NICE National Institute for Health and Care Excellence

Guidance assessment consultation document for HTG10870 Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver

17 June 2026

Cancer can start in the liver (primary) or spread to it from another part of the body (metastatic). In this procedure, a very high dose of anticancer medicine (chemosaturation) called melphalan is put into the liver. Because melphalan can be toxic to the rest of the body it is added directly to the blood supply going into the liver (percutaneous hepatic artery perfusion). Blood leaving the liver is diverted (hepatic vein isolation) and taken out of the body. It is filtered to remove any melphalan and returned to the body. The aim is to destroy the cancer without causing side effects in the rest of the body.

NICE interventional procedures guidance applies to the NHS in England, Wales and Northern Ireland.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations on the safety and efficacy of these procedures. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver in the NHS. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of safety and efficacy reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver. The recommendations in section 1 may change after consultation.

More details are available in NICE's interventional procedures programme manual and NICE's HealthTech programme manual.

Key dates:

Closing date for comments: 7 July 2026

Second committee meeting: 6 August 2026

1 Recommendations

For ocular melanoma liver metastases

1.1 Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation can be used in the NHS during the evidence generation period as an option to treat ocular melanoma liver metastases. There must be enhanced informed consent and auditing of outcomes.

For primary liver cancer or liver metastases other than ocular melanoma metastases

1.2 More research is needed on melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation to treat primary liver cancer or liver metastases other than ocular melanoma metastases before it can be used in the NHS.

1.3 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

What this means in practice

For ocular melanoma liver metastases

There are uncertainties around the safety and efficacy of this procedure. It can be used if needed while more evidence is generated.

After this, NICE will review this guidance and the recommendations may change.

Healthcare professionals do not have to offer this procedure and should always discuss the available options with the person with ocular melanoma liver metastases before a joint decision is made.

Hospital trusts will have their own policies on funding procedures and monitoring results. NHS England may also have policies on funding of procedures.

Enhanced informed consent

Because there are uncertainties about the procedure's safety and efficacy, there must be an emphasis on informed consent. Healthcare professionals must make sure that people (and their families and carers as appropriate) understand the uncertainty and lack of evidence around a procedure's safety and efficacy using NICE's advice on shared decision making and NICE's information for the public. Healthcare professionals must also inform the clinical governance leads in their organisation if they want to do the procedure.

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Details about everyone having this procedure should be entered into an appropriate registry. If there is no data collection method already available, NICE's interventional procedure

outcomes audit tool should be used. Healthcare professionals should regularly review the data on outcomes and safety.

Who should be involved with the procedure

Patient selection should be done by a multidisciplinary team. This procedure should only be done in specialist centres by healthcare professionals with specific training in this procedure. This should include licensed clinical perfusionists.

For primary liver cancer or liver metastases other than ocular melanoma metastases

There is not enough evidence to know if this procedure is safe and efficacious. Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation should only be done as part of formal research.

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Details about everyone having this procedure should be entered into an appropriate registry. If there is no data collection method already available, NICE's interventional procedure outcomes audit tool should be used. Healthcare professionals should regularly review the data on outcomes and safety.

Who should be involved with the procedure

Patient selection should be done by a multidisciplinary team. This procedure should only be done in specialist centres by healthcare

professionals with specific training in this procedure. This should include licensed clinical perfusionists.

What evidence generation is needed

Healthcare professionals must collect data specifically around the safety and efficacy of this procedure for ocular melanoma liver metastases. This can be in the form of registry studies or formal research studies that include comparative data.

This includes data on:

- patient selection, including:
  - eligibility for standard first-line treatment (tebentafusp immunotherapy) in people who test positive for the HLA-A*02 allele
  - how much of the liver is involved (tumour burden)
  - presence of metastases outside the liver
- response rate stratified by the number of treatment cycles of melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation
- short- and long-term quality of life
- other treatments used before or after melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation
- safety outcomes
  - during the procedure
  - related to chemotherapy
- how long people have before their cancer gets worse and how long people live after the procedure.

What research is needed

More research, preferably in the form of randomised controlled trials, is needed on this procedure for primary liver cancer or liver metastases other than ocular melanoma metastases. This includes data on:

- patient selection, including
  - type of tumour, including primary cancer site
  - how much of the liver is involved (tumour burden)
  - presence of metastases outside the liver
- number of treatments
- short- and long-term quality of life
- other treatments used before or after melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation
- safety outcomes
  - during the procedure
  - related to chemotherapy
- how long people have before their cancer gets worse and how long people live after the procedure.

