National Institute for Health and Care Excellence IP409/3 Liposuction for chronic lymphoedema

IPAC date: 10 February 2022

Com.	Consultee name and organisation	Sec.	Comments	Response
110.	and organisation	110.		Please respond to all comments
1	Consultee 1 British Lymphology Society Professional organisation	General	Dr (Commenting on behalf of the British Lymphology Society (BLS)): We have reviewed the draft recommendations and find them acceptable. They do not contain any factual inaccuracies. The references are up-to-date. We are delighted that NICE continue to support the use of liposuction in lymphoedema (for appropriately selected patients) as it can achieve life-changing benefits for patients.	Thank you for your comment. Consultee agrees with the main recommendation.
2	Consultee 2 British Association of Dermatologists Professional organisation	General	On behalf of the British Association of Dermatologists, thank you for the opportunity to comment on the consultation. Please find the BAD's comments below: 1. Draft recommendations • These are acceptable. 2. Information about factual inaccuracies • We did not find any factual inaccuracies. 3. Additional relevant evidence, with references if possible • To our knowledge the references are up to date. Prof and Dr Guidelines sub-committee	Thank you for your comment. Consultee agrees with the main recommendation.

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3	Consultee 3 NHS professional Specialist advisor	1.1	The recommendations are clear and based on current evidence	Thank you for your comment. Consultee agrees with the main recommendation.
4	Consultee 3 NHS professional Specialist advisor	2.1	I don't think this is accurate. Could I suggest changing to "primary lymphoedema results from a range of genetic conditions which affect the development and functioning of the lymphatic system".	Thank you for your comment. Section 2.1 of the guidance has been changed to: 'Primary lymphoedema results from a range of conditions which affect the development and functioning of the lymphatic system.'
5	Consultee 3 NHS professional Specialist advisor	2.1	The most common type of chronic lymphoedema in the UK now is leg lymphoedema secondary to obesity, with cancer -related lymphoedema representing 37% of those with lymphoedema treated by specialist services in the UK (Keeley, 2019 LIMPRINT in Specialist Lymphedema Services in United Kingdom, France, Italy, and Turkey. Lymphatic Research and Biology 17(2) DOI: 10.1089/Irb.2019.0021). However, for the purposes of this guidance, liposuction would not be relevant for those with obesity-related lymphoedema. Those of us working in lymphoedema are trying to change the current concept that most lymphoedema is related to cancer treatment, particularly breast cancer treatment as this is not the case. Perhaps it would be useful to say here that "Liposuction may be particularly appropriate for selected patients with cancer treatment related lymphoedema and primary lymphoedema"?	Thank you for your comment. The consultee describes the following publication: • Keeley V, Franks P, Quéré I et al. (2019) LIMPRINT in Specialist Lymphedema Services in United Kingdom, France, Italy, and Turkey. Lymphatic Research and Biology 17(2):141-6 This publication reports that approximately 79% of people with lymphoedema in the UK present with leg lymphoedema. The publication also reported that cancer-related lymphoedema only accounted for 34% of total cases in the UK. Section 2.1 of the guidance has been changed to: 'Secondary lymphoedema results from damage to the lymphatic system or removal of lymph nodes by surgery, radiation, infection, or injury. Liposuction may be particularly appropriate for select people with primary lymphoedema and for people with cancer- related lymphoedema.'

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_			I feel there is too much emphasis on manual lymphatic drainage in this description. There is little evidence of its additional benefit as a component of decongestive lymphoedema therapy (DLT) when used together with compression. Indeed this is mentioned in the NICE guidance on breast cancer lymphoedema. There is greater evidence for the benefit of compression treatment and exercise. Could I suggest that this paragraph is amended to read something like?: "Current conservative treatment for lymphoedema (decongestive lymphoedema therapy) is usually carried out in two stages: an intensive phase of treatment using compression bandaging with the aim of reducing the volume of the oedema. This is followed	Please respond to all comments Thank you for your comment. The consultee notes the lack of evidence for manual lymphatic drainage. Section 2.2 of the guidance has been changed to: 'The current conservative treatment for lymphoedema is decongestive lymphatic therapy. This involves compression bandaging, skin care and exercise. For some people, manual lymphatic drainage massage that stimulates lymph to move away from the affected limb may also be helpful.'
_			by a maintenance phase, where a compression garment is required to be worn every day on the affected limb to maintain the improvement achieved by the bandaging treatment. Skin care and exercises are important components of decongestive lymphoedema therapy and for some patients, manual lymphatic drainage massage may be helpful."	
7	Consultee 3 NHS professional Specialist advisor	2.2	I think the section on surgery also would benefit from amendment. Perhaps the following could be considered? "In the early stages of lymphoedema, most of the swelling is due to fluid accumulation. However, in later stages due to a chronic inflammatory process most of the swelling is due to the accumulation of fat and fibrosis. In some patients this can occur despite the use of conservative treatment and result in more severe symptoms and a greater risk of cellulitis. It is in these cases of advanced stage lymphoedema where	Thank you for your comment. The consultee describes the mechanisms of lymphoedema swelling at different stages of the disease. Please note, this section is intended to be a high-level summary of current treatments and is not intended to be comprehensive. Section 2.2 of the guidance has been changed to: 'In severe and chronic cases, in people with lymphoedema that does not respond to conservative

