NICE National Institute for Health and Care Excellence

IP1996 Transvenous embolisation for spontaneous intracranial hypotension caused by a cerebrospinal fluid-venous fistula

IPAC date: 22/01/2026

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
1.	Consultee 1 Individual	1.2 1 Recommendations	This will prevent access to this treatment for patients who desperately need it. A more appropriate recommendation would be for all patients to be selected through an MDT process, and for all treatment for this condition to be audited (be it surgical, embolisation or fibrin patching).	Thank you for your comment. Consultee disagrees with the recommendation and suggests changing the recommendation, for patients be selected through a multidisciplinary team process and that all treatments for this condition would be subject to audit. Committee discussed potential amendment to the recommendation. Committee amended from 'more research is needed' to 'can be used with evidence generation'.
2.	Consultee 1 Individual	3.15 Equality considerations	Recommending that embolisation be performed under a research setting only, will prevent many patients from accessing this treatment, and will further widen the disparity in care.	Thank you for your comment. Consultee disagrees with the recommendation and suggests that the recommendation will limit access to the treatment and widen the disparity in care.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
				Committee discussed potential amendment to the recommendation. Please see response to comment 1.
3.	Consultee 3 Individual	Not specified	This recommendation in effect will prevent this procedure from being available to patients like myself. The procedure offers a less invasive but effective method of closing CSF venous fistulas. I would much rather have this procedure than surgery but the recommendation would take that option away from patients. Causing a longer recovery and exposing people to the risks of spinal surgery. Patients would be forced to seek help abroad and seek a payment from the NHS to have a procedure that is needed but not available in the UK. Doctors in the UK have the skills to perform this procedure in the UK so it does not make sense that this procedure would be denied to patients. The reasoning that there is not enough evidence does not consider that there is not enough evidence for the alternative surgery either. Not treating a CSF leak leads to harmful consequences. Why deny patients the choice of this effective yet less invasive and cheaper alternative to surgery?	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1.
4.	Consultee 3 Individual	1.2 What research is needed	It is unreasonable to deny this procedure to patients not part of a research program.	Thank you for your comment. Consultee disagrees with the recommendation.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
				Committee discussed potential amendment to the recommendation. Please see response to comment 1.
5.	Consultee 4 Individual	Not specified	I believe that transvenous embolisation to repair a CSF venous fistula should remain available for patients who choose it - not only within formal research but also in clinical practice. I had a probable CSF leak last year which caused multiple bilateral subdural haematomas. These lasted 4 months. I was extremely fortunate to be diagnosed and treated conservatively in a city neurosurgery ward. As a result I only have mild sequelae of nightly headaches. As scans improve in line with those in Germany and the US, it is likely that more fistulas are going to be identified and a form of this procedure is surely going to be important. Waiting for another NICE review to reinstate it, would slow up advancements in this much neglected field where so many patients lead lives of very poor quality.	Thank you for your comment. Consultee disagrees with the recommendation and suggests that transvenous embolisation should remain available for patients who choose it, not only within formal research but also in routine clinical practice. Committee discussed potential amendment to the recommendation. Please see response to comment 1.
6.	Consultee 5 Individual	Not specified	I support NICE's recommendation that the procedure should be performed in specialist centres by appropriately trained consultant interventional neuroradiologists, within appropriate governance and multidisciplinary oversight. However, I do not support the proposal that the procedure should only be undertaken within a formal research setting requiring Research Ethics Committee approval. CSF venous fistula was only characterised in 2014. All	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Consultee flags the lack of standard of care. Committee acknowledged

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			available treatments rely on retrospective case series with small sample sizes, which is expected given the recent recognition of the disease. There is currently no universally acknowledged standard of care, but transvenous embolization can already be considered part of contemporary practice. This is acknowledged in the NICE specialist advice questionnaires. Mr Sayal, Consultant Neurosurgeon, describes “both surgery and transvenous embolisation” as the current “standard of care.” Dr Saqib similarly states “it is already part of the standard of care.” Dr O’Reilly notes “it is my view that this procedure would likely replace the current standard of care for this subset of SIH patients.” Dr Carlton Jones states “an established standard of care cannot yet be said to exist as such.” The recently published UK guidance document “Multidisciplinary consensus guideline for the diagnosis and management of spontaneous intracranial hypotension” states: “If a CVF is shown on myelography, then endovascular treatment may also be considered as a first-line treatment (along with targeted patching and surgery).” Embolisation could be considered current standard of care, alongside surgery and fibrin patching. Regarding this statement: "There is a lack of RCTs, and current evidence is based on small-sized prospective and retrospective case series with early to mid-term follow-up".	the lack of standard of care and highlighted that patients should be provided information on all available treatment options. Committee acknowledged that post-procedure dynamic myelography can directly demonstrate closure. However, myelography is not routinely performed as it is invasive. Change made to section 2.3: ‘the success of the procedure is judged by clinical follow-up and imaging follow-up with MRI. A post-procedure CT myelogram or digital subtraction myelogram may be performed to assess the distribution of the embolic agent and the extent to which the fistula has sealed. But, this is not done routinely for this purpose, because it is invasive.’ Change made to section 2.1: ‘Transvenous embolisation is typically done under general anaesthesia but can also be done under local anaesthesia or with conscious sedation.’