Why the committee made these recommendations

There are limited treatment options for people with ocular melanoma liver metastases, particularly for people without the HLA-A*02:01 genotype, who have no other treatment option.

A randomised controlled trial on uveal melanoma liver metastases suggests that this procedure increases how long people have before their liver cancer gets worse compared with best alternative care. But the results are uncertain because:

- the trial did not include enough people to make meaningful statistical comparisons on key outcomes
- the proportion of people with cancer outside the liver at the start of the trial was not the same in the different groups

- data on treatments offered after the procedure was not collected, so the potential effect of these on how long people live is unknown.

The trial did not show a statistically significant improvement in how long people live after the procedure. It is also unclear whether delaying cancer progression in the liver directly helps people to maintain their quality of life. So, it is uncertain whether the procedure offers any sustained benefit.

There is some evidence from observational studies that shows quality of life after the procedure was not negatively affected, even though the procedure may have serious complications. But the studies are not consistent in who was eligible for the procedure and the number of treatment sessions given.

Despite this uncertainty, the evidence is sufficient for this procedure to be used for people with ocular melanoma liver metastases while more evidence is generated. This includes registry data or studies that include comparative data.

For primary liver cancer or liver metastases other than ocular melanoma metastases, there was a lack of evidence on safety and efficacy. There are other treatment options for people with primary liver cancer or non-ocular-melanoma liver metastases. So, this procedure should only be done as part of formal research in this group of people.

2 Information about the procedure

2.1 Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation is done under general anaesthesia. A high dose of melphalan chemotherapy is delivered directly into the hepatic artery, which supplies the liver. Blood leaving the liver is diverted out of the body and filtered to reduce the level of melphalan before being returned to the circulation. The aim is to allow high doses of melphalan chemotherapy to be used, which would otherwise not be tolerated because of severe systemic side effects.

2.2 The procedure uses veno-venous bypass perfusion and the extracorporeal circulation is operated by a clinical perfusion scientist. An infusion catheter is inserted, typically into the femoral artery, and guided into the hepatic artery. A multi-lumen, double-balloon catheter is inserted into the inferior vena cava and across the hepatic veins. The balloons are inflated so that all blood leaving the liver through the hepatic veins enters the catheter rather than the systemic circulation. High doses of melphalan are infused directly into the liver through the hepatic artery infusion catheter over about 30 minutes. Blood leaving the liver passes through an extracorporeal filtration system to remove most of the melphalan and is returned to the circulation through a catheter in the internal jugular vein, in the neck. Full anticoagulation with heparin is needed throughout the procedure.

2.3 The procedure causes significant changes in the person's haemodynamic status. This is managed by the anaesthetic team with support from a clinical perfusion scientist.

3 Committee discussion

The interventional procedures advisory committee considered evidence on melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver from several sources. This included evidence submitted by 1 company, a review of efficacy and safety evidence and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 The most common types of primary liver cancer are hepatocellular carcinoma (also known as hepatoma) and cholangiocarcinoma. However, cancer in the liver has often metastasised from other sites, such as the lung, colon, stomach and eye (particularly ocular melanoma).

3.2 In the UK, around 750 people are diagnosed with ocular melanoma each year. The most common type is uveal melanoma. About half of people with uveal melanoma will develop metastases, most often in the liver. The median overall survival from developing distant metastatic disease varies from about 2 to 12 months.

Current practice

3.3 Treatment for primary or metastatic cancer in the liver depends on several factors, including the location and stage of the cancer, how much liver function is preserved and any relevant comorbidities. Treatment options include surgical resection, thermal ablation, systemic drug therapies, transarterial (chemo)embolisation, isolated hepatic perfusion, external beam radiotherapy and selective internal radiation therapy. In people with primary liver cancer, surgical removal with curative intent and liver transplant may be possible. For most people with liver metastases, treatment with curative intent is not possible.

3.4 There are few treatment options for people with ocular melanoma liver metastases. Chemotherapy is generally not used. In the UK, immunotherapy (tebentafusp) is an option for people who test positive for the HLA-A*02:01 allele, which is around half of the uveal melanoma population.

Unmet need

3.5 Different treatment options are available for primary or metastatic cancer in the liver. Systemic chemotherapy is given at a low dose to minimise damage to healthy organs. This low dose may mean undetected microtumours may not be treated. A localised higher dose of melphalan chemotherapy could treat these undetected microtumours, as well as visible tumours.

