[GID-IPG10440] Middle Meningeal Artery Embolisation for Chronic Subdural Haematomas

Final Protocol

Produced by: York Health Economics Consortium

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Date completed: 29/01/2026

1. Decision problem

Middle meningeal artery embolisation (MMAE) has been identified by NICE for a HealthTech evaluation. As described in the NICE scope, the aim of this evaluation is to assess the efficacy and safety of MMAE for chronic subdural haematomas. This protocol is a response to the NICE scope and presents the proposed methods that YHEC will undertake to evaluate MMAE.

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the published scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description
Population(s)	People with chronic subdural haematomas.

Subgroups	If the evidence allows the following subgroups may be considered:
	• People who have had evacuation surgery (burr-hole evacuation or a craniotomy) in addition to MMAE
	• People who have not had evacuation surgery because:
	  ○ evacuation surgery is unsuitable (for example due to treatment with blood-thinning medication or frailty)
	  ○ evacuation surgery is suitable, but it is not chosen as an option
	  ○ evacuation surgery is not indicated due to no symptoms or symptoms being less severe
	• People who have MMAE for recurrent chronic subdural haematomas (with or without surgery)

Intervention(s)	MMAE with an embolic agent (with a particle, liquid embolic agent, coil or in combination) as a stand-alone treatment or as an adjunct to evacuation surgery
Key efficacy outcomes	• embolisation of the target vessel • hematoma resolution • hematoma recurrence • hematoma progression • need for further intervention (including conversion to surgical procedure or reoperation) • independent ambulation

	• change in haematoma size (e.g. width, thickness, volume or midline shift) • length of hospital stay • neurological disability (e.g. modified Rankin scale) • independence in daily activity (e.g. Barthel Index) • motor function • cognitive function • quality of life
Key safety outcomes	• stroke or myocardial infarction • mortality • neurological complications • facial droop • visual loss • procedure or device-related adverse events or complications • access site bleeding or complications

1.1 Objectives

The purpose of this assessment is to conduct a rapid review to address the following key decision questions:

- What is the clinical efficacy and safety of MMAE as a treatment for chronic subdural haematomas?
- What are the key gaps in the evidence base?

2. Evidence review methods

The following sections describe the methods that the EAG will use to address the decision questions. These methods conform to the NICE Interventional Procedures Programme Manual and aim to identify the key evidence for the procedure and prioritise the most appropriate studies.

The evidence review will include a pragmatic review of the literature, including journal databases and trial registries. The evidence review will also include relevant information from company submissions and evidence requests.

2.1 Inclusion criteria

The eligibility criteria are summarised in Table 2 and reflect the decision problem set out in the NICE scope.

Table 2. Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria

Population	People with chronic subdural haematomas[1]
	
	Eligible subgroups:
	• people who have had evacuation surgery (burr-hole evacuation or a craniotomy) in addition to MMAE
	• people who have not had evacuation surgery because:
	  ○ evacuation surgery is unsuitable (for example due to treatment with blood-thinning medication or frailty)
	  ○ evacuation surgery is suitable, but it is not chosen as an option
	  ○ evacuation surgery is not indicated due to no symptoms or symptoms being less severe
	• People who have MMAE for recurrent chronic subdural haematomas (with or without surgery)
	• People who have MMAE for primary chronic subdural haematomas (with or without surgery)
		People without chronic subdural haematoma

Intervention	MMAE: • MMAE alone • MMAE as an adjunct to evacuation surgery With one or more of the following: • liquid agents, including copolymers dissolved in dimethyl sulfoxide and n-Butyl Cyanoacrylate • particle agents, including polyvinyl alcohol, tris-acyl gelatin and gelatin sponge • coil embolization with/without agent	Other treatments for chronic subdural haematomas

Comparators	• standard of care (burr hole surgery or craniotomy) • conservative management (monitoring and/or medication) • no comparator • another eligible intervention	
Outcomes	Efficacy outcomes such as: • embolisation of the target vessel • hematoma resolution • hematoma recurrence • hematoma progression • need for further intervention (including conversion to surgical procedure or reoperation) • independent ambulation • change in haematoma size (e.g. width, thickness, volume or midline shift) • length of hospital stay • neurological disability (e.g. modified Rankin scale) • independence in daily activity (e.g. Barthel Index) • motor function • cognitive function • quality of life Safety outcomes such as: • stroke or myocardial infarction • mortality • neurological complications • facial droop • visual loss • procedure or device-related adverse events or complications • access site bleeding or complications	• Studies not reporting at least one eligible outcome • Studies reporting only biochemical/ physiological measurement outcomes
Study design	• systematic reviews with meta-analysis[2] • RCTs • cohort studies • case-control studies	• systematic reviews without meta-analysis • narrative reviews • case reports[4]

	• single arm studies	• laboratory/animal studies • news items, opinion pieces, editorials, comments
Other limits	• English language publications • conference abstracts since 2023[3]	• non-English language publications • conference abstracts published pre-2023

Abbreviations: MMAE – middle meningeal artery embolisation; RCT – randomised controlled trial.

