

## **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

### **HealthTech Programme**

# **GID-IPG10448 Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver**

## **Final scope**

### **1 Introduction**

The procedure included in this NICE HealthTech evaluation is melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new and significantly modified procedures, or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This assessment is a review of existing NICE interventional procedures guidance on [melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver](#). This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the [Interventional procedures programme manual](#) and the [NICE HealthTech programme manual](#).

## Lay description

Liver 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.

## 2 The condition

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).

In the UK, there are around 6,600 new liver cancer cases diagnosed every year and around 6,300 liver cancer deaths every year ([Cancer Research UK](#)). Around a third of people in England diagnosed with liver cancer aged 15 to 44 survive their disease for 5 years or more, compared with around 5% of people diagnosed aged 75 to 99.

In the UK, around 750 people are diagnosed with ocular melanoma each year and the most common type is uveal melanoma ([Ocular Melanoma UK](#)). The average age at which an ocular melanoma develops is 55 to 60 years ([Moorfields Eye Hospital NHS Foundation Trust](#)). For people with all eye cancers in England, 70% will live at least 5 years after diagnosis and 60% will live at least 10 years after diagnosis ([Cancer Research UK](#)). About half the people with uveal melanoma will develop metastases, most often in the liver ([Ocular Melanoma UK](#)). The median overall survival from developing distant metastatic disease varies from about 2 to 12 months ([Carter T, 2025](#)).

### 3 Current practice

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.

There are few treatment options for people with ocular melanoma liver metastases and chemotherapy is generally not used. In the UK, the first line treatment for most people with metastatic uveal melanoma is immunotherapy.

### 4 Unmet need

There are a number of different treatment options available for treating primary or metastatic cancer in the liver. Systemic chemotherapy requires administration of 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 may treat these undetected microtumours as well as visible tumours.

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. Tebentafusp is recommended for treating HLA-A\*02:01-positive unresectable or metastatic uveal melanoma in adults, which is around half of the uveal melanoma population ([NICE 2025](#)). This means there are no effective treatment options for about half of the people who have advanced uveal melanoma. Melphalan chemosaturation is suitable for people with or without the HLA-A\*02:01 genotype.

## 5 The procedure

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 tumours. 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.

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.

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

### 5.1 Innovative aspects of the procedure

The proposed innovative aspects of the procedure are that it offers a targeted approach that 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

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microtumours as well as visible tumours, unlike targeted ablation or embolisation procedures. The technique allows treatment of the entire liver in a single treatment session, which is important for people with metastatic uveal melanoma who often have multiple small volume tumours in their liver, making other liver directed treatment options unsuitable.

## **5.2 Current known use of the procedure**

The procedure is done in specialist centres only. It is currently only available privately.

## **6 Potential equality issues**

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

- Liver cancer is more common in older people. In the UK, the highest rates are in 85 to 89 year olds ([Cancer Research UK](#)).
- Uveal melanoma is also more common in older people ([NICE](#)).
- In the UK, liver cancer is more common in males than in females ([Cancer Research UK](#)).
- In England, liver cancer is more common in the Asian and Black ethnic groups, but less common in people of mixed ethnicity, compared with the White ethnic group ([Cancer Research UK](#)).
- Melanoma of the eye is more common in White people than Black, Asian or Hispanic people ([Cancer Research UK](#)).
- All people with cancer and therefore people with primary or metastatic liver cancers are covered by the disability provision of the Equality Act 2010 from the point of diagnosis.

- In England, people from the most deprived areas are more likely to develop liver cancer than those from the least deprived areas ([Cancer Research UK](#)).
- The chemotherapy drug used in the procedure may harm an unborn child, so it is unsuitable for people who are pregnant, trying to become pregnant, or are breastfeeding.
- The procedure is not currently available on the NHS. It is only done privately in specialist centres, so some people may not be able to access it.

## 7 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver to determine whether it works well enough and is safe enough for use in the NHS.

**Table 1: Decision problem**

<b>Population</b>	<p>People with primary or metastatic liver cancer.</p> <p>If the evidence allows the following subgroups may be considered:</p> <p>People with liver metastasis from uveal melanoma</p>
<b>Intervention</b>	Melphalan chemosaturation of the liver with percutaneous hepatic artery perfusion and hepatic vein isolation
<b>Key efficacy outcomes</b> (may include but are not limited to)	<ul style="list-style-type: none"> <li>• Overall survival</li> <li>• Progression free survival</li> <li>• Quality of life</li> <li>• Tumour response</li> <li>• Tumour recurrence</li> </ul>

