NICE National Institute for Health and Care Excellence

HealthTech Programme

Interventional Procedure Advisory Committee (IPAC)

IPG10448 (IP1062/3) - Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver – 1st meeting

Thursday 16th April 2026

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Link to Experts register for topic:	List of experts

The following documents are made available to the Committee:

1. Cover sheet [No CON]
2. Final scope [PUB]
3. Assessment report (AR) [No CON]
4. Patient group organisation submissions
   4a. Ocular Melanoma UK [REDACTED]
5. Patient survey responses [REDACTED]
6. Professional Expert Questionnaires [REDACTED]
7. Register of interests – as of 16 April 2026 [PUB]

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

Interventional procedures assessment report

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Purpose of the assessment report

The purpose of this assessment report is to summarise the procedure and review the key efficacy and safety evidence available for the procedure. The report forms part of the papers considered by the Committee when it is making decisions about the interventional procedure.

Contents

Table 1 Abbreviations

Abbreviation	Definition
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BAC	Best alternative care
CI	Confidence interval
CS-PHP	Chemosaturation percutaneous hepatic perfusion
CTCAE	Common Terminology Criteria for Adverse Events
ECOG	Eastern Cooperative Oncology Group
EORTC-QLQC30	European Organisation for Research and Treatment of Cancer Quality-of-Life Core Questionnaire
HAI	Hepatic artery infusion
HR	Hazard ratio
INR	International normalised ratio
IQR	Interquartile range
LDH	Lactate dehydrogenase
PHP	Percutaneous hepatic perfusion
PTT	Partial thromboplastin time
RECIST	Response Evaluation Criteria in Solid Tumors
SD	Standard deviation
SE	Standard error
SIRT	Selective internal radiation therapy
TACE	Transarterial chemoembolisation

The procedure, condition, current practice and unmet need

The procedure

Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation (CS-PHP) 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.

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).

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.

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 CS-PHP is suitable for people with or without the HLA-A*02:01 genotype.

Outcome measures

The main outcomes included tumour response, overall survival, progression-free survival, quality of life, adverse events and toxicity. The measures used are detailed in the following paragraphs.

Tumour response

RECIST (version 1.1) is a standardised set of rules used to measure how well a cancer treatment is working by assessing changes in tumour size on imaging scans:

- Complete response: disappearance of all target lesions.
- Partial response: at least a 30% decrease in the sum of diameters of target lesions.

- Progressive disease: at least a 20% increase in the sum of diameters of target lesions. The appearance of 1 or more new lesions is also considered progression.
- Stable disease: small changes that do not meet the above criteria.

The disease control rate is the percentage of people with complete response, partial response, or stable disease after treatment.

Quality of life

EORTC QLQ-C30 version 3 questionnaire

The EORTC QLQ-C30 is a self-reported 30-item questionnaire developed to assess the quality of life of people with cancer.

It is composed of 5 functional scales (physical, role, cognitive, emotional, and social), 3 symptom scales (fatigue, pain, and nausea and vomiting), a global health status scale, and a number of single items assessing additional symptoms commonly reported by people with cancer (dyspnoea, loss of appetite, insomnia, constipation and diarrhoea) and perceived financial impact of the disease. All of the scales and single-item measures range in score from 0 to 100. For both the global health status and functional scales, higher scores reflect better performance. In contrast, higher scores on the symptom scales and single-item measures indicate a higher level of symptoms (worse performance).

FACT-G questionnaire

FACT-G is a self-reported questionnaire that was developed to measure quality of life in people having cancer therapy. It is a 27-item questionnaire that measures 4 separate subscales of quality of life: physical (7 items, score range 0 to 28), social (7 items, score range 0 to 28), emotional (6 items, score range 0 to 24) and functional wellbeing (7 items, score range 0 to 28). All questions in the

FACT-G use a 5-point rating scale (from 0='not at all' to 4='very much'). The FACT-G total score is the sum of the 4 subscale scores and has a possible range of 0 to 108 points. Higher subscale and total scores indicate better quality of life.

Adverse events

Most studies used the National Cancer Institute CTCAE to describe the adverse events. This is a standardised classification system used for reporting, grading, and monitoring adverse events in cancer therapy. A grading (severity) scale is provided for each adverse event, ranging from mild (grade 1) to death (grade 5). Grade 3 refers to events that are severe or medically significant but not immediately life-threatening and grade 4 events are life-threatening.

Evidence summary

Population and studies description

This interventional procedures assessment report is based on about 450 people with uveal melanoma liver metastases and 69 people with other types of primary or secondary liver tumours from 1 randomised controlled trial (FOCUS study; Zager 2025), 1 pooled analysis from the randomised controlled trial and non-randomised phase of the same study (Zager 2024 and 2026), 1 pooled analysis of multicentre case series (Tong 2022), 1 retrospective non-randomised comparative study (Kolb 2023), 3 prospective single-arm studies (Meijer 2021 and 2019, Tong 2024; Meijer 2022) and 7 retrospective case series (Modi 2022; Dewald 2022; Vigneswaran 2024; Reiner 2025, Schönfeld 2020, Dewald 2023; Veelken 2024). There is some overlap of study populations between the studies, which is described in more detail in table 2. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This assessment report presents 14 studies (reported in 16 papers) as the key

evidence in table 2a, table 2b, table 3a and table 3b, and lists 38 other relevant studies in appendix B, table 5.

The studies included evidence from Europe, including the UK, and the US. Of the 14 prioritised studies, 10 focused on people with uveal melanoma liver metastases. Four other studies included other types of liver cancer, although 2 also included some people with ocular melanoma (Schönfeld 2020, Veelken 2024). The mean or median age of people who had CS-PHP in these studies ranged from 57 to 63 years and the proportion of males ranged from 20% to 58%. In the 4 studies that included other types of liver cancer, the mean or median age ranged from 56 to 61 years, and the proportion of males ranged from 30% to 62%.

Studies including people with uveal melanoma

In the randomised controlled trial by Zager (2025), 85 people with unresectable metastatic uveal melanoma to the liver were randomised, 40 of whom had CS-PHP and 32 had best alternative care (BAC). The planned sample size was 240 but enrolment was slow and people were reluctant to have BAC, so the study design was amended to a single arm study. This meant the study was underpowered and all efficacy analyses were treated as exploratory. The primary efficacy endpoint was overall survival, and secondary efficacy endpoints were progression-free survival and objective response rate. People were included in the study if there was up to 50% liver tumour involvement and they could still be included if they had limited extrahepatic disease that was amenable to resection or radiation. The median follow up was 56.1 months. Zager (2024) reports pooled results of 102 people from the randomised study and the non-randomised phase of the study, with a median follow up of 36.4 months. The primary end point of the study was the objective response rate. A subgroup analysis from the same study is reported in Zager (2026), including age, gender, presence of

extrahepatic disease, previous treatment, liver tumour burden and LDH levels at baseline. Efficacy endpoints included in the subgroup analyses were objective response rate, progression-free survival, and overall survival.

Tong (2022) is a retrospective analysis of pooled data on 101 people with unresectable uveal melanoma liver metastases from multicentre case series. There were differences between the study centres in selection criteria regarding extrahepatic disease. In 1 centre, people with extrahepatic disease were excluded, in another people with extrahepatic metastases more than 10 mm were excluded and in the third centre extrahepatic disease was not a reason for exclusion. Study outcome measures were response rate, progression-free survival, liver progression-free survival, overall survival and safety. Predictors for prolonged overall survival were also analysed. The median follow up was 15.0 months.

Kolb (2023) is a retrospective single-centre non-randomised study comparing 28 people who had CS-PHP with 34 people who had SIRT, for uveal melanoma liver metastases. A high proportion (68%) of people who had CS-PHP had extrahepatic metastasis compared with 41% of people who had SIRT. At baseline, the hepatic load was over 50% in 14% of people who has CS-PHP and none of the SIRT group. Study outcome measures included tumour response, overall survival and progression-free survival. The follow up period was not reported.

Meijer (2021) and Meijer (2019) both describe a prospective single-centre single arm trial including 35 people with unresectable ocular melanoma metastases confined to the liver. Of the 35 people, 20 (57%) had 10 or more metastases and 8 (23%) had elevated LDH levels at baseline. People with extrahepatic metastatic disease were excluded. Primary endpoints were overall response rate and best

overall response. The median follow up was 19.1 months. Meijer (2019) described the safety outcomes from the study in more detail.

Modi (2022) is a UK-based retrospective single-centre case series including 83 people with uveal melanoma liver metastases. There was a high tumour burden (more than 10 lesions or over 50% volume replacement) in 52% (42 out of 81) of people and 15% (12 out of 81) had extrahepatic disease. The aim of the study was to assess safety and efficacy of the procedure. The median follow up was 12.9 months.

Dewald (2022) is a retrospective 2-centre case series from Germany, including 66 people with hepatic-dominant metastatic uveal melanoma. The median tumour load at baseline was 5% (IQR 1 to 12). The study aimed to assess safety, response to therapy, and survival. Length of follow up was not reported.

Two studies (Tong 2024 and Vigneswaran 2024) focused on the effect of CS-PHP on quality of life. Tong (2024) is a prospective single-centre cohort study form the Netherlands, including 24 people. The study was terminated early because of slow recruitment. Follow up was 21 days for quality-of-life data and 30 days for adverse events. The study by Vigneswaran (2024) is a UK-based retrospective single-centre case series of 20 people, including some people also reported by Modi (2022). Half the study population had a high disease burden and 5% had extrahepatic disease at baseline. The follow up period was 28 days.

Reiner (2025) is a retrospective single-centre case series from Germany, including 38 people with liver-dominant metastatic uveal melanoma. Most people (89%) had 25% or less liver involvement at baseline. Extrahepatic disease was reported in 16% of people and 53% had elevated LDH at baseline. People with extrahepatic metastases larger than 10 mm in lymph nodes or uncontrollable, progressive, or predominant extra hepatic disease at other organ sites were

excluded from the study. The primary efficacy endpoint was the median overall survival after CS-PHP. The median follow up was 25.8 months.

