National Institute for Health and Care Excellence

IP1148/2 Cyanoacrylate glue occlusion for varicose veins

IPAC date: 12/12/19

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company Medtronic Ltd	**1.1**	Medtronic wish to thank NICE for the opportunity to comment on the Draft IPG for Cyanoacrylate Glue Occlusion for Varicose Veins. We agree that the evidence on the safety and efficacy of this procedure is adequate and therefore support the classification of standard arrangements. Medtronic would like to make the committee aware that the Five Year Follow-Up Extension VeClose Study which demonstrates sustained improvements in disease-specific, generic QoL and functional outcomes at 60 months, including VCSS, AVVQ, and EQ-5D assessments is currently in the review process and is due for publication in 2020. We would also like to make the committee aware that the eSCOPE Three Year study is currently being submitted for publication which is scheduled for 2020.	Thank you for your comment. The Committee has noted the 2 studies which are planned for publication. NICE would consider them should a further update of this guidance be required.
2	Consultee 2. Health Professional. Private Sector	**1.1**	In the light of the greatly expanded and positive evidence base since 2015 I am pleased that NICE has drafted a "standard arrangements" recommendation for the use of cyanoacrylate (CAC) glue for treating varicose veins. I moved on from using endothermal ablation (RFA and then EVLA) two years ago because CAC offers such palpable	Thank you for your comment. Relevant wording in section 3.5 has been added to reflect the low incidence of granuloma formation.

			advantages for patients, in terms of less pain during the procedure and avoidance of compression, with an equally good long-term outcome. Concerns have been raised recently (and will doubtless reach you through this consultation) about occasional severe granulomatous reactions to CAC. As a part of an imminent invited presentation to the Vascular Society of GB & Ireland, I requested information from Medtronic about all the adverse event reports they have received relating to VenaSeal (CAC) - which is the most widely used type of CAC - and their denominator. They have informed me that >150,000 VenaSeal (CAC) kits have been sold and that they have received "less than 12" reports that may be describing serious reactions to CAC. That gives an incidence of <1:10,000. In balancing that very rare risk against the advantages for the many, it has been my judgement - and that of my patients, whom I inform explicitly - that CAC is a good treatment option, based on the balance of benefits and risks. I offer this information in support of the draft recommendation by NICE for "standard arrangements" but, as ever, with normal and clear information for patients about the risks.	