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			This does not correctly contextualise the evidence base. This is equally true for all treatments for this condition, as would be expected given its recent characterisation. NICE has not reviewed the evidence for fibrin injection or surgery with the same level of scrutiny. It is not clear why transvenous embolisation is singled out in isolation when comparable evidence for other modalities is also limited. For both surgery and fibrin injections, the evidence is currently limited to retrospective case series. The largest series of surgical patients consists of just 42 patients [1]. There are multiple series for CSF-venous embolisation, with the current largest of 100 patients demonstrating 95% of patients reported significant improvement or resolution [2]. This study had a neurological evaluation by a neurologist specialising in CSF disorders before and after endovascular therapy. For fibrin injections the largest series is of 119 patients but technique and follow-up were heterogenous and the mean clinical follow-up time was a mean of 5.0 months compared to 15 months for the embolisation series [3]. Imaging follow-up was also not complete. Regarding this statement: “None of the studies were conducted in the UK.” Although none of the studies were conducted in the UK, evidence from other developed countries such as France and the United States remains relevant. These countries have comparable healthcare systems, patient populations, and	The trial NCT03691870 has been removed from “Ongoing trials” in the overview. NICE considered producing interventional procedure guidance on transvenous embolisation for cerebrospinal fluid venous fistula as it was notified to us and met the remit for NICE Interventional Procedures guidance. You can notify an interventional procedure for consideration here. Committee acknowledged that fibrin glue is currently unlicensed for this indication and material used during transvenous embolisation is widely used in other endovascular procedures. Please see section 3.10 and 3.11 of the guidance.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			treatment standards, so their findings can reasonably be applied to the UK. Onyx is licensed in the UK and Europe for neurovascular vessel occlusion (unlike fibrin glue, which is used off-licence for intravascular injection). Standard techniques are employed for the procedure, it is only the indication that is new. Transvenous embolisation has been performed in at least 14 UK hospitals (the National Hospital for Neurology and Neurosurgery, Leeds, Romford, Birmingham, Belfast, Cambridge, Plymouth, Newcastle, Preston, Edinburgh, Royal London, Glasgow, HCA Wellington, Cleveland Clinic). In many hospitals, this is the only therapy being offered for CSF venous fistulas. To restrict it to a research-only context would reduce equitable access for patients, removing the sole treatment options in some centres. The UK Neurointerventional Group was not asked for their view during the consultation stage. This group represents the UK's leading experts in neurointervention. Its members perform these procedures, set national standards, and advise on safety and training, ensuring that any guidance reflects current practice, evidence, and technical realities within UK services.	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			In addition, the NICE procedure description, the statement that embolisation provides no means of confirming fistula occlusion is incorrect (""The procedure does not offer a way to check that the fistula has successfully sealed. So, the success of the procedure is judged by symptom resolution." "). Post-procedure dynamic myelography can directly demonstrate closure. The suggestion that the procedure always requires general anaesthesia is also inaccurate. It can be performed under local anaesthetic or sedation as a day case. I note an unexplained reference to a brain arteriovenous malformation embolisation trial (NCT03691870) in the "Ongoing trials" section. This relates to a completely different disease process and should not be used to contextualise venous fistula treatment. “Canda” is also spelt incorrectly. References [1] Duvall JR, Robertson CE, Cutsforth-Gregory JK, Carr CM, Atkinson JL, Garza I. Headache due to spontaneous spinal cerebrospinal fluid leak secondary to cerebrospinal fluid-venous fistula: Case series. Cephalalgia. 2019 Dec;39(14):1847-1854. doi: 10.1177/0333102419881673. Epub 2019 Oct 9. Erratum in: Cephalalgia. 2019 Dec;39(14):1867. doi: 10.1177/0333102419886803. PMID: 31597463.	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			[2] Brinjikji W, Madhavan A, Garza I, Whealy M, Kissoon N, Mark I, Morris PP, Verdoorn J, Benson JC, Atkinson JLD, Kobeissi H, Cutsforth-Gregory JK. Clinical and imaging outcomes of 100 patients with cerebrospinal fluid-venous fistulas treated by transvenous embolization. J Neurointerv Surg. 2024 Nov 22;16(12):1256-1263. doi: 10.1136/jnis-2023-021012. PMID: 37898553. [3] Callen AL, Carlton Jones L, Timpone VM, Pattee J, Scoffings DJ, Butteriss D, Huynh T, Shen PY, Mamlouk MD. Factors Predictive of Treatment Success in CT-Guided Fibrin Occlusion of CSF-Venous Fistulas: A Multicenter Retrospective Cross-Sectional Study. AJNR Am J Neuroradiol. 2023 Nov;44(11):1332-1338. doi: 10.3174/ajnr.A8005. Epub 2023 Oct 5. PMID: 37798111; PMCID: PMC10631531.	
7.	Consultee 6 Individual	Not specified	I am a patient, who after a year of waiting, various scans, and a failed epidural blood patch locally, I now have a diagnosis of one CSF venous fistula following CT myelogram at The National Hospital of Neurology and Neurosurgery in London. I am lucky to be able to weigh up the evidence available. After my diagnosis a few weeks ago, the consultant, following a discussion by the MDT, offered me a choice of the treatments to seal my CSF venous fistula. Although being initially unsure as the evidence is not good for any of the options available, I chose embolization and I am now waiting	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Consultee suggests all available treatments be compared with each other and not looked at individually. Interventional procedures guidance

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			for an appointment. My reasons, were: 1) I discounted fibrin glue patching as the rates of effectiveness are not as good as the other two options and as I have already had to wait over a year, I am keen to get my leak fixed quickly with as much certainty as possible. 2) I have already had to undergo surgery for other (unrelated) conditions and did not want another long period of recovery 3) The waiting time was quite considerably shorter for embolization than surgery. After a year of considerable limitations I traded a little effectiveness (I was told 90% vs 99%, based on experience and research evidence available) for quicker potential resolution. 4) If I am to get rebound headaches, then that would be the same whether I had surgery or embolization. The success of the embolization, I have been told will be assessed not only by resolution of symptoms but by MRI of my head 3 months after the procedure to see changes in the signs that are currently present, e.g. brain sag, etc. In my opinion, patients should be offered a full range of treatment options and be able to make an informed choice with the help of their consultant and the MDT. Restricting the options available will put more pressure on the NHS to do more surgeries and increase waiting times for patients who are already waiting lengthy periods to get diagnosed. None of the treatments have strong research evidence to support them and RCTs or large cohort studies are going to be extremely challenging due to relatively small numbers of	looks at the safety and efficacy of individual procedures. Please see response to comment 6. Committee acknowledged that randomised controlled trials may be challenging to conduct, however they remain the gold standard and should be done where feasible. Please see section 3.14 of the guidance.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			patients and only a few UK-based specialist centres able to offer all the treatments, let alone diagnosing the condition. A consensus of specialists (for example those who conducted the clinical guidelines and algorithm for spontaneous intracranial hypotension) and patients is needed as the research is poor. It would be helpful to have all the treatments considered alongside each other and not individually.	
8.	Consultee 7 Individual	Not specified	I think this is shocking and appalling that this treatment for csf leakers will not continue. This will be one massive set back for these leakers. Where is the justification in this? How can there possibly be long term evidence of the effectiveness of this treatment if it is discontinued. Csf leakers already have a raw deal. Ive had a leak over ten years and I have been on a NHS waiting list for a CT myelogram for over a year and still waiting, whilst left to suffer. I could have a csf venous fistula. If this treatment is stopped what then for us csf leakers? How can ordinary people who have this afford to go to the USA or Germany for treatment? Words fail me.	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1.