Studies including people with other types of liver cancer

Of the 4 prioritised studies that included liver tumours other than uveal melanoma liver metastases, 3 were based in Germany. Schönfeld (2020) is a retrospective single centre case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma, and other secondary cancers. The tumour volume was more than 30% in 20% of people at baseline and 12% had extrahepatic disease. The aim of the study was to analyse the safety and efficacy of CS-PHP as a last-line treatment. The median follow up was 27 months. Dewald (2023) is a retrospective single centre case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases, 15 of whom were also included in Schönfeld (2020). The median tumour load was 6% for people with extrahepatic cholangiocarcinoma (n=4) and 21% for people with intrahepatic cholangiocarcinoma (n=13). At baseline, 2 people had an extrahepatic tumour. The aim of the study was an analysis of CS-PHP as a palliative therapy in people with inoperable tumours. Outcome measures included tumour response, overall and progression-free survival, and complications. The mean or median follow up period was not reported. Veelken (2024) is a retrospective single centre case series of 33 people with unresectable hepatic metastases of uveal melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma or hepatic metastases originating from other primary cancers. At baseline, 21% of people had extrahepatic metastases. Endpoints of the study were overall survival, hepatic disease control rate and hepatic progression-free survival. The mean or median follow up period was not reported.

Meijer (2022) is a prospective single centre, single-arm trial from the Netherlands, including 8 people with unresectable colorectal liver metastases.

The study was terminated early because of slow recruitment. People with extrahepatic metastatic disease were excluded from the study. The primary endpoint was the overall response rate. The mean or median follow up period was not reported.

Table 2a presents study details for evidence on uveal melanoma liver metastases and Table 2b presents study details for evidence on other types of liver tumour.

Figure 1 Flow chart of study selection

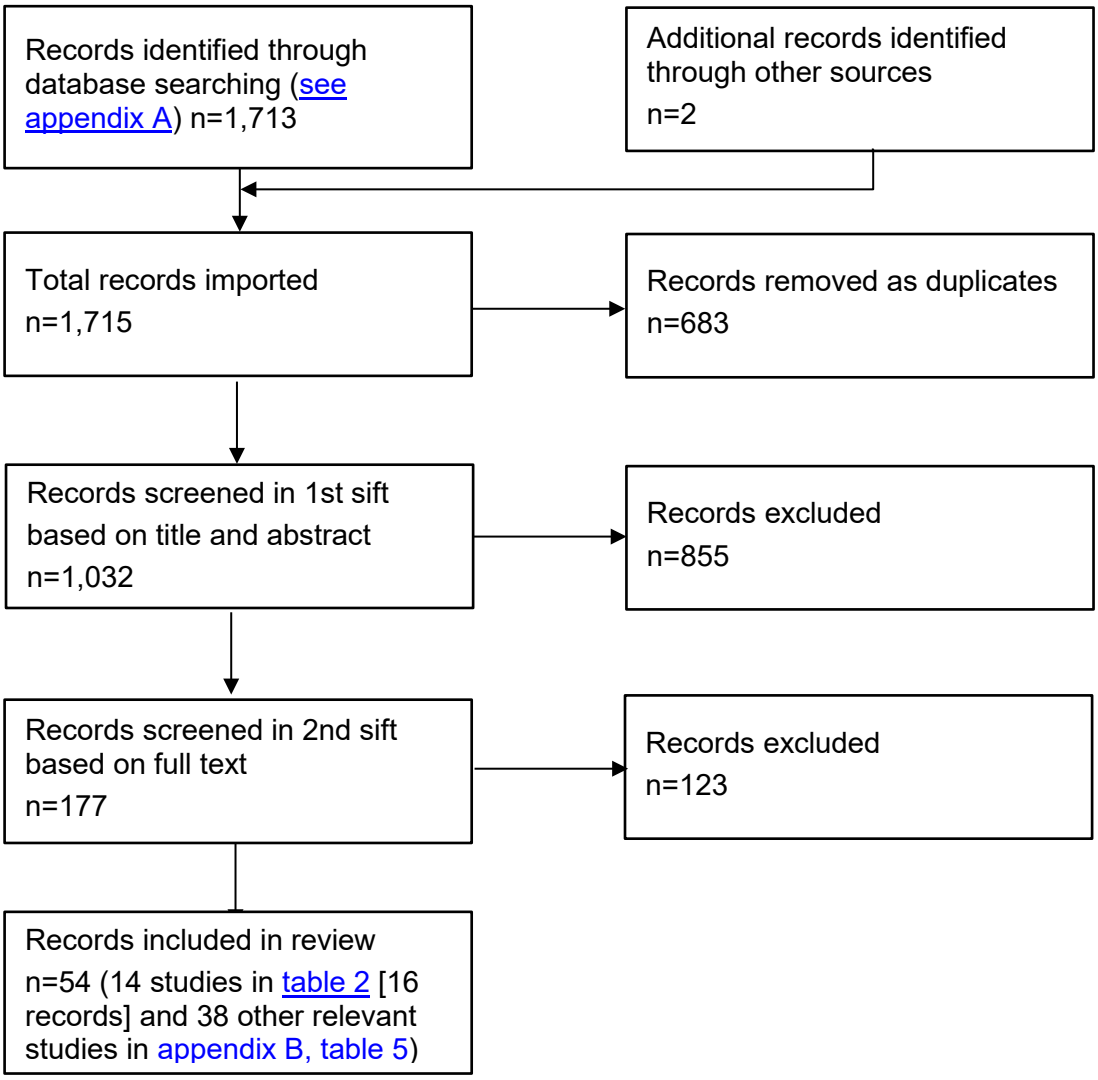

Table 2a Study details – uveal melanoma liver metastases

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
1	Zager, 2025 Europe and USA FOCUS trial, NCT02678572 This article reports on results from the randomised phase of the FOCUS study.	n=85 people were randomised (43 CS-PHP, 42 BAC) and 72 had treatment (40 CS-PHP, 32 BAC) Indication: unresectable metastatic uveal melanoma to the liver Prior therapy • CS-PHP=48% (19/40) • BAC=44% (14/32) Male sex • CS-PHP=50% (20/40) • BAC=44% (14/32) Median age (years) • CS-PHP=63 (range 20 to 78)	Randomised controlled trial. The planned study size was 240. Because of slow enrolment and reluctance to have BAC treatment, the study design was amended to a single-arm CS-PHP study, and all efficacy analyses of the randomised study, comparing between treatment groups, were treated as exploratory. The primary efficacy endpoint	• Age 18 years or older • histologically verified unresectable metastatic uveal melanoma to the liver, with up to 50% liver tumour involvement • ECOG 24 performance status of 0 to 1 at screening • measurable liver metastases • people could have limited extrahepatic	• CS-PHP, n=40 (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US) • BAC, n=32 (BAC was investigator's choice of TACE, pembrolizumab, ipilimumab, or dacarbazine) 45% of people in the CS-PHP group completed the maximum of 6 procedures permitted per protocol; the	Median 56.1 months

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		• BAC=61 (range 31 to 82) Extra-hepatic lesions • CS-PHP=13% (5/40) • BAC=22% (7/32)	was overall survival. Screening for study enrolment was done between February 2016 and October 2018.	disease that was amenable to resection or radiation. Exclusion criteria were extensive and included: • moderate or severe liver cirrhosis • portal hypertension • New York Heart Association 2 to 4 status.	primary reasons for discontinuation were disease progression (35%) and adverse events (15%). 34% of people in the BAC group completed treatment per protocol; the primary reasons for discontinuation were disease progression (56%) and withdrawal of consent (9%).	
2	Zager, 2024 and Zager, 2026	n=102 people enrolled, 95 had at least 1 CS-PHP procedure initiated (safety population), and 91 completed at least 1	Single arm, open label, multicentre phase 3 study (23 centres).	As per Zager 2025 (study 1).	CS-PHP (using the Hepatic CHEMOSAT Delivery System,	Median 36.4 months

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
	Europe and USA FOCUS trial, NCT02678572 These articles report on results pooled from the randomised (study 1) and non-randomised phases of the FOCUS study. Zager 2026 is a subgroup analysis.	CS-PHP (treated population). Indication: unresectable metastatic uveal melanoma to the liver • Median age=61.0 years (range 20 to 78) • Male sex=48% (44/91) • Prior therapy=44% (40/91) • Extra-hepatic lesions=30% (27/91) • Median time from diagnosis of primary tumour to study entry=39.3 months (range 0.7 to198.9) • Median time from diagnosis of metastatic disease to	The FOCUS study was initiated as a 2-arm randomised controlled trial. Because of slow enrolment and patients being reluctant to have BAC treatment, the study design was amended to a single-arm study, after which all eligible participants had CS-PHP. The primary end point of the study was the objective response rate. Enrolment period: February 2016 to October 2020.		Delcath Systems Inc., US) 37% of the treated population completed the maximum of 6 procedures permitted per protocol. The primary reasons for discontinuation were disease progression (29%) and adverse events (19%).	