3.6 There is a particular unmet need for people with metastases in the liver from ocular melanoma, of which uveal melanoma is the most

common type. Metastatic uveal melanoma is associated with poor survival and there is a lack of effective treatment options. NICE's technology appraisal guidance on tebentafusp recommends tebentafusp for treating HLA-A*02:01-positive unresectable or metastatic uveal melanoma in adults, which is around half of the uveal melanoma population. This means there are no effective treatment options for about half of the people who have advanced uveal melanoma. This can create a significant psychological burden for patients and their families, who may feel distress and uncertainty in the absence of viable treatments. Also, tebentafusp is not curative and some people may have tumours that do not respond to it. Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation is suitable for people with or without the HLA-A*02:01 genotype.

Innovative aspects

3.7 The procedure's targeted approach minimises systemic exposure to the chemotherapy drug. Because the hepatic vein is isolated, a much higher concentration of the chemotherapy drug can be administered than in systemic chemotherapy. By delivering the drug to the entire liver, it can potentially treat undetected microtumours in the liver as well as visible tumours, unlike targeted ablation or embolisation procedures. The technique allows treatment of the entire liver in a single session. This is important for people with metastatic uveal melanoma for whom other liver-directed treatment options may be unsuitable because often they have multiple small-volume tumours in their liver.

The evidence

3.8 NICE did a rapid review of the literature on the efficacy and safety of this procedure. The prioritised evidence included 1 randomised controlled trial, 1 pooled analysis from the randomised controlled trial and a non-randomised phase of the same study, 1 pooled

analysis of multicentre case series, 1 retrospective non-randomised comparative study, 3 prospective single-arm studies and 7 retrospective case series. The evidence informing this guidance was only in 1 device. It is presented in the summary of key evidence section in the interventional procedures assessment report. Other relevant literature is in the appendix of the assessment report.

3.9 The professional experts and the committee considered the key efficacy outcomes to be:

- overall survival
- progression-free survival
- tumour response
- quality of life.

3.10 The professional experts and the committee considered the key safety outcomes to be:

- procedure-related complications (including vascular injury, bleeding, thrombosis and cardiovascular events)
- bone marrow or haematological toxicity
- death.

3.11 19 commentaries from people who have had this procedure were discussed by the committee. Survey respondents cited an improvement in quality of life and extended survival after having the procedure. A patient organisation submission highlighted the physical, emotional and psychological burden on people with the condition and their carers.

Committee comments

3.12 Patient selection and timely access to treatment is important because people who are physiologically fitter and have less extensive cancer in the liver can have better outcomes.

3.13 This procedure addresses only cancer in the liver. People might have metastatic disease in other areas of the body.

3.14 The procedure is highly complex with a steep learning curve, so it should only be done in specialist centres with access to a multiple disciplinary team trained in this procedure. The committee was informed that there are fewer intraprocedural adverse events when the procedure is done in specialist centres with more experience.

3.15 Although the reported rate of adverse events is high, most chemotherapy-related events are transient and some may be asymptomatic.

3.16 People with lived experience stated that this procedure allows them to maintain quality of life as they can quickly return to usual activities.

3.17 Collection of data as part of a randomised controlled trial may be limited by people being unwilling to receive best alternative care. But, the committee acknowledged that data can be collected through registries or by using indirect comparisons or historical control data to address some evidence gaps.

3.18 The evidence to be generated should include analysis of response rate stratified by the number of treatment cycles, and subgroup analyses to better understand which patient groups are most likely to benefit from the procedure. There should be adequate matching for confounders between treatment and control groups.

3.19 The evidence considered by the committee only included adults.

Equality considerations

3.20 The incidence rates for eye cancer in the UK are highest in people aged 75 to 79. The committee was informed that a notable proportion of people diagnosed with uveal melanoma are younger than 60.

3.21 The procedure is only offered in a small number of specialist centres in the UK. This may create challenges in accessibility and geographic equity. Delays in diagnosis and treatment may also further widen disparities in care.

4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Rick Body

Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a consultant clinical adviser, a project manager and an associate director.

Helen Gallo and Robbie Pitcher

Technical leads

Evan Campbell

Technical adviser

Anthony Akobeng

Consultant clinical adviser

Corrina Purdue

Project manager

Rebecca Albrow

Associate director

ISBN: [to be added at publication]