9.	Consultee 9 Individual	Not specified	I believe transvenous embolisation to repair a CSF venous fistulas should remain available for patients who suffer this debilitating condition. Options are already limited and removing this procedure is a step backwards. This less invasive procedure than surgery should remain available in the uk.	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
10	Consultee 12 Society of British Neurological Surgeons (SBNS)	Not specified	Dear Colleague, Please accept the following comments from the SBNS (Society of British Neurological Surgeons). Please be good enough to include these comments to the online process. I am commenting on behalf of the Council of Society of British Neurological Surgeons (SBNS) as the NICE Co-ordinator for the Society. We support the NICE recommendation that the procedure should be performed in specialised centres by suitably trained interventional neuroradiologists. We disagree with the recommendation that it should be performed within a research setting for the following reasons: (1) the treatment is already in practice in at least a dozen if not more centres. In the larger larger units the treatment decisions are made with a MDT including other specialists. (2) The standard of care treatments are not universally agreed. (3) A research only recommendation will discourage some units from using the method of treatment and will exclude patients in some areas of England from having access to the treatment. There is no agreed process of centralisation of this treatment. The SBNS is in favour of recommending the treatment to be done with special governance, consenting and audit	Thank you for your comment. Consultee disagrees with the recommendation and suggests allowing the treatment to be used with special governance, consenting and audit arrangements in place. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Consultee flags lack of agreed standard of care. Please see response to comment 6. Committee acknowledged the lack of registry in the UK and presence other international registries. The amended recommendation states data should be collected in an appropriate registry that meets NICE registry standards. Please see section 3.15 of the guidance

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			arrangements in place. Ideally, the audit should be a national registry. Allowing the treatment to be used with special arrangements will provide a better opportunity to assess the outcomes in a more effective way with a larger number of patients. Thank you. Very best wishes,	
11	Consultee 13 Individual	Not specified	Hi, I have read the NICE Transvenous embolisation for SIH guideline. As a patient with SIH I have had a very positive outcome from this treatment. Prior to embolisation I was unable to be upright (sitting or standing) for more than 20 minutes with a devastating effect on my life as a young (24 year old) woman. Following the procedure this has increased substantially to a duration of approximately 6 hours at a time. This has obviously greatly improved my independence and	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			quality of life. I did not have any adverse effects. Previous treatments (blood patch x 3, iv caffeine, migraine medications) had no beneficial effect. I am very keen to have the option of repeat transvenous embolisation available, should my clinicians offer this. I am concerned that I, and patients like me, will not have this treatment option which is the only reasonable treatment option for patients with multiple CSF venous fistulas. Many thanks for considering this,	
12	Consultee 14 King's College Hospital	1.2 1 Recommendations	The proposal to limit embolisation to formal research settings is disproportionate and risks reducing or eliminating access for patients. Embolisation is already offered routinely in at least 14 UK centres and is the only available therapy in several regions. Restriction would significantly worsen geographic equity and delay treatment. I suggest to revise recommendations to allow continued routine clinical use. Replace the research-only requirement with the establishment of a prospective national registry for all treatment modalities (embolisation, fibrin injection, and surgery).	Thank you for your comment. Consultee disagrees with the recommendation and suggests revising the recommendation to establish a national registry for all available treatment options for cerebrospinal fluid-venous fistula. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Please see response to comment 10.
13	Consultee 15 UK Neurointerventional Group	Not specified	UK Neurointerventional Group Response to NICE Proposed Guidance: Transvenous Embolisation for Spontaneous Intracranial Hypotension Caused by a Cerebrospinal Fluid Venous Fistula (IP1996)	Thank you for your comment. Consultee disagrees with the recommendation and suggests:

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			The UK Neurointerventional Group is the main professional body representing neurointervention practitioners in the UK. It helps set national standards and advises on safety and training. Its members undertake CSF venous fistula embolisation and are core contributors to the relevant multidisciplinary teams, so input from our group is directly relevant to the guidance. Summary of key points ● CSF venous fistula as a disease entity was only characterised in 2014. All treatment approaches (embolisation, fibrin patching, and surgery) have emerged in the same short timeframe with similarly limited evidence. ● Current standards of care have not been clearly defined, and it is unclear why guidance is being developed for embolisation alone rather than for all treatment options currently in use. ● Published international series show high rates of improvement and no major adverse events. Embolisation has been adopted in the UK and internationally as a first-line option and is already delivered in more than a dozen UK centres. ● Restricting transvenous embolisation to formal research would reduce access for patients, especially in regions where it is already the only available therapy.	- acknowledging absence of established standard of care for CSF venous fistula. - applying equal scrutiny to surgical and fibrin glue treatments regarding evidence, risks, and regulatory status. - avoid limiting the procedure to research-only settings to maintain patient access. prospective national registry covering all treatment modalities of CSF venous fistula. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Consultee recommends that the procedure be carried out by consultant interventional neuroradiologists. The committee has specified that a multidisciplinary team including a neurologist, neurosurgeon and interventional radiologist should be involved with patient selection and post-

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			Critique of the proposed guidance: Current practice “Once the fistula is located, targeted treatments are considered. These may include CT-guided fibrin glue injections, which are usually done as a day-case procedure under local anaesthesia and may be offered immediately after the scan, or surgical ligation… Existing treatment options may not always be feasible or suitable.” [1, p. 3] It would be helpful for NICE to set out on what basis certain treatments are considered “existing” while transvenous embolisation is treated as a newer option requiring distinct guidance. CSF venous fistula as a disease entity was only characterised in 2014, and all treatment approaches have emerged in the same short timeframe with similarly limited evidence. Ethylene vinyl alcohol copolymer (EVOH) is a licensed agent for neurovascular vessel occlusion in the UK and has been used for intravascular treatment of fistulas for more than three decades. The technical steps of transvenous embolisation for CSF venous fistulas do not differ from its established use in other neurovascular applications; the only element that is new is the clinical indication. There is no current universal standard of care in treating CSF-venous fistulas. This is acknowledged in the NICE specialist questionnaires. Parag Sayal, Consultant Neurosurgeon, describes “both surgery and transvenous	procedure follow-up. Please see section ‘What this means in practice’ of the guidance. Please see responses to comment 6, 7 and 10.