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		study entry=5.5 months (range 0.2 to 67.5) • Most people (88%) had an ECOG performance status score of 0.				
3	Tong, 2022 The Netherlands and Germany (3 centres) Results of part of the study population (n=74) have been published previously in single-centre analyses: • Meijer, 2021	n=101 Indication: unresectable uveal melanoma liver metastases • Median age=59 years (range 38 to 83) • Male sex=48% (48/101) • Median interval from primary tumour to metastases=28 months (range -1 to 232) • No prior therapy of liver	Retrospective pooled analysis of multicentre case series. Study outcome measures were response rate, progression-free survival, liver progression-free survival, overall survival and safety. Predictors for prolonged overall survival were also analysed.	People eligible for treatment were at least 18 years old with unresectable uveal melanoma liver metastases. There were differences between study centres in selection regarding people with limited extrahepatic disease: these were not considered eligible for CS-PHP at the Dutch centre. In 1 German centre,	CS-PHP Median number of treatments=2 (range 1 to 5). 77 (76%) people had at least 2 CS-PHP procedures. 25 (25%) had more than 2 procedures. The median interval was 8 weeks (range 5 to 34) between the	Median 15.0 months

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
	• Brüning, 2020 • Kirstein, 2017 • Dewald, 2021 • Dewald, 2022	metastases=65% (66/101) • Extrahepatic metastases=7% (7/101) • Median LDH=228 U/L (range 123 to 4,608) • Normal LDH at baseline=53% (54/101)	Treatment period: February 2014 to December 2019.	extrahepatic disease was not an exclusion criterion and at the other centre people with extrahepatic metastases more than 10 mm were excluded.	first and second procedures.	
4	Kolb, 2023 Germany	n=62 (28 CS-PHP, 34 SIRT) Indication: uveal melanoma liver metastases Mean age (years) • CS-PHP=63 • SIRT=71 Male sex • CS-PHP=36% • SIRT=56%	Retrospective single-centre non-randomised comparative study. The aim of the study was to retrospectively compare the outcome of people with liver-dominant metastatic uveal melanoma who	Adults with metastasised uveal melanoma who had CS-PHP or SIRT. Exclusion criteria: • having both SIRT and CS-PHP in succession • having another liver-targeted	• CS-PHP, n=28 (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US) • SIRT, n=34 (using SIR-Spheres; Sirtex Medical Europe	Not reported

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		Extrahepatic metastasis • CS-PHP=68% • SIRT=41% Previous systemic therapy • CS-PHP=36% • SIRT=29% Previous liver-targeted therapy • CS-PHP=21% • SIRT=18% Hepatic load 0 to 25% • CS-PHP=57% • SIRT=76% Hepatic load over 50% • CS-PHP=14% • SIRT=0%	had either SIRT or CS-PHP. Treatment period: December 2013 to February 2020.	therapy (such as surgery, interventional ablation or targeted radiotherapy) after the beginning of treatment with SIRT or CS-PHP.	GmbH, Germany) or glass microspheres (Therasphere s; Boston Scientific Medizintechni k GmbH, Germany). The number of CS-PHP procedures was 56, ranging from 1 to 6 per person. In the SIRT group, 39 cycles were given over 41 treatment sessions.	
5	Meijer, 2021 and Meijer, 2019	n=35	Prospective, single-centre single arm trial.	Exclusion criteria included:	CS-PHP (using the Hepatic CHEMOSAT	Median 19.1 months

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
	The Netherlands Efficacy data was extracted from Meijer, 2021 and safety data from Meijer, 2019.	Indication: unresectable ocular melanoma metastases confined to the liver • Median age=59 years (range 41 to 71) • Male sex=46% (16/35) • No prior therapy for liver metastases=60% (21/35) • 10 or more metastases=57% (20/35) • Elevated LDH=23% (8/35)	Primary endpoints were overall response rate and best overall response. The primary endpoint in Meijer (2019) was the number of serious adverse events reported within 30 days after CS-PHP. Enrolment period: February 2014 to June 2017.	• age less than 18 or more than 75 years • extrahepatic metastatic disease • World Health Organization performance status 2 or above • severe comorbidity • less than 40% healthy liver tissue • prior Whipple's surgery • intracranial lesions with propensity to bleed • pregnancy	Delivery System, Delcath Systems Inc., US) Treatment consisted of 2 CS-PHP procedures at an interval of 5 to 8 weeks. People with progressive disease or unacceptable adverse events after the first CS-PHP had only 1 procedure (n=6).	(for efficacy data)

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
				• insufficient haematological, renal or hepatic function.		
6	Modi, 2022 UK	n=83 Indication: uveal melanoma liver metastases • Median age=59 years • Male sex=44% • Prior treatment for metastatic uveal melanoma=51% (41/81) • High disease burden (more than 10 lesions or over 50% volume replacement)=52% (42/81) • Extrahepatic disease=15% (12/81)	Retrospective single-centre case series. The aim of the study was to assess safety and efficacy of the procedure. Treatment period: August 2012 to September 2020.	• Uveal melanoma with confirmed hepatic predominant metastatic disease • ECOG performance status of 0 to 1 • People with known single-site extrahepatic disease were included if the disease was non-progressive after previous treatment or	CS-PHP (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US) Procedures were done at about 6 to 10-week intervals with the number of procedures depending upon disease response and tolerability. The median number of procedures was 3 (range 1 to 8).	Median 12.9 months (13.9 months for those people still alive and being followed up).

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
				amenable to ablative treatment. • Any number and type of prior treatments were permitted. Exclusion criteria included: • Age less than 18 or over 80 years • Severe cardiac or respiratory disease preventing general anaesthesia • Pregnancy • Known clotting or bleeding disorder • Hepatic arterial or venous		

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
				vascular anatomy preventing M-PHP • Underlying liver disease (Childs-Pugh B or C) • Greater than 60% disease replacement in liver • More than 1 site of extra hepatic disease.		
7	Dewald 2022 Germany Data of 48 people (mostly with a shorter observational interval) have	n=66 Indication: hepatic-dominant metastatic uveal melanoma • Median age=58 years	Retrospective 2-centre case series. The study aimed to assess safety, response to	Inclusion criteria included: • sufficient renal, haematological and hepatic function.	CS-PHP People were scheduled for 1 CS-PHP with the option of re-treatment in case of stable disease	Not reported

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
	already been included in single-centre observational studies: • Brüning, 2020 • Schönfeld, 2020 Dewald, 2021	• Male sex=45% • Previous systemic therapy=18% • Previous local liver therapy=38% • Median tumour load=5% (IQR 1 to 12)	therapy, and survival. Treatment period: April 2014 to May 2020.	CS-PHP was deemed unsuitable for people with • cardiac failure (left ventricular ejection fraction less than 40%) • relevant chronic restrictive or obstructive respiratory conditions • history of intracranial lesions with a high bleeding risk • recent (less than 6 months) apoplex or transient ischaemic attack.	or partial response. Median number of treatments=2 (IQR 1 to 3)	

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
8	Tong, 2024 The Netherlands NCT03266042	n=24 Indication: hepatic metastases from uveal melanoma (all people had multifocal disease) • Median age=63 years (range 47 to 74) • Male sex=58% • Prior therapy for hepatic metastases=38%	Prospective single-centre cohort study. The study was terminated early because of slow recruitment as competing clinical trials were ongoing in the participating centre. Treatment period: January 2019 to April 2023.	Consecutive people having a first CS-PHP for hepatic metastases from uveal melanoma. Individuals were included in this quality-of-life analysis if they consented to participate and all questionnaires were completed. Individuals were excluded if they had combination treatment with CS-PHP and immunotherapy.	CS-PHP (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US)	21 days (quality-of-life) 30 days (adverse events)
9	Vigneswaran, 2024 UK The study cohort	n=20 Indication: uveal melanoma liver metastases	Retrospective single-centre case series. Data were collected from a	A full description of the selection criteria for the overall group can be found under	CS-PHP (using the Hepatic CHEMOSAT Delivery System,	28 days

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
	included a subset of another study (Modi 2022) and 7 further individuals with quality-of-life assessments.	• Mean age=57 years • Male sex=20% • High disease burden (more than 10 lesions or over 50% volume replacement)=50% • Extrahepatic disease=5%	subset of people who had CS-PHP therapy between August 2020 and January 2023.	study 5 (Modi 2022).	Delcath Systems Inc., US)	
10	Reiner, 2025 Germany	n=38 Indication: liver-dominant metastatic uveal melanoma • Median age=57.5 years (range 29 to 77) • Male sex=50% (19/38) • ECOG performance score 1 or less=100% (38/38) • 25% or less liver involvement at first	Retrospective single-centre case series. The primary efficacy endpoint was the median overall survival after CS-PHP. Treatment period: April 2014 to March 2024.	Inclusion criteria: • ECOG performance status 0 or 1 • haemoglobin levels 10 g/dL or higher • platelet counts 150,000/μL or above • bilirubin levels 2 or less times the upper limit of normal	CS-PHP (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US) 50% (n=19) of the cohort had 1 or 2 CS-PHP cycles, while the other 19 had 3 or more cycles (range 3 to 6).	Median 25.8 months

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		CS-PHP=89.4% (34/38) • Extrahepatic disease=15.8% (6/38) • Elevated LDH at baseline=52.6% (20/38) • Additional systemic treatment before or after CS-PHP=55.2% (21/38) • Local liver-directed interventions=21.0% (8/38)		• less than 70% liver tumour involvement. Exclusion criteria: • extrahepatic metastases larger than 10 mm in lymph nodes • uncontrollable, progressive, or predominant extra hepatic disease at other organ sites • recent history of transient ischaemic attacks • heart failure with a left ventricular		

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
				ejection fraction less than 40% • significant chronic obstructive or restrictive pulmonary disorders • contraindication to general anaesthesia.		

Table 2b Study details – primary or secondary liver cancer, other than metastatic uveal melanoma

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
11	Schönfeld, 2020 Germany Part of this study population (n=29)	n=60 Indications: • Ocular melanoma, n=30	Retrospective single centre case series. The aim of the study was to analyse	Inclusion criteria: • Adequate haematological, renal, and hepatic function.	CS-PHP (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US)	Median 27 months.

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
	has previously been included and described in Kirstein (2017), which is in table 5. Some people were also included in Dewald, 2023 (study 12).	• Cholangiocarcinoma, n=14 • Hepatocellular carcinoma, n=6 • Other secondary cancer, n=10 (2 colorectal cancer, 2 pancreatic cancer, 2 periampular carcinoma, 2 neuroendocrine tumours, 1 breast cancer, 1 endometrial cancer) • Median age=60.5 years (IQR 52 to 66) • Male sex=40% (24/60) • LDH more than 247 U/L=66.1% (39/59) • Tumour volume more than 30%=20.3% (12/59)	the safety and efficacy of CS-PHP in people with primary and secondary hepatic tumours as last-line treatment. Treatment period: October 2014 to January 2019.	Exclusion criteria: • history of transient ischaemic attacks • heart failure with a left-ventricular ejection fraction less than 40% • significant chronic obstructive or restrictive pulmonary disorder.	In total, 141 CS-PHP procedures were done with a maximum of 7 in 1 person. Most people had at least 2 procedures. 36.7% (22/60) of people had more than 2 procedures. Median time between first procedure and second procedure was 63 days (IQR 45 to 98).	