[1]Studies of populations with mixed diagnoses e.g. subdural or epidural haematomas, will be included where ≥80% of participants have subdural haematomas

[2] Most recent systematic reviews or those that target relevant subgroups

[3] Provided they contain sufficient detail on methods and outcomes

[4] Due to the large evidence base, case reports will be excluded.

2.2 Search strategy

The external assessment group (EAG) will use methodology based on that outlined in section 5 of the interventional procedures programme manual to conduct a literature search.

A MEDLINE (OvidSP) search strategy designed to identify studies of MMAE for people with chronic subdural haematoma is presented in Appendix A.

The strategy comprises three concepts:

- chronic subdural haematoma (search lines 1 to 6)
- middle meningeal artery (search lines 7 to 10)
- embolisation (search lines 11 to 17).

The concepts are combined as follows: Chronic subdural haematoma AND middle meningeal artery AND embolisation.

The strategy was devised using a combination of subject indexing terms and free text search terms in the Title, Abstract, and Keyword Heading Word fields. The search terms were identified through scanning background literature and browsing database thesauri.

The strategy excludes animal studies from MEDLINE using a standard algorithm (search line 19). The strategy also excludes some ineligible publication types which are unlikely to yield relevant study reports (editorials and news items) (search line 20).

The strategy is restricted to studies published in English language.

The final Ovid MEDLINE strategy will be peer-reviewed before execution by a second Information Specialist. Peer review will consider the appropriateness of the strategy for the review scope and eligibility criteria, inclusion of key search terms, errors in spelling, syntax and line combinations, and application of exclusions.

We will conduct the literature search in the databases shown in Table 3.

Table 3: Databases and information sources to be searched

Resource	**Interface / URL**
Databases	
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Cochrane Database of Systematic Reviews (CDSR)	Cochrane Library/Wiley
Cochrane Central Register of Controlled Trials (CENTRAL)	Cochrane Library/Wiley
HTA Database	https://database.inahta.org/
Conference Proceedings Citation Index – Science (CPCI-S)	Web of Science
Trials Registers	
ClinicalTrials.gov	https://clinicaltrials.gov/
WHO International Clinical Trials Registry Platform (ICTRP)	https://trialsearch.who.int/
Device safety alerts	
Medicines and Healthcare products Regulatory Agency (MHRA)	https://www.gov.uk/drug-device-alerts
FDA Manufacturer and User Facility Device Experience (MAUDE) Database **(if appropriate)**	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
Company Submission Evidence	n/a

Reflecting the eligibility criteria, CPCI-S search results and records indexed in Embase as conference abstracts will be restricted to studies published from 2023 to date.

Recent research published as conference abstracts will be identified by searching Embase (which indexes a significant number of conference publications) and CPCI-S (a conference proceedings citation index for science disciplines).

Medicines and Healthcare products Regulatory Agency (MHRA) device alerts will be searched to check for any safety alerts for the named technologies identified. If there is sufficient safety data identified as part of the literature search, the FDA Manufacturer and User Facility Device Experience (MAUDE) will not be searched as the technologies of interest are used for multiple indications and MAUDE reports will be unlikely to provide additional information. Reporting of safety alerts will be prioritised if the outcomes are not reported elsewhere in the literature.

Published and unpublished studies provided by companies and other stakeholders will also be considered if relevant to the decision problem.

2.3 Study selection

The EAG will use the methodology outlined in section 5 of the interventional procedures programme manual for study selection.

Record assessment for database/registry searches will be undertaken as follows:

- Records will be uploaded to EndNote, where they will be manually deduplicated. A single reviewer will assess the search results according to their relevance in providing information on the safety and clinical effectiveness of MMAE for CSDH and will remove the obviously irrelevant records such as those about ineligible diseases.

- Relevant records will be uploaded to Covidence, to be manually screened. A single reviewer will independently assess the titles and abstracts of remaining records for relevance against the eligibility criteria. A senior reviewer will be available to consult in all cases of uncertainty.

- We will obtain the full text of potentially relevant studies and a single reviewer will assess the full texts for relevance against the eligibility criteria. A senior reviewer will be available to consult in all cases of uncertainty.

The selection of information from company submissions and other relevant sources will be undertaken as follows:

- A single reviewer will evaluate all documents for relevance.
- A senior reviewer will check the relevance of all included studies/documents.