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			embolisation" as the current "standard of care." Dr Rukhtam Saqib similarly states "[embolisation] is already part of the standard of care." Dr Sean O'Reilly states "it is my view that this procedure would likely replace the current standard of care for this subset of SIH patients." Dr Lalani Carlton Jones states "an established standard of care cannot yet be said to exist as such." Our position is that all current treatments have been performed for similar lengths of time and have similarly limited evidence and availability. There is little basis for framing some as "newer" than others and therefore deserving of increased regulatory scrutiny. Treatment pathways "Transvenous embolisation offers an alternative treatment option. It could be particularly useful when nerve root ligation cannot be done, when people are unfit for or decline surgery, or when there is treatment failure or recurrence after a CT-guided fibrin glue injection." [2, section 3.4] There is no universal consensus on the treatment pathway for CSF venous fistulas, and it is most commonly used as a first-line therapy rather than an "alternative" option after other treatments have failed or are unsuitable. Evidence base "Sample sizes were small across all studies, reflecting the recent recognition of CSFVF in SIH and the limited use of this	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			procedure in clinical practice." [1, p. 3] "There is a lack of RCTs, and current evidence is based on small-sized prospective and retrospective case series with early to mid-term follow-up." [1, p. 37] This is equally true for all treatments for this condition, as would be expected given its recent characterisation. NICE has not reviewed the evidence for fibrin injection or surgery with the same level of rigour. Given that similar evidence constraints apply to surgery and fibrin injections, singling out embolisation for specific recommendations does not support a fair comparison between modalities at similar stages of development. For both surgery and fibrin injections, the evidence is currently limited to retrospective case series. The largest series of surgical patients consists of 42 patients [3]. There are multiple series for CSF-venous embolisation, with the current largest of 100 patients demonstrating 95% of patients reported significant improvement or resolution [2]. For fibrin injections the largest series is of 119 patients but technique and follow-up was heterogeneous and the mean clinical follow-up time was a mean of 5 months compared to 15 months for embolisation [4]. Imaging follow-up was also not complete. "None of the studies were conducted in the UK." [1, p. 34] Although none of the studies were conducted in the UK, evidence from countries such as France and the United	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			States remains relevant. These healthcare systems are comparable in terms of patient populations and treatment standards, and reliance on international data is common in rarer conditions where local evidence is limited. We understand that UK data is being compiled and would urge NICE to wait until its imminent publication. “Ongoing trials… Transvenous Approach for the Treatment of Cerebral Arteriovenous Malformations. NCT03691870. N = 77. Canada. Completion: July 2025. (Completed)” [1, p. 37] This trial is not relevant to the treatment of CSF venous fistulas, as brain AVMs are a separate disease with a different aetiology and management pathway. Invasiveness and safety “Although the procedure is more invasive than CT-guided fibrin glue injection, it is less invasive than surgery and may reduce hospital length of stay and overall patient risk.” [2, section 3.4] We do not consider transvenous embolisation to be more invasive than CT-guided fibrin glue injection. Transvenous embolisation involves venous access through a single groin puncture, leaves no scar, allows early mobilisation and can be performed as a same-day procedure without general anaesthesia. Although embolisation now has the largest published experience among the available modalities, no major adverse events have been reported in the literature or	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			encountered anecdotally in UK practice. Embolisation allows more precise delivery of embolic material at the level of the fistula and avoids placing needles close to the thecal sac (as in fibrin glue injection), reducing the risk of nerve injury, spinal cord damage, bleeding, or spinal infarction. All licensed fibrin glues are authorised only for topical use and none are licensed for needle injection into tissue spaces. Injection for CSF-venous embolisation often results in spread into the vasculature [5]. The United States FDA has produced a black box warning that intravascular application must be avoided because accidental entry can cause thromboembolic events, disseminated intravascular coagulation, and anaphylactic reactions [6]. Although such events appear rare, the proposed NICE guidance creates an inconsistency in which a licensed intravascular embolic agent such as EVOH would be restricted to research use while an off-licence product carrying an explicit intravascular warning would remain unrestricted. Availability of treatments and equity “The procedure is offered in a limited number of specialist centres in the UK. This may create challenges in accessibility and geographic equity” [2, section 3.15] To our knowledge 14 hospitals in the UK perform the procedure: The National Hospital for Neurology and Neurosurgery, Leeds, Romford, Birmingham, Belfast, Cambridge, Plymouth, Newcastle, Preston, Edinburgh, Royal	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			London, Glasgow, HCA Wellington, and the Cleveland Clinic. Additional hospitals likely have the willingness and expertise. A survey of hospitals offering fibrin glue or surgery has not been undertaken to our knowledge. Embolisation is currently the sole therapy in some regions. Limiting treatments to only fibrin glue and surgery, which as NICE acknowledges may not be suitable or available, could reduce equitable access to care. General anaesthesia and day case procedures “Across all studies, the procedure was performed under general anaesthesia.” [1, p. 25] This is not correct. In the evidence reviewed, Brinjikji et al. (2024) do not specify the anaesthetic approach for all patients, but the statement ‘All awake patients reported some intraoperative pain during Onyx injection’ confirms that at least a proportion were treated under local anaesthesia [3]. An earlier paper from the same group includes a subgroup of the same patients and reports that of forty procedures, thirty-one were performed with conscious sedation and nine under general endotracheal anaesthesia [7]. “Whereas transvenous embolisation is usually done under general anaesthesia” [5, section 3.10] Transvenous embolisation does not require general anaesthesia, and the evidence reviewed by NICE does not support the claim that it “usually” is performed as such. Published series, including the large Mayo cohort, show that	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			the procedure is performed safely and effectively without general anaesthesia, usually as a day case. Describing it as a procedure that is usually performed under general anaesthesia gives the impression that it is more resource intensive or higher risk than the evidence suggests. "... CT-guided fibrin glue injections, which are usually done as a day-case procedure under local anaesthesia and may be offered immediately after the scan, or surgical ligation." [1, p. 3] By implication, the guidance currently suggests that only fibrin glue injection can be done as a day-case procedure under local anaesthesia. We would recommend explicitly stating that transvenous embolisation can also be performed as a day-case procedure under local anaesthesia and may similarly be offered immediately after the scan. Fistula resolution "The procedure does not offer a way to check that the fistula has successfully sealed. So, the success of the procedure is judged by symptom resolution." [2, section 2.3] Myelography can be performed at the end of the procedure or for follow up in patients after an embolisation. This includes digital subtraction myelography or Dynamic CT myelography with metal artefact reduction Research recommendations "1.1 More research is needed on transvenous embolisation for spontaneous intracranial hypotension caused by a	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			cerebrospinal fluid (CSF)–venous fistula before it can be used in the NHS. 1.2 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use." [2, section 1.1] As NICE acknowledges, there is "evidence of efficacy and safety". In many hospitals, embolisation is the only current therapy being offered for CSF venous fistulas. On this basis, a requirement that the procedure only be offered within formal research would be disproportionate and could have unintended negative consequences for access. We suggest that a prospective registry of all current treatments would be an appropriate mechanism for continued data collection at this stage of clinical adoption. Practitioner recommendations "This procedure should only be done in specialist centres by healthcare professionals with specific training and experience in this procedure." [2, section 1.2] We suggest that it should be undertaken specifically by consultant interventional neuroradiologists, who routinely perform spinal and cranial venous embolisation procedures and have specialist expertise in catheter navigation, spinal and cranial imaging, and endovascular management. Conclusions 1. It would be helpful for the guidance to recognise the absence of an established standard of care for cerebrospinal	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			fluid venous fistulas, reflecting the novelty of the condition and the emerging nature of all available therapies. 