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		• Extrahepatic spread=11.9% (7/59) • ECOG performance status 0=69.5% (41/59)				
12	Dewald, 2023 Germany 15 people were also reported in Schönfeld (2020; study 11) with shorter observational periods and fewer CS-PHP procedures.	n=17 Indications: • intrahepatic cholangiocarcinoma (n=13) • cholangiocarcinoma liver metastases (n=4) • Median age at first CS-PHP=59 years (IQR 53 to 62) • Female sex=59% • ECOG performance status 0=71% • Median tumour load=6% (extrahepatic cholangiocarcinoma, n=4), 21% (intrahepatic	Retrospective single centre case series. The aim of the study was an analysis of CS-PHP as a palliative therapy plan in people with inoperable intrahepatic cholangio-carcinoma or cholangio-carcinoma liver metastases. Treatment period: April 2014 to	Inclusion criteria: liver dominant tumour distribution and an adequate haematological, renal, and hepatic function. Exclusion criteria: • heart failure with a left-ventricular ejection fraction less than 40% • significant chronic obstructive or restrictive pulmonary disorder.	CS-PHP (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US) There were 42 procedures in total, ranging from 1 to 8 per person (mean 2.5).	Not reported

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		cholangiocarcinoma, n=13) • Extrahepatic tumour, n=2	September 2020.	• intracranial lesions with a high bleeding risk • history of transient ischaemic attacks or stroke within the last 6 months.		
13	Veelken, 2024 Germany	n=33 Indications: • unresectable intrahepatic metastases of uveal melanoma (n=19) • intrahepatic cholangiocarcinoma (n=8) • hepatocellular carcinoma (n=2)	Retrospective single centre case series. Endpoints were overall survival, hepatic disease control rate and hepatic progression-free survival time.	Inclusion criteria: • staging imaging by either MRI or CT not older than 8 weeks • sufficient haematological, renal and hepatic function • tumour burden less than 50% of the liver volume.	CS-PHP (using the Hepatic CHEMOSAT Delivery System, Delcath Systems Inc., US) There were 97 CS-PHP procedures, ranging from 1 to 7 per person (median 2). The interval between CS-PHP treatments was	Not reported.

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		• hepatic metastases originating from other primary cancers (n=4; ciliary body melanoma, acinar cell carcinoma of the head and neck region, pancreatic carcinoma and tonsil carcinoma) • Median age at first treatment=61 years (range 26 to 81) • Male sex=30% (10/33) • Systemic treatment before first CS-PHP=24.3% (8/33) • Extrahepatic metastases=21.2% (7/33)	Treatment period: January 2016 to October 2023.	CS-PHP treatment was chosen for people with dominant intrahepatic tumour spread and non-prognostic extrahepatic manifestations that were asymptomatic. Exclusion criteria: • pre-existing conditions such as liver cirrhosis, heart failure, chronic pulmonary disorders • intolerance to a previous CS-PHP treatment.	between 6 and 12 weeks in 85% of people and ranged up to 56 weeks. CS-PHP was not repeated if intrahepatic tumours showed progression or complete response.	
14	Meijer, 2022 The Netherlands	n=8	Prospective, single centre,	Inclusion criteria: • Histologically proven and	CS-PHP (using the Hepatic CHEMOSAT	Not reported

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
		Indication: unresectable colorectal liver metastases • Median age=56 years (range 46 to 68) • Male sex=62% (5/8) • Previous treatment for liver metastases=100% (8/8; 4 had resection and 8 had systemic therapy) • Median interval from diagnosis of colorectal liver metastases to CS-PHP=23.7 months	single-arm trial. The study was terminated early because of a slow recruitment. The primary endpoint was the overall response rate. Treatment period: March 2014 to December 2015.	unresectable colorectal liver metastases. Exclusion criteria included: • age less than 18 or more than 75 years • extrahepatic metastatic disease • World Health Organization performance status 2 or above • severe comorbidity; less than 40% healthy liver tissue • prior Whipple's surgery	Delivery System, Delcath Systems Inc., US) Treatment consisted of 2 CS-PHP procedures at an interval of 5 to 8 weeks. 6 people had 2 CS-PHP procedures as per protocol. The other 2 only had 1 procedure because of progressive disease after the first procedure.	

Study no.	Study or author name, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention and comparator	Follow up
				• intracranial lesions with propensity to bleed • pregnancy • insufficient haematological, renal or hepatic function.		

Table 3a Study outcomes - uveal melanoma liver metastases

Study or author name, date	Efficacy outcomes	Safety outcomes
Zager, 2025 FOCUS trial (randomised part)	Number of people included in analysis: 72 A formal statistical analysis was not feasible because of early termination of the study and the small sample (85 enrolled versus 240 planned). For the calculation of time-to-event endpoints the start date was the randomisation date. Progression-free survival and objective response rate were determined by investigators based on RECIST version 1.1.	Number of people analysed: 73 **Treatment-emergent adverse event leading to discontinuation of treatment** • CS-PHP=14.6% (6/41) • BAC=0% (0/32) **Treatment-emergent adverse event leading to dose reduction**

Study or author name, date	Efficacy outcomes	Safety outcomes
	Hazard ratios are relative to BAC with less than 1 favouring CS-PHP. **Median overall survival (months)** • CS-PHP=18.5 (95% CI 16.30 to 22.41) • BAC=14.5 (95% CI 11.10 to 19.78), p=0.714 HR=0.91 (95% CI 0.54 to 1.54; p=0.728) **Overall survival at 1 year** • CS-PHP=79% (95% CI 62 to 89) • BAC=67% (95% CI 47 to 81) **Overall survival at 2 years** • CS-PHP=27% (95% CI 14 to 42) • BAC=26% (95% CI 12 to 43) **Median progression-free survival (months)** • CS-PHP=9.0 (95% CI 6.37 to 11.83) • BAC=3.1 (95% CI 2.89 to 5.91), p=0.015 HR=0.35 (95% CI 0.20 to 0.61; p=0.0002)	• CS-PHP=7.3% (3/41) • BAC=0% (0/32) **Mortality** 2 people died during the study, both in the CS-PHP arm. The causes of death were acute hepatic failure and bacterial peritonitis, occurring at 62 and 64 days, respectively, after the last study treatment. Neither of the deaths were considered related to study treatment, device, or procedure. **At least 1 severe (grade 3 or 4) treatment-emergent adverse event** • CS-PHP=85.4% • BAC=34.4% **Severe treatment-emergent adverse events in CS-PHP arm with a rate more than 10%** • Thrombocytopenia=56.1% • Leukopenia=36.6% • Neutropenia=36.6% • Anaemia=34.1% • Hypophosphatemia=14.6%

Study or author name, date	Efficacy outcomes	Safety outcomes
	Median hepatic progression-free survival (months) • CS-PHP=11.4 (95% CI 9.03 to 15.90) • BAC=3.3 (95% CI 2.89 to 8.18), p=0.0008 HR=0.28 (95% CI 0.16 to 0.51; p<0.0001) **Progression-free survival at 6 months** • CS-PHP=64% (95% CI 54 to 83) • BAC=32% (95% CI 12 to 43) **Progression-free survival at 1 year** • CS-PHP=31% (95% CI 20 to 50) • BAC=11% (95% CI 3 to 26) **Objective response rate** • CS-PHP=27.5% (95% CI 14.60 to 43.89) • BAC=9.4% (95% CI 1.98 to 25.02), p=0.074 **Best overall response, n (%)** • Complete response: CS-PHP=3 (8), BAC=0 (0) • Partial response: CS-PHP=8 (20), BAC=3 (9)	**Serious adverse events in CS-PHP arm** • Thrombocytopenia=19.5% • Leukopenia=9.8% • Neutropenia=9.8% • Febrile neutropenia=7.3% Haematological toxicity was transient and manageable with standard supportive care. None of the people in the BAC arm had serious haematological adverse events.

Study or author name, date	Efficacy outcomes	Safety outcomes
	• Stable disease: CS-PHP=21 (53), BAC=12 (38) • Progressive disease: CS-PHP=8 (20), BAC=16 (50) • Not evaluable: CS-PHP=0 (0), BAC=1 (3)	
Zager, 2024 and Zager, 2026 FOCUS trial (randomised and non-randomised parts)	Number of people included in analysis: 91 For the calculation of time-to-event end points, the start date was the study eligibility date. Progression-free survival and objective response rate were determined by investigators based on RECIST version 1.1. **Median overall survival** 20.5 months (95% CI 16.79 to 25.26) **Median progression-free survival** 9.0 months (95% CI 6.34 to 11.56) **Median hepatic progression-free survival** 13.9 months (95% CI 9.30 to 16.66) **Best overall response, n (%)** • Complete response=7 (8)	Number of people analysed: 95 **Any treatment-emergent adverse event leading to discontinuation of study treatment=17.9% (17/95)** **Any treatment-emergent adverse event leading to dose reduction of study treatment=13.7% (13/95)** **Mortality=3.2% (3/95)** The causes of death were cardiac arrest, acute hepatic failure, and bacterial peritonitis, occurring at 43, 62, and 64 days, respectively, after the last study treatment. None were considered related to study treatment, device, or procedure. **Grade 3 or 4 treatment-emergent adverse events (in more than 5% of people)** • Thrombocytopenia=54.7% (52/95)