<b>Key safety outcomes</b> (may include but are not limited to)	<ul style="list-style-type: none"> <li>• 30-day mortality</li> <li>• Hepatic arterial thrombosis, dissection, or perforation</li> <li>• Inferior vena cava thrombosis or perforation</li> <li>• Liver toxicity, including increase in alanine aminotransferase (ALT)</li> <li>• Cholangitis</li> <li>• Haematological toxicity</li> <li>• Gastrointestinal toxicity</li> <li>• Hypotension</li> <li>• Haemorrhage</li> <li>• Cardiovascular events</li> <li>• Fatigue</li> </ul>
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## 8 Other issues for information

There is currently only 1 device available to do this procedure. According to the instructions for use for the device, the intended patient population is adults with surgically unresectable primary or metastatic cancer of the liver, but the use of melphalan to treat unresectable primary or metastatic hepatic tumours represents an unlicensed indication for the drug.

## 9 NICE team

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## Appendix A: Related evidence or guidance

### Relevant registries or emerging key trials

None identified

### Related NICE guidance, standards or indicators

#### NICE interventional procedures guidance

- [Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver](#) (2021) NICE interventional procedures guidance 691 - **current guidance**  
(Recommendation: special arrangements for patients with metastases in the liver from ocular melanoma; research only for patients with primary liver cancer or metastases in the liver that are not from ocular melanoma)
- [Image-guided percutaneous laser ablation for primary and secondary liver tumours](#) (2024) NICE interventional procedures guidance 788  
(Recommendation: special arrangements)
- [Selective internal radiation therapy for neuroendocrine tumours that have metastasised to the liver](#) (2024) NICE interventional procedures guidance 786 (Recommendation: standard arrangements)
- [Selective internal radiation therapy for unresectable colorectal metastases in the liver](#) (2020) NICE interventional procedures guidance 672  
(Recommendation: special arrangements for people who cannot have chemotherapy, research only for people who can have chemotherapy).
- [Irreversible electroporation for primary liver cancer](#) (2019) NICE interventional procedures guidance 664 (Recommendation: research only).
- [Selective internal radiation therapy for unresectable primary intrahepatic cholangiocarcinoma](#) (2018) NICE interventional procedures guidance 630  
(Recommendation: research only).
- [Microwave ablation for treating liver metastases](#) (2016) NICE interventional procedures guidance 553 (Recommendation: standard arrangements).

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- [Selective internal radiation therapy for primary hepatocellular carcinoma](#) (2013) NICE interventional procedures guidance 460 (Recommendation: standard arrangements).
- [Irreversible electroporation for treating liver metastases](#) (2013) NICE interventional procedures guidance 445 (Recommendation: research only).
- [Cryotherapy for the treatment of liver metastases](#) (2010) NICE interventional procedures guidance 369 (Recommendation: special arrangements).
- [Radiofrequency ablation for colorectal liver metastases](#) (2009) NICE interventional procedures guidance 327 (Recommendation: standard arrangements).
- [Ex-vivo hepatic resection and reimplantation for liver cancer](#) (2009) NICE interventional procedures guidance 298 (Recommendation: special arrangements).
- [Microwave ablation of hepatocellular carcinoma](#) (2007) NICE interventional procedures guidance 214 (Recommendation: standard arrangements).
- [Radiofrequency-assisted liver resection](#) (2007) NICE interventional procedures guidance 211 (Recommendation: standard arrangements).
- [Laparoscopic liver resection](#) (2005) NICE interventional procedures guidance 135 (Recommendation: standard arrangements).
- [Radiofrequency ablation of hepatocellular carcinoma](#) (2003) NICE interventional procedures guidance 2 (Recommendation: standard arrangements).

## **NICE technology appraisal guidance**

- [Tebentafusp for treating advanced uveal melanoma](#) (2025) NICE technology appraisal guidance 1027
- [Cabozantinib for previously treated advanced hepatocellular carcinoma](#) (2022) NICE technology appraisal guidance 849
- [Selective internal radiation therapies for treating hepatocellular carcinoma](#) (2021) NICE technology appraisal guidance 688 (Last updated: 03 July 2024)

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- [Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma](#) (2020) NICE technology appraisal guidance 666
- [Regorafenib for previously treated advanced hepatocellular carcinoma](#) (2019) NICE technology appraisal guidance 555
- [Lenvatinib for untreated advanced hepatocellular carcinoma](#) (2018) NICE technology appraisal guidance 551
- [NICE technology appraisal guidance on Sorafenib for treating advanced hepatocellular carcinoma](#) (2017) NICE technology appraisal guidance 474

## Other related documents

### National policy documents

[NHS England Clinical Commissioning Policy: Chemosaturation for liver metastases from ocular melanomas](#) (2016). Reference: NHS England: 16014/P (Not Routinely Commissioned - NHS England will not routinely commission this specialised treatment in accordance with the criteria described in this policy).