2. The guidance should recognise that transvenous embolisation currently has a comparable evidence base among the available treatment options and has been adopted internationally as a first-line approach in centres experienced in CSF venous fistula management. 3. Surgical and fibrin glue treatments should be evaluated with the same level of scrutiny applied to transvenous embolisation, including review of the evidence base, procedural risks, adoption levels, regulatory status, and reported outcomes. 4. If the procedure were restricted to use only within research settings, its incorporation into routine clinical pathways would be constrained. This could limit access to treatment for patients in regions where it is currently the sole available option. 5. The guidance should recognise embolisation without general anaesthesia and as a day case procedure, which has implications for patient experience and resource use. 6. We would support a prospective national registry covering all treatment modalities to enable continued evaluation of safety, efficacy and long-term outcomes, and to promote consistent data collection across approaches. 7. We suggest the treatment should only be performed by consultant interventional neuroradiologists.	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			References: [1] National Institute for Health and Care Excellence (2025). IP overview: Transvenous embolisation for spontaneous intracranial hypotension caused by a cerebrospinal fluid-venous fistula. London: National Institute for Health and Care Excellence. [2] National Institute for Health and Care Excellence (2025) Draft guidance – Transvenous embolisation for spontaneous intracranial hypotension caused by a cerebrospinal fluid–venous fistula (IP1996), Issue date October 2025. London: NICE. [3] Brinjikji W, Madhavan A, Garza I, Whealy M, Kissoon N, Mark I, Morris PP, Verdoorn J, Benson JC, Atkinson JLD, Kobeissi H, Cutsforth-Gregory JK. Clinical and imaging outcomes of 100 patients with cerebrospinal fluid-venous fistulas treated by transvenous embolization. J Neurointerv Surg. 2024 Nov 22;16(12):1256-1263. doi: 10.1136/jnis-2023-021012. PMID: 37898553. [4] Duvall JR, Robertson CE, Cutsforth-Gregory JK, Carr CM, Atkinson JL, Garza I. Headache due to spontaneous spinal cerebrospinal fluid leak secondary to cerebrospinal fluid-venous fistula: Case series. Cephalalgia. 2019 Dec;39(14):1847-1854. doi: 10.1177/0333102419881673. Epub 2019 Oct 9. Erratum in: Cephalalgia. 2019 Dec;39(14):1867. doi: 10.1177/0333102419886803. PMID: 31597463. [5] Callen AL, Carlton Jones L, Timpone VM, Pattee J,	

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			Scoffings DJ, Butteriss D, Huynh T, Shen PY, Mamlouk MD. Factors Predictive of Treatment Success in CT-Guided Fibrin Occlusion of CSF-Venous Fistulas: A Multicenter Retrospective Cross-Sectional Study. AJNR Am J Neuroradiol. 2023 Nov;44(11):1332-1338. doi: 10.3174/ajnr.A8005. Epub 2023 Oct 5. PMID: 37798111; PMCID: PMC10631531. [6] Food and Drug Administration. Clinical review: TISSEEL (STN 103980/5601) [Internet]. Silver Spring (MD): U.S. Dept. of Health & Human Services; 2011 April. Available from: https://www.fda.gov/media/83108/download [7] Brinjikji W, Garza I, Whealy M, Kissoon N, Atkinson JLD, Savastano L, Madhavan A, Cutsforth-Gregory J. Clinical and imaging outcomes of cerebrospinal fluid-venous fistula embolization. J Neurointerv Surg. 2022 Oct;14(10):953-956. doi: 10.1136/neurintsurg-2021-018466. Epub 2022 Jan 24. PMID: 35074899.	
14	Consultee 21 On behalf of Interventional Neuroradiology colleagues at the Royal Victoria Hospital in Belfast	Not specified	To whom it may concern, On behalf of my Interventional Neuroradiology colleagues at The Royal Victoria Hospital in Belfast, I would like to echo all of the points made in the UK Neurovascular Group (UKNG) response, to the above draft proposal regarding endovascular treatment of CSF-venous fistulas. In addition, we would like to add that we have been offering this procedure to our patients in Northern Ireland, having	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Please see response to comment 10.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			gone through our local trust governance structures. These include initial discussion and approval from the Belfast Trust 'New Procedure Committee', subject to ongoing audit of clinical outcomes - including monitoring for any adverse events, and patients being discussed in a multidisciplinary forum which involves input from Neurology and Neuroradiology teams, as well as Neurosurgery and Anaesthetic teams as required. We would be very happy to contribute to a prospectively maintained UK registry, subject to local trust approval. Ours concerns are that the NICE proposals in their current form may unfairly limit patients access to treatment for this relatively recently described entity.	
15	Consultee 16 Individual	Not specified	Restricting this form of repair for CSF Venous Fistulas in the UK to "research only" will leave thousands of patients suffering for potentially much longer (especially for a form of repair that is less invasive & uses less resources). CSF Leaks have already gone under the radar for far too long, awareness and understanding of CSF Venous Fistulas has made significant progress in the last decade, to introduce this restriction is a setback and gives limited options to sufferers (especially for those who might not be good candidates for invasive surgery). Please consider the lives of CSF Leak patients and the consequences of these decisions	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
16	Consultee 18 CSF Leak Association	Not specified	The proposed restriction of CSF–venous fistula (CSF-VF) embolisation exclusively to formal research settings does not reflect the favourable safety profile reported in all available studies, nor the clinical experience of UK specialist centres. Evidence reviewed by NICE identifies no major safety concerns and acknowledges consistent symptom resolution rates in published series. Restricting access risks denying patients a less invasive, less morbid option compared with currently available surgical approaches. A more proportionate recommendation would permit use within specialist centres under governance and registry participation.	Thank you for your comment. Consultee disagrees with the recommendation and suggests changing the recommendation to allow the procedure in specialist centres with appropriate governance and registry oversight. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Please see response to comment 10.
17	Consultee 18 CSF Leak Association	Not specified	The current draft guidance conflates two distinct concepts: 1. the need for long-term data (appropriately collected via a registry), and 2. a prohibition on clinical access outside RCTs. A registry is not a substitute for clinical access. A national SIH registry — which the CSF Leak Association is actively developing — can run alongside standard-of-care embolisation in specialist centres. Requiring an RCT before any NHS access would create multi-year delay for a small but severely disabled group of patients who currently have no acceptable alternative.	Thank you for your comment. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Consultee names embolisation as standard of care. Please see responses to comments 6, 7 and 10.
18	Consultee 18 CSF Leak Association	Not specified	The committee correctly notes patient heterogeneity. This strengthens (rather than weakens) the case for permitting	Thank you for your comment.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			embolisation in specialist centres: these centres already use MDT review, dynamic myelography expertise, and case-by-case selection. Restricting treatment to research sites would exacerbate the very inequity highlighted in Section 3.15, since only patients living near a research centre would have access.	Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1.