Study or author name, date	Efficacy outcomes	Safety outcomes
	• Partial response=26 (29) • Stable disease=34 (37) • Progressive disease=23 (25) • Not evaluable=1 (1) **Objective response rate** 36.3% (95% CI 26.44 to 47.01) People without at least 1 post-baseline response assessment were designated as non-responders. **Results reported in Zager (2026)** Of the 33 people with complete or partial response, 19 (58%) had a response within the first or second CS-PHP procedure. 33% of responses were observed in CS-PHP procedures 4 to 6. Analyses of objective response rate by subgroup did not indicate marked differences in response to treatment based on age, sex, region, extent (%) of liver involvement, presence or absence of extrahepatic lesions, baseline LDH level, or number of prior therapies.	• Anaemia=32.6% (31/95) • Leukopenia=33.7% (32/95) • Neutropenia=29.5% (28/95) • INR increased=8.4% (8/95) • Activated PTT prolonged=8.4% (8/95) • Hypophosphatemia=7.4% (7/95) • Febrile neutropenia=7.4% (7/95) **Any serious grade 3 or 4 treatment-emergent adverse events** • Thrombocytopenia=15.8% (15/95) • Neutropenia=10.5% (10/95) • Febrile neutropenia=6.3% (6/95) • Leukopenia=5.3% (5/95) **Results reported in Zager (2026)** The incidence of serious adverse events among subgroups was similar to that for the overall safety population, with the exception of a higher incidence for people with only hepatic lesions compared to those with hepatic and extrahepatic lesions (53.0 versus 25.9%), which appeared to be driven by differing rates of serious thrombocytopenia (21.2

Study or author name, date	Efficacy outcomes	Safety outcomes
	Objective response rate according to baseline hepatic tumour burden • Tumour burden below median (n=45): 51.1% (95% CI 35.8 to 66.3) • Tumour burden above median (n=45): 22.2% (95% CI 11.2 to 37.1), p=0.008 Median progression-free survival according to baseline hepatic tumour burden (months) • Tumour burden below median (n=45): 11.3 (95% CI 9.00 to 15.9) • Tumour burden above median (n=45): 5.8 (95% CI 3.68 to 9.17), p=0.007 Median overall survival according to baseline hepatic tumour burden (months) • Tumour burden below median (n=45): 26.7 (95% CI 22.3 to 34.5) • Tumour burden above median (n=45): 15.4 (95% CI 12.2 to 18.6), p=0.008 Median overall survival according to extent of liver involvement at baseline (months)	versus 3.7%) and leukopenia (7.3 versus 0%), and people with low or normal LDH compared to those with elevated LDH (50.9 versus 37.1%), which appeared to be driven by differing rates of serious thrombocytopenia (20.0 versus 11.4%) Across subgroups, the percentage of people with grade 3 or 4 adverse events was similar to that of the overall study population. There was a higher incidence of adverse events leading to dose reduction in males compared to females (23.4 versus 4.2%). There was no evidence of cumulative toxicity with successive procedures.

Study or author name, date	Efficacy outcomes	Safety outcomes
	• 1 to 25% (n=72): 22.4 (95% CI 16.8 to 28.2) • 26 to 50% (n=19): 16.9 (95% CI 9.26 to 25.9), p=0.03 Median overall survival according to LDH level at baseline (months) • Low or normal (n=54): 23.5 (95% CI 18.3 to 28.2) • Elevated (n=32): 15.3 (95% CI 11.7 to 20.8), p=0.019	
Tong, 2022	Number of people included in analysis: 101 **Tumour response (according to RECIST 1.1)** • Complete response=5.0% (5/101) • Partial response=54.5% (55/101) • Stable disease=29.7% (30/101) • Progressive disease=10.9% (11/101) **Objective response rate=59.4%** **Disease control rate=89.1%** **Survival** Time to death was unknown in 12 people who were lost to follow-up.	Number of procedures: 183 **Periprocedural complications** • Dissection or occlusion of hepatic artery=3.8% (7/183) • Clot formation in the extracorporeal filtration circuit=1.1% (2/183) • Atrial fibrillation with cardioversion=0.6% (1/183) • Balloon leakage=0.6% (1/183) • Vaginal haemorrhage=0.6% (1/183) • Neck haematoma=0.6% (1/183) • Hypothermia and metabolic acidosis=0.6% (1/183)

Study or author name, date	Efficacy outcomes	Safety outcomes
	• Median progression-free survival=9.0 months (95% CI 7.7 to 10.3) • Median hepatic progression-free survival=11.0 months (95% CI 9.0 to 13.0) • Median overall survival=20.0 months (95% CI 13.7 to 26.3) There was a statistically significant difference in overall survival for people who had 2 or more CS-PHP procedures (n=77) versus 1 procedure (n=24; 20 versus 8 months, respectively, p<0.05). **Regression analysis** In univariate analysis, a larger sum of target lesions, only 1 CS-PHP procedure (compared with 2 or more procedures) and LDH levels higher than 248 U/L were correlated with poor overall survival. In multivariate analysis, treatment of the primary tumour with radiotherapy (compared to enucleation) as well as 2 or more CS-PHP procedures was associated with improved overall survival, while elevated LDH levels at baseline remained an independent predictor of worse overall survival.	• Haemodynamic instability and decreased saturations=0.6% (1/183) **Postprocedural complications** • Anaemia: grade 3=7.1% (13/183), grade 4=0.6% (1/183) • Leukopenia: grade 3=8.7% (16/183), grade 4=15.3% (28/183) • Thrombocytopenia: grade 3=14.2% (26/183), grade 4=14.2% (26/183) • Increased AST: grade 3=6.6% (12/183), grade 4=1.1% (2/183) • Increased ALT: grade 3=5.4% (10/183), grade 4=1.1% (2/183) • Increased bilirubin: grade 3=2.2% (4/183) • Gastric ulcer: grade 3=0.6% (1/183) • Pulmonary embolism: grade 3=2.7% (5/183) • Cardiac ischaemia: grade 3=0.6% (1/183) • Hyperglycaemia: grade 3=0.6% (1/183) • Tumour lysis syndrome: grade 3=0.6% (1/183) • Acute kidney injury: grade 3=1.6% (3/183) • Vulvar infection: grade 3=0.6% (1/183)

Study or author name, date	Efficacy outcomes	Safety outcomes
		• Sepsis: grade 4=0.6% (1/183) • Febrile neutropenia: grade 3=2.7% (5/183) • Other infection: grade 3=0.6% (1/183) • Vasovagal reaction: grade 3=1.1% (2/183) • Stroke: grade 3=2.7% (5/183) • Fatigue: grade 3=0.6% (1/183) **30-day mortality, n=2** 1 person died 3 days after CS-PHP from toxic liver failure, generalised bleeding because of coagulopathy and lactate acidosis. A second person died 12 days after the procedure because of rapid tumour progression and subsequent progressive multiorgan failure.
Kolb, 2023	Number of people included in analysis: 62 **Median overall survival** Median overall survival from first study treatment • CS-PHP=516 days (range 5 to 1,836); 16.96 months • SIRT=300.5 days (range 19 to 1,912); 9.90 months Cox regression adjusted via propensity score analysis for confounders, including the amount of hepatic involvement showed a statistically significant difference in risk of	Not reported

Study or author name, date	Efficacy outcomes	Safety outcomes
	mortality in favour of CS-PHP (HR 0.32, 95% CI 0.14 to 0.73; p=0.006). **Median progression-free survival** Median progression-free survival from first study treatment • CS-PHP=408.5 days (range 3 to 1,809); 13.43 months • SIRT=127.5 days (range 19 to 1,912); 4.16 months Adjusted Cox regression showed no statistically significant difference (HR 0.58, 95% CI 0.31 to 1.09; p=0.090). **Overall response** (per treatment cycle, according to RECIST 1.1) • Complete response: CS-PHP=0% (0/56), SIRT=0% (0/39) • Partial response: CS-PHP=9% (5/56), SIRT=3% (1/39) • Stable disease: CS-PHP=18% (10/56), SIRT=5% (2/39) • Progressive disease: CS-PHP=70% (39/56), SIRT=82% (32/39) • Non-complete response and non-progressive disease: CS-PHP=2% (1/56), SIRT=0% (0/39) No follow-up: CS-PHP=2% (1/56), SIRT=10% (4/39)	

Study or author name, date	Efficacy outcomes	Safety outcomes
Meijer, 2021 and Meijer, 2019	**Response assessment (n=32)** • Overall response rate=71.9% (23/32) • Complete response=3.1% (1/32) • Partial response=68.8% (22/32) • Hepatic response=81.2% (26/32) • Progressive disease because of extrahepatic disease=15.6% (5/32) **Survival (n=35)** • Median overall survival=19.1 months • 1-year overall survival=77% • 2-year overall survival=43% • Median progression-free survival=7.6 months (95% CI 4.9 to 10.3) • 1-year progression-free survival=26.5% • Median hepatic progression-free survival=11.2 months (95% CI 9.0 to 13.4) • 1-year hepatic progression-free survival=35.3% Median overall survival was statistically significantly longer in people with complete or partial response as best overall response (27.5 months, 95% CI 23.7 to 31.3), than in	**Serious adverse events reported after 67 procedures** • Transient cardiac ischaemia, n=1 • Asymptomatic postprocedural hypotension, n=1 • Periprocedural difficulties with oxygenation, n=1 • Asymptomatic postprocedural ECG changes, n=1 • Pulmonary emboli, n=2 • Nausea and vomiting with mild hypokalemia, n=1 • Sepsis with bacterial pharyngitis and retropharyngeal abscess, n=1 • Vaginal haemorrhage with grade 2 anaemia, n=1 • Febrile neutropenia, n=2 • Febrile neutropenia with mucositis or oesophagitis, n=1 • Prostatitis, n=1 • Abdominal pain (unknown cause), n=1 **Grade 3 or 4 haematological events in all people who had at least 1 technically successful CS-PHP (n=33)**

