2023 Apr;160(2S):S38-S46. doi: 10.1016/j.jviscsurg.2022.12.003. Epub 2023 Jan 30. PMID: 36725451.). Apollo/Boston Scientific believe these studies provide further evidence in support of the recommendation and add additional data on the benefit of ESG with regards to resolution of co-morbidities.	
25	Consultee 3 British Obesity and Metabolic Surgery Society	3.8	BOMSS notes that in selected patients a day-case or ambulatory approach is possible for ESG. Greater experience is likely to facilitate this patient selection.	Thank you for your comment. Section 3.8 in the guidance states that in some patients where the procedure was done as a day case there was a high incidence of readmission for abdominal pain and self-limiting side effects.
26	Consultee 3 British Obesity and Metabolic Surgery Society	3.9	BOMSS notes, as per the Validity and Generalisability section, the presented evidence is for ESG using Apollo Overstitch. The Evidence for other endoscopic suturing devices is not yet as extensive.	Thank you for your comment. The evidence was considered on ESG (in which stomach capacity is reduced by making full-thickness sutures along the greater curvature using the OverStitch endoscopic suturing system) as a primary obesity procedure. All other ESG techniques are not considered in this evidence summary as 2 of these procedures

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				(POSE and E-ESG) are not undertaken in the NHS and the remaining systems are not currently available for commercial use in the UK. Committee comment 3.9 also states that 'more than one device is available for doing this procedure and the exact suture technique may vary'.
27	Consultee 3 British Obesity and Metabolic Surgery Society	2 indications-and-current-treatment-overview	BOMSS agree with the specific subgroups identified. It is noteworthy to comment that Gastro-oesophageal reflux is not a contraindication to ESG.	Thank you for your comment. IPAC considered your comment and added a committee comment that 'Gastroesophageal reflux is not a contraindication to ESG'.
28	Consultee 3 British Obesity and Metabolic Surgery Society	Validity and generalisability	BOMSS wishes to note that the UK health economic study by Kelly et al., has now been peer-reviewed and published. (Kelly, J., Menon, V., O'Neill, F. et al. UK cost-effectiveness analysis of endoscopic sleeve gastroplasty versus lifestyle modification alone for adults with class II obesity. Int J Obes (2023). https://doi.org/10.1038/s41366-023-01374-6). The study represents the first UK cost-utility analysis of ESG and further supports the recommendation by concluding that ESG is cost-effective compared to Tier 3 weight management from the NHS perspective.	Thank you for your comment. IPAC considered the comments about the health economic study (Kelly 2023) which had already been added to the overview.
29	Consultee 4 Obesity UK	Patient organisation	A group discussion was held at a regular support group amongst 28 members of Obesity UK. There were pre and post operative bariatric surgery patients and some who were currently in weight management. Some people were aware of this procedure, and a video produced by a bariatric surgery provider was shown. There was good debate. All agreed that this procedure would offer a useful addition to the options available to people. Members expressed their concern at	Thank you for your helpful comments and submission. These comments are extremely important to the committee. IPAC considered positive feedback from the patient organisation in their deliberations.

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			growing waiting lists for bariatric surgery. Some members saw this procedure as attractive, for being less invasive, and shorter stay in hospital and quicker return to normal living than with conventional bariatric procedures. Members hoped that if this procedure is made available on the NHS that GP's are educated in who would benefit most. There was a discussion as to whether it was reversible, and it was assumed it was some members found that attractive. People wanted to know more about risks and complications both long and short term. There was discussion if the procedure can be "revised" if needed if for instance weight gain isnt what was expected. There were many questions beyond the scope of the document which were about the effect on the digestive tract, will vitamins and minerals be needed and what aftercare would be needed. In conclusion the group were unanimous that more choice of procedures and improved access to services was certainly a good thing. Several of the pre-op and newly post operative patients felt they would have seriously considered this if that had been an option.	The risks and complications in the short and long term are presented in the evidence summary in detail. Section 2.6 of the document states that *'there is no resection of the stomach and the procedure may be reversible'.*
30	Consultee 5 Association for the Study of Obesity	Lay description	Would it be helpful to mention whether this procedure needs a general anaesthetic? I see that it is mentioned later but I also wondered about including it here.	Thank you for your comment. Section 2.6 of the document states that *'The procedure is done under general anaesthesia'.* The lay description has been amended to mention this.

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