19	Consultee 18 CSF Leak Association	Not specified	Dynamic myelography is already the recommended standard in the 2023 UK SIH guideline and is available only in a small number of national specialist centres. This supports a model in which embolisation is permitted within those centres, not confined to research environments. These centres already have: • required imaging infrastructure • experienced neurointerventional radiologists • MDT case review • governance and audit capability. This is the safest environment in which to deliver embolisation.	Thank you for your comment.
20	Consultee 18 CSF Leak Association	Not specified	Restricting embolisation solely to formal research will significantly worsen geographic inequity. SIH care is already highly unequal, as documented in multiple service evaluations. Patients in underserved areas already face >1-year delays to diagnosis and appropriate imaging. Placing the only definitive treatment for many patients behind research-only barriers will deepen this inequity and may amount to	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			indirect discrimination against disabled patients experiencing debilitating SIH symptoms.	
21	Consultee 18 CSF Leak Association	Not specified	Surgery for CSF-VF is currently available on the NHS and carries significantly higher risk and cost than embolisation, including permanent neurological deficit. The draft guidance creates an inconsistency: allowing a high-risk option as standard care while restricting a lower-risk alternative until research is complete. This raises a practical ethical concern: patients may be forced into surgery solely because embolisation is administratively unavailable, not because it is clinically inferior. A more balanced approach is to permit embolisation within specialist centres alongside robust prospective data collection via a national registry.	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Please see response to comment 10.
22	Consultee 1 Individual	Not specified	NCT03691870: This study has no relevance to this consultation as it deals with a completely different pathology (Brain AVMs)	Thank you for your comment. Please see response to comment 6.
23	Consultee 1 Individual	2.3 2 Information about the procedure	This is not accurate. CT Myelography and digital subtraction myelography can be performed after an embolisation.	Thank you for your comment. Please see response to comment 6 for changes made.
24	Consultee 1 Individual	3.3 Current practice	Once a CSF-venous fistula is confirmed on dynamic myelography either surgery, embolisation or targeted fibrin	Thank you for your comment. Please see response to comment 6.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			patching can be offered to the patient. There is no standard of treatment for CSF-venous fistulas	
25	Consultee 1 Individual	3.4 Unmet need	Another indication for embolisation, and one that has been utilised in my own institution, is in treatment of multi-level CSF-venous fistulae. The procedure is minimally invasive.	Thank you for your comment.
26	Consultee 1 Individual	3.7 Clinical effectiveness	Rebound intracranial hypertension can occur following the successful occlusion of a CSF venous fistula (whether this is achieved surgically, by fibrin patching, or by embolisation). This is often an indicator of successful fistula treatment. Rebound intracranial hypertension is often self limiting, but can also be easily managed medically.	Thank you for your comment.
27	Consultee 1 Individual	3.11 Committee comments	The procedure is performed by interventional neuroradiologists, who have the requisite skill and knowledge required to access and navigate the relevant vascular anatomy, using equipment utilised in daily practice.	Thank you for your comment. Please see response to comment 13.
28	Consultee 1 Individual	3.13 Committee comments	This implies surgery and or fibrin patching is the standard of care for CSF-venous fistulas (which is incorrect).	Thank you for your comment. Please see response to comment 6.
29	Consultee 1 Individual	3.14 Committee comments	As mentioned earlier, this is incorrect. Both modalities can be performed following embolisation.	Thank you for your comment.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
30	Consultee 6 Individual	Not specified	The lack of CSF volume, indicating a leak can be seen on head MRI - brain sag (pseudo chiari malformation), venous engorgement, etc. The full impact of this condition has not been mentioned. The impact on quality of life of people with a CSF leak is enormous. Many are bedridden or at least have severe limitations to their daily lives this is often completely resolved with successful sealing of the CSF venous fistula. I would say the main aim of embolisation is to treat and seal the present CSF venous fistula and to therefore stop CSF leaking. The secondary aim is to prevent a CSF leak at the same point.	Thank you for your comment. People with lived experience, a patient organisation and clinical experts shared impact of the condition during the committee meeting. Committee took this into consideration when making their recommendation. Please see section 3.9 of the guidance.
31	Consultee 14 King's College Hospital	Not specified	The guidance repeatedly treats transvenous embolisation as "new" or exceptional compared with fibrin injection and surgery. This does not reflect clinical reality: CSF–venous fistula (CSF-VF) was only characterised in 2014 and all current treatments have emerged concurrently and share a similarly limited evidence base. EVOH embolisation uses long-established, licensed neurovascular techniques already familiar to interventional neuroradiologists. I suggest to acknowledge explicitly that no established standard of care exists, that all treatments are equally recent, and that embolisation should not be uniquely categorised as novel or exceptional. The current draft risks inadvertently promoting off-label fibrin	Thank you for your comment. Consultee suggests reframing the guidance to acknowledge the lack of a defined standard of care, recognise that embolisation has a comparable evidence base, permit continued clinical use, support a national registry, and ensure balanced evaluation of all treatment options. Please see responses to comments 1, 6, 10 and 12.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			injection (with acknowledged risks and limited evidence) while restricting the only fully intravascular, licensed embolic option. This could harm equity and undermine patient care pathways. I suggest to reframe the guidance to: 1) acknowledge the absence of a defined standard of care; 2) reflect that embolisation has a comparable or stronger evidence base; 3) allow ongoing clinical use; 4) support a national registry; 5) ensure even-handed evaluation of all treatment modalities.	
32	Consultee 14 King's College Hospital	2.3 2 Information about the procedure	The document states the procedure does not offer a way to confirm fistula closure. This is inaccurate: intra-procedural or follow-up dynamic CT myelography or digital subtraction myelography can assess fistula resolution where clinically appropriate. I suggest to amend text to note that objective radiological confirmation is possible using established myelographic techniques.	Thank you for your comment. Please see response to comment 6 for changes made.
33	Consultee 14 King's College Hospital	3.4 Unmet need	The guidance incorrectly describes embolisation as an "alternative" when surgery is unsuitable or when fibrin glue fails. In practice, transvenous embolisation is widely used as a first-line treatment in the UK and internationally, with high rates of improvement and no major complications reported. I suggest to revise section to state that embolisation is a first-line treatment option in many centres and should not be	Thank you for your comment. Consultee suggests updating guidance to clarify: - transvenous embolisation not to be framed as alternative as the procedure

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			framed as secondary to fibrin injection or surgery. The claim that transvenous embolisation is “more invasive” than CT-guided fibrin glue injection is not supported by evidence. Embolisation requires a single venous puncture, often without GA, and avoids needle placement near the thecal sac. Conversely, fibrin glue products are licensed only for topical use, often spread intravascularly, and carry FDA black-box warnings. I suggest to update the text to reflect that embolisation is not more invasive than fibrin injection and is associated with a favourable safety profile. Ensure consistency by acknowledging the regulatory and safety considerations surrounding fibrin glue.	is used as first-line treatment in the UK and internationally. - not more invasive than fibrin injection. Please see response to comment 6. Committee acknowledged that transvenous embolisation is not more invasive than fibrin injection. The amendment in recommendation reflects that. Please see section 3.10 of the guidance.