Study or author name, date	Efficacy outcomes	Safety outcomes
	people with stable (14.2 months, 95% CI 11.4 to 17.0) or progressive disease (9.1 months, 95% CI 5.5 to 12.8) as best overall response (p<0.001). Median overall survival was also statistically significantly longer (p=0.001) in people with complete or partial response as best hepatic response than in people with stable disease as best hepatic response: 26.3 months (95% CI 15.8 to 36.8) versus 11.9 months (95% CI 7.3 to 16.5). Univariate analysis revealed that the presence of a liver metastasis with diameter 3 cm or more (p=0.01) and an elevated baseline LDH (p=0.03) were statistically significantly associated with a poorer overall survival. 59% (20/34) of people who eventually showed progressive disease during the study period had 1 or more subsequent treatments. 74% (26/35) of people developed extrahepatic metastases during follow-up. **Quality of life** (questionnaire return rates ranged from 49% to 74% at different time points) Questionnaire scores after treatment did not statistically significantly differ from scores before treatment, except for physical functioning which was impaired 6 weeks after the	• Anaemia=18.1% (6/33) • Thrombocytopenia=54.5% (18/33) • Leukopenia=75.6% (25/33) • Neutropenia=66.7% (22/33) • Lymphocytopenia=84.8% (28/33)

Study or author name, date	Efficacy outcomes	Safety outcomes
	second CS-PHP (p=0.011). The level of physical functioning was restored to normal 3 months later. Median global health status score was 83 out of 100 at baseline, at 6 weeks after each CS-PHP and at 6 months after the first CS-PHP.	
Modi, 2022	Number of people included in analysis: 81 **Median overall survival**=14.9 months (from first CS-PHP treatment) **Median progression-free survival**=8.4 months (from first CS-PHP treatment) **Best overall response** • Complete response=9% (7/81) • Partial response=52% (42/81) • Stable disease=20% (16/81) • Progressive disease=20% (16/81) **Objective response rate**=61%	Number of people included in analysis: 83 (including 2 people who had an incomplete intervention) **Mortality** There were no treatment-related deaths. 1 person died of disease progression on day 88 after CS-PHP. • Dose reduction because of toxicity, interval abnormal liver function tests or filter blockage=6% (5/83) • Discontinuation of treatment because of toxicity=10% (8/83) **Intraprocedural complications (grade 3 or 4)** • Filter blockage event, n=1 • Prolonged hypotension, n=1

Study or author name, date	Efficacy outcomes	Safety outcomes
		Postprocedural complications (grade 3 or 4) • Anaemia=13% (11/83) • Thrombocytopenia (after intensive care unit stay)=12% (10/83) • Neutropenia=13% (11/83) • Fatigue=1% (1/83) • Arrhythmia=2% (2/83) • Alopecia=1% (1/83) • Diarrhoea=1% (1/83) • Other=7% (6/83)
Dewald, 2022	Number of people included in analysis: 66 Survival data was available for 61 people (3 people died shortly after the first CS-PHP and 2 were lost to follow-up after discharge). **Median overall survival after first CS-PHP**=18.4 months (95% CI 7 to 24.6) **Median hepatic progression-free survival after first CS-PHP**=12.4 months (95% CI 4 to 18.4) **Median overall survival from first diagnosis of hepatic metastases**=29.9 months (95% CI 14.3 to 36.8)	Number of people included in analysis: 66 **Mortality, n=3** 1 person died from sepsis 3 days after the first CS-PHP. 2 people with high tumour burden died shortly (3 days and 12 days, respectively) after the first CS-PHP caused by tumour lysis syndrome combined with fast tumour progression. **Grade 3 or 4 haematological, hepatic, and biliary adverse events after any CS-PHP (per person)** • Thrombocytopenia=54.5% (36/66)

Study or author name, date	Efficacy outcomes	Safety outcomes
	Radiological response after first CS-PHP • Complete or partial response=42.6% (26/61) • Stable disease=45.9% (28/61) • Progressive disease=11.5% (7/61) **Overall response rate**=59% (36/61) **Disease control rate**=93.4% (59/61)	• Leukopenia=9.1% (6/66) • Anaemia=25.8% (17/66) • AST increase=16.7% (11/66) • ALT increase=15.2% (10/66) • Hyperbilirubinemia=9.1% (6/66) • Hypoalbuminemia=9.1% (6/66) **Major thromboembolic adverse cardiovascular events after CS-PHP, n=5** • 1 left cerebral artery occlusion; despite immediate thrombectomy, there were persistent neurological symptoms. • 1 basilar artery thrombosis; prompt thrombectomy and pharmaceutical cardioversion were done. The same person developed pulmonary embolism subsequent to deep vein thrombosis (treated with anticoagulation). • 2 minor strokes without sequelae. • 1 central pulmonary embolism with good response to conservative treatment (anticoagulation).

Study or author name, date	Efficacy outcomes	Safety outcomes
		Other grade 3 and 4 complications after CS-PHP • Active bleeding at puncture site with subsequent haemorrhagic shock, n=1 • Ulcer bleeding, n=1 • Non-ST-segment elevation myocardial infarction, n=1 • Tumour lysis syndrome, n=1 • Acute kidney failure, n=1 • Sepsis, n=1 • Tachyarrhythmia absoluta, n=1
Tong, 2024	Number of people included in analysis: 24 Quality-of-life was measured for the first CS-PHP procedure only, before a second procedure was done. Bonferroni multiple testing correction was applied when testing difference between timepoints, leading to the adjusted p-values of ≤0.0167 to be considered statistically significant. **Median EORTC QLQC30 global health status score (higher score indicates better quality of life)** • Baseline=83 (range 50 to 100) • Day 2 or 3 after CS-PHP=58 (range 17 to 100), p<0.001	Number of people included in analysis: 24 **Periprocedural complications, n=2** 1 person had hypothermia (grade 4) combined with hypotension, metabolic acidosis, and cardiac complications (atrial fibrillation, bradycardia, and ST-depressions) and needed to stay intubated after the procedure. They recovered within hours after the procedure and could be discharged on day 3 without any sequelae. The other person had a pseudoaneurysm of the common femoral artery (grade 1) treated with thrombin injection.

Study or author name, date	Efficacy outcomes	Safety outcomes
	• Day 7=67 (range 17 to 100), p<0.001 • Day 21=83 (range 33 to 100), p=0.034 Most scores declined on day 2 or 3 after CS-PHP. On day 21, 12 out of 15 scores returned to baseline, including median global health status scores. 3 variables were statistically significantly worse on day 21 compared to baseline: fatigue (33 versus 6; p=0.002), physical functioning (87 versus 100; p=0.003), and role functioning (67 versus 100; p=0.001).	**Adverse events within 30 days after CS-PHP** All people had at least 1 postprocedural adverse event. There were 21 grade 3 or 4 events in 9 people: • Anaemia, n=1 • Leukopenia, n=6 • Thrombocytopenia, n=3 • Increased AST, n=1 • Increased gamma-glutamyl transferase, n=2 • Nausea, n=6 • Postprocedural groin haemorrhage, n=1 • Febrile neutropenia, n=1 • Fatigue, n=5 • Eye infection, n=1 The median global health score in these 9 people was 67 on day 21.
Vigneswaran, 2024	Number of people included in analysis: 20 **Median quality of life scores (FACT-G questionnaire)** • Baseline=101.8	**Complications** • Hepatic artery dissection=5% (1/20) • Mild toxicity=5% (1/20)

Study or author name, date	Efficacy outcomes	Safety outcomes
	• Day 1=85, p=0.002 • Day 14=95, p=0.57 • Day 28=100, p=0.31 Most of the initial drop in quality-of-life at day 1 after the procedure was attributable to the physical wellbeing domain (28 before procedure compared to 24 afterwards, p=0.001) and the functional wellbeing domain (26 before the procedure compared to 18.5 afterwards, p<0.001). By day 28 there was a statistically significant improvement in the emotional wellbeing domain compared to baseline (before procedure 20.5 compared to 22 afterwards, p=0.01). **Best liver response by RECIST 1.1 criteria** • Complete response=25% (5/20) • Partial response=55% (11/20) • Stable disease=15% (3/20) • Progressive disease=5% (1/20)	• None=90% (18/20)
Reiner, 2025	Number of people included in analysis: 38 **Survival** 23 (60.5%) people died during the follow-up period. None of the deaths were considered related to CS-PHP treatment,	Number of people included in analysis: 38 **Procedure-related adverse events graded 2 or higher=10.5% (4/38)** • heparin-induced thrombocytopenia type 2, n=1

Study or author name, date	Efficacy outcomes	Safety outcomes

	device, or procedure. 4 people who were lost to follow-up were censored as alive (all 4 were international patients and had returned to their home country after CS-PHP treatment). They were all known to be alive at 6 months after CS-PHP.
	• Median overall survival=29.1 months (95% CI 18.4 to 38.9)
	  ○ 3 or more CS-PHP cycles=29.8 months
	  ○ 1 or 2 CS-PHP cycles=21.4 months, p=0.058
	• 1-year overall survival=79.5% (95% CI 67.0 to 94.3%)
	• 2-year overall survival=53.2% (95% CI 38.2 to 74.0%)
	• 3-year overall survival=28.5% (95% CI 15.4 to 52.8%)
		• pulmonary embolism, n=1
		• non-ST elevation myocardial infarction, n=1 (due to an intravasal coronary thrombus treated successfully by coronary stenting and thrombolysis)
		• cerebral artery basilar embolism in conjunction with bilateral pulmonary embolism, n=1 (treated by interventional neuroradiological thrombectomy and systemic thrombolysis, and leaving long-term mild sequalae)
		There were no procedure-related deaths.