Following study selection:

- We will record the number of records included and removed at each selection stage in the PRISMA flow diagram. We will list studies excluded after assessment of the full document in an excluded studies table, with the reasons for exclusion.
- Where results for one study are reported in more than one paper, all related papers will be identified and grouped together to ensure that participants in individual studies are only included once.
- If large numbers of eligible studies are found, selected evidence for reporting in the main text will be prioritised and the studies most relevant to the decision problem will be extracted. Where there are large numbers of potentially eligibility studies, there may also be prioritisation in the selection of studies reported as supporting information in the appendix. Criteria for prioritisation will be agreed with NICE following study selection and will depend on how large the evidence base is but may include:
    - limiting by study design (e.g. systematic review or RCT evidence)
    - limiting by location of study (e.g. UK or Europe)
    - limiting to studies with larger sample sizes
    - limiting by date.
    - limiting to studies reporting priority outcomes e.g. rates of resolution

2.4 Data extraction strategy

A data extraction template will be developed in Word and piloted on 3 included studies. One reviewer will extract data and a second reviewer will check outcome data points. Any discrepancies will be resolved by discussion, or the involvement of a third reviewer when required. Data extraction will be targeted, involving the extraction of key details describing the study reference (bibliographic details), study design, key patient characteristics, key intervention / comparator characteristics, and outcomes.

Data extraction elements will include:

- bibliographic details
- study type/design
- country (or countries) where study was done
- recruitment period
- study population and number (total number of patients and, when relevant, number of patients treated with the procedure of interest)
- age and sex of patients and whether haematoma is de novo or recurrent
- key patient selection criteria e.g. ineligible for surgery
- intervention type e.g.: MMAE alone or in combination with surgery
- intervention technique (such as femoral, radial or temporal artery, local or general anaesthetic, blocking agent used)
- comparator (where relevant)
- length of follow-up (mean or median when stated)
- funding source

- for each relevant outcome, outcome definition, the unit of measurement, the number of patients included in the analysis, and the size of the effect.

2.5 Quality assessment strategy

One reviewer will assess the risk of bias and generalisability of each included study with reference to key identified issues. A formal risk of bias will not be presented but identified issues will be highlighted. A second reviewer will check the risk of bias and generalisability judgements.

The report will comment on the generalisability of results to clinical practice in the NHS.

2.6 Reporting

Following prioritisation, the most valid and relevant studies will be presented in evidence summary tables in the assessment report. We will provide a brief narrative summary exploring the quality of the studies and patterns that have discerned in the data. Depending on the available data, studies may be presented sub-grouped by MMAE delivery (e.g. as a stand-alone procedure or adjunct to surgery), population group (e.g. those with a primary or recurrent disease), or procedure type.

The evidence summary table will comprise:

- study and population details
- analysis (brief critical appraisal of risk of bias and generalisability)
- efficacy outcomes
- safety outcomes.

The remaining eligible studies (those not included in the evidence summary table) will be listed in an appendix, with brief details of each study.

3. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders will be considered by the EAG if received by 23/02/2026. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any 'commercial in confidence' data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report. Any 'academic in confidence' data provided by company(s), and specified as such, will be highlighted in yellow and underlined in the assessment report.

4. Additional information sources

NICE will recruit experts for this assessment. Experts are recruited in accordance with NICE's appointments to advisory bodies policy and procedure.

5. Competing interests of authors

The EAG can confirm that there are no conflicts of interests to declare for the project team.

Appendix A: Draft search strategy

Search strategy for Ovid MEDLINE® ALL

1	hematoma, subdural, chronic/	2260
2	((subdural or sub-dural) adj3 (hematoma* or haematoma*)).ti,ab,kf.	12244
3	((subdural or sub-dural) adj3 (hemorrhag* or haemorrhag*)).ti,ab,kf.	2221
4	((subdural or sub-dural) adj3 (bleed* or blood*)).ti,ab,kf.	395

5 (csdh or sdh).ti,ab,kf. 9552

6 or/1-5 20447

7 meningeal arteries/ 1318

8 middle meningeal.ti,ab,kf. 2007

9 (meningeal artery or meningeal arteries).ti,ab,kf. 2228

10 or/7-9 2766

11 embolization, therapeutic/ 39606

12 endovascular procedures/ 33608

13 (embolotherap* or embolo-therap*).ti,ab,kf,ot. 876

14 emboli*.ti,ab,kf,ot. 174986

15 (endovascular* or intravascular* or intraarter* or endo vascular* or intra vascular* or intra arter*).ti,ab,kf,ot. 162587

16 (block* or particle* or liquid* or coil*).ti,ab,kf,ot. 2051259

17 or/11-16 2352238

18 6 and 10 and 17 673

19 exp animals/ not humans/ 5414501

20 (news or editorial).pt. 979895

21 or/19-20 6366647

22 18 not 21 659

23 limit 22 to english language 645

Saved in Ovid as: temp - MMAE for CSDH – MEDLINE3 - for protocol