34	Consultee 14 King’s College Hospital	3.10 Committee comments	The guidance states embolisation is “usually” performed under general anaesthesia. This is incorrect: major published series and UK practice demonstrate frequent use of local anaesthesia or conscious sedation, often as a day-case procedure. I suggest to amend stating that the procedure can be performed without general anaesthesia and is commonly delivered as a day-case.	Thank you for your comment. Please see response to comment 6 for changes made.
35	Consultee 14 King’s College Hospital	3.11 Committee comments	The recommendation for “specialist centres” is appropriate but not sufficiently specific. Technical skills required for spinal and cranial venous navigation are core to interventional neuroradiology.	Thank you for your comment. Please see response to comment 13 for changes made.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			I would specify that the procedure should be performed by consultant interventional neuroradiologists with appropriate experience in neurovascular embolisation and spinal imaging.	
36	Consultee 14 King's College Hospital	3.15 Equality considerations	The guidance describes the procedure as available only in a "limited number" of centres. At least 14 UK hospitals currently provide embolisation, and more have relevant expertise. No comparable survey of fibrin injection or surgery availability has been undertaken. I would update centre availability data; note that embolisation is already widely adopted and in some regions represents the only accessible treatment.	Thank you for your comment. Consultee reports that at least 14 hospitals currently provide embolisation. Committee noted that while the procedure is carried out in at least 14 hospitals, the volume of cases varies between hospitals, ranging from single case to multiple cases. Some centres are more specialised than others and accept referrals from other hospitals. Change made to section 3.16 'The procedure is only offered in specialist centres in the UK.' Committee acknowledged that embolisation is widely adopted procedure. Please see response to comment 6.
37	Consultee 18 CSF Leak Association	Not specified	While the Committee notes the absence of UK comparative trials, it is important to contextualise this. CSF-VF is a rare condition; randomised trials comparing embolisation versus surgery are unlikely to be feasible or ethical for patients in	Thank you for your comment. Please see response to comment 17.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			whom surgery risks permanent neurological deficit. International data from centres performing >300 procedures demonstrate reproducible success and low complication rates. This amounts to “best available evidence” for a rare condition and should be weighed accordingly	
38	Consultee 1 Individual	1.2 What research is needed	Several UK centres have performed this procedure with good results. Data collection is underway and manuscript preparation in progress for publication in the 1st half of next year	Thank you for your comment.
39	Consultee 11 Medtronic	Not specified	Onyx	Thank you for your comment.
40	Consultee 11 Medtronic	Not specified	Onyx 18	Thank you for your comment.
41	Consultee 11 Medtronic	1	Medtronic would like to thank NICE for the opportunity to comment on the IPG draft recommendation. Furthermore, Medtronic would like to publicly state we have consistently and will continue to support the approach that NICE in all its forms takes in the evaluation of technologies and its place in ensuring best value for the NHS.	Thank you for your comment.
42	Consultee 1 Individual	1.1 1 Recommendations	Spontaneous Intracranial Hypotension is a debilitating condition caused by a spinal CSF leak. It has an incidence of 5 in 100000 per year, though this may be underestimated. CSF-venous fistulae are a subtype of spinal leak and account for approximately 25% of spinal CSF leaks. Their incidence	Thank you for your comment. Please see responses to comments 7 and 30.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			therefore is not common. Furthermore, this disease entity was only recently described (first described in 2014). The three available treatments for this: surgery, embolisation and targeted fibrin patching are by extension all relatively novel. The evidence base for all three methods of treatment is modest. It would be appropriate to collect data on treatment outcomes and safety for all available treatment	
43	Consultee 1 Individual	1.2 Why the committee made these recommendations	An analysis of safety and efficacy of surgical and targeted fibrin patching should also be performed prior to making this recommendation. There is no greater evidence for surgery or fibrin patching	Thank you for your comment. Please see response to comment 7.
44	Consultee 1 Individual	3.12 Committee comments	This applies equally to surgery and targeted fibrin patching for CSF-venous fistulas. One may argue that the evidence base for embolisation is greater than, if not equal to, that of surgery or fibrin patching.	Thank you for your comment. Please see response to comment 7.
45	Consultee 14 King's College Hospital	1.2 Why the committee made these recommendations	NICE applied greater scrutiny to embolisation than to fibrin injections or surgery, despite all three treatments sharing similar evidence constraints. The largest published series for embolisation exceeds the sample size and follow-up quality for either surgical or fibrin injection cohorts. I think that equivalent scrutiny should be applied to all treatment modalities. Consider including the forthcoming UK	Thank you for your comment. Please see responses to comments 6 and 7.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			data before finalising the guidance. Remove the unrelated AVM trial from the evidence list.	
46	Consultee 2 Individual	Not specified	My best friend had a transvenous embolisation for spontaneous intracranial hypotension caused by a CSF - venous fistula. She had this procedure done at NNH (Queens Square) after the consultants identified that a venous fistula was the issue. Prior to this it had taken a number of years for the medical profession to recognise that she had a CSF leak at all; in fact it was only because I'd researched her symptoms and assisted in conveying this information to a doctor that she was referred to NNH in the first place. At NNH my friend had caffeine and blood patch treatments but these only offered temporary relief from her symptoms. The consultants' discovery of a venous fistula and the subsequent treatment were life changing for my friend, meaning that she could at last live a normal life again.	Thank you for your comment. Please see response to comment 30.
47	Consultee 8 Individual	Not specified	This embolisation treatment truly changed my life. By late 2023 I had been suffering with tinnitus, bad headaches in the back of my head and a general feeling of "fogginess" for several months, which all gradually became worse. I was suddenly admitted to A&E one morning in December '23, when I was violently sick and suffering intense headaches and balance problems. After various CT and MRI scans at Queen's Hospital (neurology) in Romford, I underwent an epidural blood patch procedure because they suspected a CSF leak resulting in SIH. This did not improve my	Thank you for your comment. Please see response to comment 30.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			symptoms and I was then transferred to the NHNN in Queen Square. There I underwent a second epidural blood patch but, after discharge, although my symptoms improved slightly for a while, they all returned as before. I was feeling the same general slowness and "fogginess" and suffering the same tinnitus and headaches, which adversely affected my ability to work and my general ability to function, and my general quality of life was seriously impaired. After a myelogram which identified the precise position of the fistulas suspected to be causing the CSF leak, I underwent this transvenous embolisation procedure under general anaesthetic. I can only say that the beneficial effects were immediate, the headaches and tinnitus stopped and my head "cleared". There were no side effects from the procedure and I suffered no complications. I was aware that, without this treatment, I was heading for progressively deteriorating neurological symptoms, so I will for ever be grateful that this treatment was available to me. It has restored my health completely and as at the date of writing these comments I have had no recurrence of any symptoms.	