Table 3b Study outcomes – primary or secondary liver cancer, other than metastatic uveal melanoma

Study or author name, date	Efficacy outcomes	Safety outcomes
Schönfeld, 2020	**Response assessment –** for all types of tumour, including 30 people with ocular melanoma	**Overall toxicity and complications** • Grade 3 or 4 thrombocytopenia=80% • Grade 3 or 4 anaemia=45%

Study or author name, date	Efficacy outcomes	Safety outcomes
	Overall, 54 people (90%) were available for radiological response assessment. 1 person with ocular melanoma died from sepsis shortly after the first CS-PHP. 2 other people with ocular melanoma died because of rapid tumour progression. Both had a high tumour burden. The remaining 3 people were lost to follow-up. • Response after first CS-PHP=25.9% (14/54) • Stable disease after first CS-PHP=46.3% (25/54) • Progressive disease after first CS-PHP=27.8% (15/54) • Overall disease stabilisation=70.3% (38/54) • Overall response rate=33.3% (18/54) The overall response rate was in trend higher for people with ocular melanoma (n=11; 42.3%) compared to other cancers (n=7; 25.0%; p=0.178). The overall response rate for people with cholangiocarcinoma was 30.8% (n=4) and 33.3% for people with secondary malignancies other than ocular melanoma (n=3). None of the people with hepatocellular carcinoma had a radiological response. One person with cholangiocarcinoma	• Grade 3 or 4 leukopenia=31.6% • Platelet transfusion=30% • Erythrocyte concentrate transfusion=31.7% • Grade 3 or 4 increase in ALT=26.7% • Grade 3 or 4 increase in AST=48.3% • Grade 3 or 4 hyperbilirubinemia=15.3% • Grade 3 or 4 hypoalbuminemia=15.4% **Major intervention-associated complications** • Ulcerous bleeding, n=3.3% (2/60; 1 needed surgical intervention) • Generalised oedema, ascites, or pleural effusion because of overhydration or hypoalbuminemia, n=21.7% (13/60) • Cardiovascular events=5.0% (3/60)

Study or author name, date	Efficacy outcomes	Safety outcomes
	had a complete response after the first CS-PHP but was lost to follow-up. **Predictors of radiological response** • Ocular melanoma versus non-ocular melanoma: OR=9.265, 95% CI 1.26 to 67.86, p=0.028 • LDH normal versus increased: OR=13.66, 95% CI 1.65 to 112.9, p=0.015 **Survival** • Median overall survival from first diagnosis=56 months • Median overall survival from first CS-PHP=9 months • Median progression-free survival=4 months • Median hepatic progression-free survival=5 months **Survival by indication** Median overall survival • Ocular melanoma=12 months • Other liver tumours=8 months, p=0.893	

Study or author name, date	Efficacy outcomes	Safety outcomes
	Median progression-free survival • Ocular melanoma=6 months • Other liver tumours=3 months, p=0.539 Median hepatic progression-free survival • Ocular melanoma=6 months • Other liver tumours=5 months, p=0.657 1 person with cholangiocarcinoma had the longest survival since first CS-PHP of 3.7 years. In total, 16 people (26.7%) were still on treatment and being evaluated for further CS-PHS (10 with ocular melanoma, 3 with cholangiocarcinoma, 1 with hepatocellular carcinoma and 2 with other secondary malignancies).	
Dewald, 2023	Number of people included in analysis: 17 1 person died without follow-up imaging 13 weeks after the first CS-PHP. **Response assessment after first CS-PHP** • Complete response=6% (1/16)	**Complications** • Transient hemiparesis, n=1 (day after fifth CS-PHP, mild symptoms spontaneously resolved) • Aspiration pneumonia caused by postoperative nausea and vomiting, n=1 • Persistent catecholamine-dependent hypotension, n=1

Study or author name, date	Efficacy outcomes	Safety outcomes
	• Partial response=18% (3/16) • Stable disease=44% (7/16) • Tumour progression=31% (5/16) **Overall response rate**=25% **Disease control rate**=75% **Median time from the first PHP to overall response**=44 days **Survival** • Median progression-free survival=3.5 months (IQR 2.2 to 7.4) • Median hepatic progression-free survival=3.6 months (IQR 2.6 to 9.5) • Median survival from first diagnosis of intrahepatic cholangiocarcinoma or liver metastases=27.6 months (IQR 16.5 to 37) • Median survival from first CS-PHP=9.9 months (IQR 3.8 to 21) • 1-year survival rate=41%	There were no procedure-related deaths. **Toxicity (proportion of procedures)** • Clinically significant thrombocytopenia (grade 3 or 4)=50% • Grade 3 or 4 anaemia=26% • Leukopenia=21% • AST increase=21% • ALT increase=24% • Hyperbilirubinemia=5% • Hypoalbuminemia=14% The myelosuppressive effect was transitory and values returned to baseline within 3 weeks.
Veelken, 2024	Number of people included in analysis: 33 **Treatment response**	**Adverse events** There were 8 adverse events during or shortly after CS-PHP: • Tissue oedema

Study or author name, date	Efficacy outcomes	Safety outcomes
	• Disease control rate of hepatic tumours=91% • Hepatic complete response=18.2% (6/33) • Hepatic partial response=36.4% (12/33) • Hepatic stable disease=36.4% (12/33) In 6 people, hepatic complete response was achieved after a median of 5 (range 2 to 7) CS-PHP cycles. **Survival** • Median overall survival from first CS-PHP treatment=65 weeks (SE 13.6, 95% CI 38.2 to 91.5) • Median overall survival for people with uveal melanoma=69 weeks (SE 6.9, 95% CI 55.6 to 82.9) • Median overall survival for people with intrahepatic cholangiocarcinoma=38 weeks (SE 2.9, 95% CI 32.0 to 43.7) • Median hepatic progression-free survival=52 weeks (SE 13.9, 95% CI 24.7 to 79.2) There were no discernible differences in median overall survival between people with or without	• Haematoma • Bleeding • Renal failure 2 people with intrahepatic cholangiocarcinoma developed persistent grade 3 or 4 pancytopenia. 1 person had severe leukocytopenia and thrombocytopenia because of bone marrow infiltration of uveal melanoma. CS-PHP was discontinued in 2 people because of complications (takotsubo cardiomyopathy or non-catheterisable splenic artery) and in 2 others because of unspecified discomfort at their own choice.

Study or author name, date	Efficacy outcomes	Safety outcomes
	extrahepatic tumour manifestations at baseline (log-rank chi-square 1.755, p=0.185). At the time of analysis, 11 people were still alive, with 6 of them actively having CS-PHP treatment. Of the 22 people who died, 3 (2 with uveal melanoma and 1 with pancreatic cancer) did not respond to CS-PHP and died from intrahepatic tumour progression. 10 people with intrahepatic disease control from CS-PHP had dominant extrahepatic progression, leading to CS-PHP cessation. CS-PHP was abandoned as a treatment because of hepatic disease progression in 3 people, intolerability in 2 people and loss to follow-up in 4 people.	
Meijer, 2022	Number of people included in analysis: 8 **Treatment response** • Overall response rate=25.0% (2/8) • Partial response=25.0% (2/8) • Stable disease=37.5% (3/8) • Progressive disease=37.5% (3/8)	**Adverse events** • Grade 3 or 4 thrombocytopenia=75.0% (6/8) • Grade 3 or 4 anaemia=37.5% (3/8) • Grade 3 or 4 leukocytopenia=87.5% (7/8) • Grade 3 or 4 lymphocytopenia=100% (8/8) • Grade 4 neutropenia=50.0% (4/8) • Grade 3 elevation of AST=25.0% (2/8)

Study or author name, date	Efficacy outcomes	Safety outcomes
	Survival • Median overall survival=17.3 months (range 2.6 to 30.9) • 1-year overall survival=50% • 2-year overall survival=50% • 3-year overall survival=0% • Median progression-free survival=4.4 months (range 1.1 to 23.6) • Median hepatic progression-free survival=4.5 months (range 1.1 to 23.6) 6 out of 8 people had some form of subsequent treatment after progression of disease occurred.	

Procedure technique

Of the 14 studies, 12 studies detailed the procedure technique and devices used. They all used the Hepatic CHEMOSAT Delivery System (Delcath Systems Inc., US), with the second-generation haemofiltration system. Most studies described a protocol that included up to 6 procedures, with intervals typically ranging from 5 to 12 weeks between them. One study (Meijer 2021) offered 2 procedures and people with progressive disease or unacceptable adverse events after the first CS-PHP only had 1 procedure. Another study (Dewald 2022) scheduled 1 CS-PHP with the option of retreatment if there was stable disease or a partial response.

Efficacy

Uveal melanoma liver metastases

Overall survival

Unless stated otherwise, survival was measured from the first CS-PHP treatment. Median overall survival was reported in 8 studies and ranged from 14.9 months to 29.1 months. Overall survival at 1 year was reported in 3 studies and ranged from 77% to 79.5%.

In the randomised controlled trial of 72 people who had CS-PHP or BAC, the median overall survival was 18.5 months (95% CI 16.3 to 22.4) and 14.5 months (95% CI 11.1 to 19.8), respectively (p=0.714). Overall survival at 1 year was 79% (95% CI 62 to 89) in the CS-PHP group and 67% (95% CI 47 to 81) in the BAC group. At 2 years, overall survival was 27% (95% CI 14 to 42) and 26% (95% CI 12 to 43), respectively (Zager 2025). In the pooled analysis of 102 people enrolled from the same randomised controlled trial and from non-randomised phases of the study, median overall survival was 20.5 months (95% CI 16.8 to

25.3; Zager 2024). In the subgroup analysis, people with baseline hepatic tumour burden below the median (n=45) had a longer median overall survival than those with baseline hepatic tumour burden above the median (n=45; 26.7 [95% CI 22.3 to 34.5] versus 15.4 [95% CI 12.2 to 18.6] months, p=0.008). People with 1 to 25% liver involvement at baseline (n=72) had longer overall survival compared to those with 26 to 50% liver involvement (n=19; median 22.4 [95% CI 16.8 to 28.2] versus 16.9 [95% CI 9.26 to 25.9] months, p=0.030), as did those with low or normal LDH values (n=54) compared to those with elevated values (n=32; median 23.5 [95% CI 18.3 to 28.2] versus 15.3 [95% CI 11.7 to 20.8] months, p=0.019; Zager 2026).

In the retrospective non-randomised comparative study of 62 people who had CS-PHP or SIRT, median overall survival was 17.0 months and 9.9 months, respectively. Cox regression adjusted via propensity score analysis for confounders, including the amount of hepatic involvement, showed a statistically significant difference (HR 0.32, 95% CI 0.14 to 0.73, p=0.006; Kolb 2023).