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			reduction surgery with liposuction can be helpful". I would suggest omitting the section on reconstructive procedures such as lymphovenous anastomosis or lymph node transfer, as these are most commonly recommended in the earlier stages of lymphoedema particularly after lymph-node excision for cancer treatment and have not been approved by NICE. As such they are not routinely funded by the NHS in the UK.	treatment, liposuction can be used. Procedures to restore lymphatic flow from the limb, such as lymphovenous anastomosis or lymph node transfer, are less commonly used and are usually reserved for earlier-stage lymphoedema.
8	Consultee 3 NHS professional Specialist advisor	3.1	A valuable overview of the current evidence.	Thank you for your comment.
9	Consultee 3 NHS professional Specialist advisor	3.2	One of the aims of decongestive lymphoedema therapy is to reduce the risk of developing cellulitis and there is good evidence of its benefit in this. I suggest adding this to the list. I would suggest adding "reduced incidence of cellulitis" as a key efficacy outcome measure.	Thank you for your comment. Section 3.2 of the guidance has been changed to: 'The professional experts and the committee considered the key efficacy outcomes to be: sustained reduction in limb volume, improvement in quality of life including discomfort, limb symmetry and mobility, and reduced incidence of cellulitis.'
10	Consultee 3 NHS professional Specialist advisor	3.3	I suggest adding the word post-operative in front of infection so that it reads "post-operative infection (including cellulitis)". I think there is a need to clarify that there may be a risk of post-operative infection as with any surgical procedure but it is also important to recognise as in 3.2 that one of the aims of liposuction for lymphoedema is to reduce the long-term risk of cellulitis. Evidence for this benefit is quoted in the literature review.	Thank you for your comment. Section 3.3 of the guidance has been changed to: 'The professional experts and the committee considered the key safety outcomes to be: pain, postoperative infection (including cellulitis), bleeding, venous thromboembolism and fat embolism, and fluid overload.'
11	Consultee 4	Other	Since submitting Lipoedema Uk's response to the Interventional Procedures Consultation Documents for	Thank you for your comment.

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	Lipoedema UK Patient organisation		lipoedema, the lymphoedema consultation document has been issued. In addition I have held conversations with international surgeons who have long term experience of treating both types of patients. In both cases I wholeheartedly support the case that both sets of patients have to be very carefully selected by a suitably qualified expert, such as Dr of St	This comment, after approval from the Committee Chair, was included in the consultation comments table for IP1843 – Liposuction for chronic lipoedema. The consultation comments for IP1843 were discussed by the committee at the January Committee meeting. This is in accordance with the Interventional Procedures programme manual, which states that 'late comments received after the 4-week deadline are shown to the
			Georges University Trust, London or a surgeon with a good track record of success, operating in a reputable clinic.	Committee only at the discretion of the Chair, on the advice of the programme team.' The committee considers the quantity and quality of the
			I am confused by the discrepancy between the opening statements of the two ongoing reviews, especially as renowned and experienced surgeons have informed me they use the same techniques on both types of carefully selected patients. Lipoedema UK have already commented on the impracticability of 1.2 for lipoedema, but it does seem there is an unjustifiable amount of inconsistency being applied to the two categories of patients and interpretation of the evidence regarding potential risks.	evidence in the context of the particular indication, taking into account any specific concerns such as the potential for serious adverse events or the lack of long-term data. Though the techniques are similar, the evidence available for liposuction for chronic lipoedema and liposuction for chronic lymphoedema is different in quantity and quality and shows different outcomes, especially in respect to the safety signal. There are also differences in the structure of the clinical pathway between the two conditions including the ability to establish a diagnosis.
			We have already drawn NICE's attention to similar inconsistencies in another ongoing Interventional Procedure - Percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis.	
			Additionally I would like to draw the committees attention to a newly released research paper from Australia, attached, showing new evidence that demonstrates "the profoundly distinct nature of lipedema and non-lipedema adipose tissue' which	

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			further builds the case that the current recommendations in Section 2.2 regarding healthy lifestyle changes are appropriate for obesity but not for lipoedema tissue.	
			This latest paper,	
			'Key signaling networks are dysregulated in patients with the adipose tissue disorder, lipedema'. Musarat Ishaq 1,2 ☒, Nadeeka Bandara1, Steven Morgan1, Cameron Nowell 3, Ahmad M. Mehdi4, Ruqian Lyu5, Davis McCarthy 5, Dovile Anderson 3, Darren J. Creek3, Marc G. Achen1,2, Ramin Shayan1,2 and Tara Karnezis1,2 ☒ ◎ The Author(s) 2021	
			also supports the statement that fat associated with lipoedema may be resistant to diet modification and exercise, so I would like to draw the committees attention to this new evidence and how it significantly alters previous assumptions regarding 'healthy lifestyles guidelines" for lipoedema.	
			As I believe the same committee are looking at the two guidelines side by side, I feel that the committee should be aware of the similarities in treatments and also the new evidence regarding lipoedema adipose tissue, before their meeting on 13th January to review their recommendations for lipoedema IP1843.	
			Thank you for any help you are able to give to make the committee aware of my comments.	
			Best wishes	

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			Lipoedema UK.	

[&]quot;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."