48	Consultee 10 Individual	Not specified	I suffered with CSF Leak in 2018 which was undiagnosed for 7 months leaving me bedridden. Eventually my friend researched my symptoms and found them compatible with SIH and helped me talk with my consultant neurologist who eventually referred me to NHNN in Queens Square London. I had various treatments from intravenous caffeine infusions to two epidural blood patches, the second using fibrin glue. The	Thank you for your comment. Please see response to comment 30.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			second blood patch did give me significant relief of my symptoms - mainly headache and vertigo. However after a year or so all symptoms gradually returned. I was continually monitored and eventually had an MDT who decided to give me a CT Myelogram as MRIs hadn't shown where I was leaking. This showed a venous fistula on my spinal cord and with very little time wasted I had an embolisation at Queens Square in September 2023 which has given my life back. I'm only left with tinnitus, slight hearing loss and slight cognitive impairment. If only this treatment was readily available, many more people like me could be helped and given their life back. Please make it readily available to all who could benefit from it.	
49	Consultee 17 Individual	Not specified	Having suffered from SIH for several years and suffering from life restricting symptoms affecting my daily life and ability to work and once diagnosed I was offered pain relief in the first instance followed by two failed blood patches it was identified I had multiple venous fistulas and was therefore given the Transvenous Embolisation, this procedure offered me relief of my symptoms and has enabled me to begin to carry out my daily life routines and a return to a normal lifestyle. This has immensely improved the quality of my life and the benefits of this treatment means that I can return back to life as normal. I feel that without this treatment option that my severe symptoms would have not been resolved and my quality of life limited as there is currently no effective pain relief for this condition, the fatigue of brain fog, severe headaches,	Thank you for your comment. Please see response to comment 30.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			dizziness, back/spinal pain is totally disabling which impacts on your physical and mental wellbeing. This condition causes deconditioning as you are unable to do any form of exercise without severe pain and this causes other medical conditions. This treatment was my only solution for multiple fistulas and the only option to return to a good quality of life and thus should be offered to suffers of venous fistulas.	
50	Consultee 19 Individual	Not specified	I'm responding to your Instagram page, Your Voice Matters, Transvenous embolisation to repair CSF Venous Fistulas. My son has been under the care of a excellent team in [redacted] My son suffered numerous falls which caused, contributed too him having multiple CSF venous fistulas. It's taken some years for my son now to start living a normal life, upright position after having to continually lay down because of the complications, complexity, disabling symptoms of his Venous Fistulas, which took some time for Dr [redacted] team to identify and repair, seal, by means of transvenous embolisation. He is still under the care & future treatment plans under the excellent care of Dr [redacted], with hope they can have him back doing the job he loved. I've attached a recent report from one of Dr [redacted] team, who operated on him, but he and Dr [redacted] will be able to give you more details on everything, His care, procedures ect in more detail, along with Dr [redacted] plans for him, further	Thank you for your comment. Please see response to comment 30.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			procedures ect. We will look forward too hearing back from yourselves, hopefully his journey, challenges and Dr [redacted] & his team can help others.	
51	Consultee 18 CSF Leak Association	Not specified	We strongly support a national SIH registry and agree it should capture: • patient selection criteria • imaging findings • procedural details • outcomes and recurrence • long-term follow-up. However, registries and RCTs are not substitutes for each other. A registry can run now; an RCT may never be feasible. Restricting NHS care until an RCT exists — particularly given the small population — may unintentionally deny treatment to an entire generation of patients.	Thank you for your comment. Committee discussed potential amendment to the recommendation. Please see response to comment 1. Please see responses to comments 10 and 17.
52	Consultee 1 Individual	Not specified	British Society of Neuroradiology (BSNR) UK Neurointerventional Group (UKNG) Both these organisations are directly involved in management of patients with SIH and CSF-venous fistulas and should be included	Thank you for your comments. The specified stakeholders have been added to the 'Professional societies' section of the overview.
53	Consultee 1 Individual	Not specified	It is important to differentiate recurrence at the site of treatment (treatment failure) from development of a new	Thank you for your comment.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			fistula at a different site. The latter is an effect of the underlying pathophysiology and does not constitute treatment failure. Treatment failure in surgery and embolisation is very low, whereas is more frequent in fibrin patching.	For the outcome "rate of recurrence or retreatment", comprised two components: recurrence or residual fistulas at the original treatment site, and the development of new fistulas at different spinal levels that required further treatment.
54	Consultee 20 Individual	Not specified	Along with other UK clinicians in this field, I am concerned that the decision to recommend that this procedure should only be performed in the context of formal research that has been approved by a REC is unduly stringent and will effectively stifle the generation of the further evidence regarding the procedure within the UK that the committee consider necessary. Previous recommendations, for procedures such as middle meningeal artery embolisation, have been less prescriptive and defined research as potentially being 'analysis of registry data with long term outcomes, randomised controlled trials or other suitable studies'. My opinion is that such an approach for transvenous embolisation would be more likely to generate the data needed to provide further evidence regarding the use of this procedure. Centres currently undertaking this procedure have already followed local Trust governance requirements regarding the introduction of new procedures, including assessment of	Thank you for your comment. Consultee disagrees with the recommendation. Committee discussed potential amendment to the recommendation. Please see response to comment 1 Consultee flags that, although a UK registry is in development, established alternatives already exist, including the multicentre European 'SEAL' registry (University Hospital Freiburg) and the international iLeak registry (National Organisations of Rare Disorders), and that centres should be able to decide independently which registry they submit their data to. Please see response to comment 10.

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
			existing data on effectiveness and safety. Collection of outcome data and analysis of complications forms part of these requirements and to subsequently mandate REC approved research as being necessary would potentially exclude this data gathered already from being used. With respect to the submission of data to patient registries, I would repeat a previous comment I have made that I do not think that the guidance should be prescriptive with regards to a specific registry. Whilst I am aware that there are plans underway to form a UK registry, there are also more established efforts for a multicentre European registry ('SEAL') co-ordinated by University Hospital Freiburg and also an international registry ('iLeak') hosted by the National Organisation for Rare Disorders (NORD). My firm opinion is that it should be at the discretion of each centre as to which registry they submit their data to.	

"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."