In the retrospective case series of 101 people, median overall survival was 20.0 months (95% CI 13.7 to 26.3). There was a statistically significant difference in overall survival for people who had 2 or more CS-PHP treatments versus 1 treatment (20 versus 8 months, respectively, $p<0.05$; Tong 2022). In the retrospective case series of 83 people, median overall survival was 14.9 months (Modi 2022). In the retrospective case series of 66 people, median overall survival was 18.4 months (95% CI 7 to 24.6; Dewald 2022). In the retrospective case series of 38 people, median overall survival was 29.1 months (95% CI 18.4 to 38.9). Overall survival at 1, 2 and 3 years was 79.5% (95% CI 67.0 to 94.3), 53.2% (95% CI 38.2 to 74.0) and 28.5% (95% CI 15.4 to 52.8), respectively (Reiner 2025). In the prospective single arm trial of 35 people, median overall

survival was 19.1 months. Overall survival at 1 and 2 years was 77% and 43%, respectively (Meijer 2021).

Progression-free survival

Unless stated otherwise, progression-free survival was measured from the first CS-PHP treatment. Median progression-free survival was reported in 6 studies and ranged from 7.6 months to 13.4 months. Median hepatic progression-free survival was reported in 5 studies and ranged from 11.0 months to 13.9 months.

In the randomised controlled trial of 72 people, median progression-free survival was statistically significantly longer in people who had CS-PHP (9.0 months, 95% CI 6.4 to 11.8) compared with people who had BAC (3.1 months, 95% CI 2.9 to 5.9, p=0.015). Median hepatic progression-free survival was also statistically significantly longer (11.4 months for people who had CS-PHP [95% CI 9.0 to 15.9], compared with 3.3 months for people who had BAC [95% CI 2.9 to 8.2], p=0.0008). Progression-free survival at 6 months was 64% (95% CI 54 to 83) in the CS-PHP group and 32% (95% CI 12 to 43) in the BAC group. At 1 year, progression-free survival was 31% (95% CI 20 to 50) for people who had CS-PHP and 11% (95% 3 to 26) for people who had BAC (Zager 2025). In the pooled analysis of 102 people enrolled from the same randomised controlled trial and from non-randomised phases of the study, median progression-free survival was 9.0 months (95% CI 6.3 to 11.6) and median hepatic progression-free survival was 13.9 months (95% CI 9.3 to 16.7; Zager 2024). In the subgroup analysis, people with baseline hepatic tumour burden below the median (n=45) had a longer median progression-free survival than those with baseline hepatic tumour burden above the median (n=45; 11.3 months [95% CI 9.00 to 15.9] versus 5.8 months [95% CI 3.68 to 9.17], p=0.007; Zager 2026).

In the retrospective non-randomised comparative study of 62 people, median progression-free survival was 13.4 months for people who had CS-PHP and

4.2 months for people who had SIRT (HR 0.58, 95% CI 0.3 to 1.1; p=0.09; Kolb 2023).

In the retrospective case series of 101 people, median progression-free survival was 9.0 months (95% CI 7.7 to 10.3) and median hepatic progression-free survival was 11.0 months (95% CI 9.0 to 13.0; Tong 2022). In the retrospective case series of 83 people, median progression-free survival was 8.4 months (Modi 2022). In the retrospective case series of 66 people, median hepatic progression-free survival was 12.4 months (95% CI 4 to 18.4; Dewald 2022). In the prospective single arm trial of 35 people, median progression-free survival was 7.6 months (95% CI 4.9 to 10.3), and median hepatic progression-free survival was 11.2 months (95% CI 9.0 to 13.4). At 1 year, progression-free survival was 26.5% and hepatic progression-free survival was 35.3% (Meijer 2021).

Tumour response

Tumour response was reported as an outcome in 8 studies. The objective response rate was reported in 6 studies and ranged from 28% to 72%.

In the randomised controlled trial of 72 people comparing CS-PHP with BAC, there was no statistically significant difference in objective response rate (27.5% [95% CI 14.6 to 43.9] for CS-PHP and 9.4% [95% CI 2.0 to 25.0] for BAC, p=0.074). Complete response was reported in 3 people who had CS-PHP and none who had BAC. Progressive disease was reported as the best overall response in 20% (8/40) of people who had CS-PHP and 50% (16/32) of people who had BAC (Zager 2025). In the pooled analysis of 102 people enrolled from the same randomised controlled trial and from non-randomised phases of the study, the objective response rate was 36% (95% CI 26 to 47). A complete response was reported for 8% (7/91) of people, a partial response for 29% (26/91), stable disease for 37% (34/91) and progressive disease for 25% (23/91; Zager 2024). Of the 33 people with complete or partial response, 19 (58%) had a

response within the first or second cycle of treatment (Zager 2026). People for whom baseline hepatic tumour burden was below the median (n=45) had a statistically significant higher objective response rate compared to those with baseline hepatic tumour burden above the median (n=45; 51% [95% CI 25.8 to 66.3] versus 22% [95% CI 11.2 to 37.1], p=0.008).

In the retrospective non-randomised comparative study of 62 people who had CS-PHP or SIRT, there were no complete responses per treatment cycle in either group. A partial response was reported in 9% (5 out of 56) of people who had CS-PHP and 3% (1 out of 39) of people who had SIRT. Progressive disease was reported in 70% (39 out of 56) of people who had CS-PHP and 82% (32 out of 39) of people who had SIRT (Kolb 2023).

In the retrospective case series of 101 people, the objective response rate was 59% and the disease control rate was 89%. There was a complete response in 5% (5 out of 101) of people, partial response in 54% (55 out of 101), stable disease in 30% (30 out of 101) and progressive disease in 11% (11 out of 101; Tong 2022). In the retrospective case series of 83 people, the objective response rate was 61%. The best overall response was a complete response in 9% (7 out of 81) of people, partial response in 52% (42 out of 81), stable disease in 20% (16 out of 81) and progressive disease in 20% (16 out of 81; Modi 2022). In the retrospective case series of 66 people, the overall response rate was 59% (36 out of 61) and the disease control rate was 93% (59 out of 61). After the first CS-PHP, 43% (26 out of 61) of people had a complete or partial response, 46% (28 out of 61) had stable disease and 12% (7 out of 61) had progressive disease (Dewald 2022). In the retrospective case series of 20 people, the best liver response was complete response in 25% (5 out of 20) of people, partial response in 55% (11 out of 20), stable disease in 15% (3 out of 20) and progressive disease in 5% (1 out of 20; Vigneswaran, 2024). In the prospective single arm

trial of 35 people, the overall response rate was 72% (23 out of 32). There was a complete response in 3% (1 out of 32) of people, partial response in 69% (22 out of 32) and hepatic response in 81% (26 out of 32). Progressive disease because of extrahepatic disease was reported in 16% (5 out of 32) of people (Meijer 2021).

Quality of life

Quality of life was reported as an outcome in 3 studies.

In the prospective study of 24 people, most quality-of-life scores on EORTC QLQC30 declined on day 2 or 3 after CS-PHP. On day 21, 12 out of 15 scores returned to baseline, including median global health status scores. Three variables were statistically significantly worse on day 21 compared to baseline: fatigue (33 versus 6; p=0.002), physical functioning (87 versus 100; p=0.003), and role functioning (67 versus 100; p=0.001; Tong 2024). In the retrospective case series of 20 people, the median quality of life scores dropped at day 1 but had recovered to near baseline levels by day 14 (95 compared to 101.8 at baseline, p=0.57). By day 28, there was a statistically significant improvement in the emotional wellbeing domain compared to baseline (before procedure 20.5 compared to 22 afterwards, p=0.01; Vigneswaran 2024). In the prospective single arm trial of 35 people, quality-of-life questionnaire scores after treatment did not statistically significantly differ from scores before treatment, except for physical functioning which was impaired 6 weeks after the second CS-PHP (p=0.011). The level of physical functioning was restored to normal 3 months later (Meijer 2021).

Primary or secondary liver cancer, other than metastatic uveal melanoma

Overall survival

Median overall survival was reported in all 4 studies.

In the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers, median overall survival from the first CS-PHP procedure was 9 months. Median overall survival was 12 months for people with ocular melanoma and 8 months for people with other liver tumours, p=0.893). One person with cholangiocarcinoma had the longest survival of 3.7 years (Schönfeld 2020). In the retrospective case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases, median survival from first CS-PHP was 9.9 months (IQR 3.8 to 21). The survival rate at 1 year was 41% (Dewald 2023). In the retrospective case series of 33 people with unresectable intrahepatic metastases of uveal melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma or hepatic metastases originating from other primary cancers, the median overall survival was 65 weeks (95% CI 38.2 to 91.5). For people with intrahepatic cholangiocarcinoma, median overall survival was 38 weeks (95% CI 32.0 to 43.7; Veelken 2024). In the prospective single-arm trial of 8 people with unresectable colorectal liver metastases, median overall survival was 17.3 months (range 2.6 to 30.9). At 1 year, 2 years and 3 years survival was 50%, 50% and 0%, respectively (Meijer 2022).

Progression-free survival

Progression-free survival was reported in all 4 studies.

In the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers,

median progression-free survival from first CS-PHP was 4 months and median hepatic progression-free survival was 5 months (Schönfeld 2020). In the retrospective case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases, median progression-free survival was 3.5 months (IQR 2.2 to 7.4) and median hepatic progression-free survival was 3.6 months (IQR 2.6 to 9.5; Dewald 2023). In the retrospective case series of 33 people with unresectable intrahepatic metastases of uveal melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma or hepatic metastases originating from other primary cancers, the median hepatic progression-free survival was 52 weeks (95% CI 24.7 to 79.2; Veelken 2024). In the prospective single-arm trial of 8 people with unresectable colorectal liver metastases, median progression-free survival was 4.4 months (range 1.1 to 23.6) and median hepatic progression-free survival was 4.5 months (range 1.1 to 23.6; Meijer 2022).

Tumour response

Tumour response was reported as an outcome in all 4 studies.

In the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers, the overall response rate was 33% (18 out of 54) and overall disease stabilisation was 70% (38 out of 54). After the first CS-PHP, 26% (14 out of 54) of people had a response, 46% (25 out of 54) had stable disease and 28% (15 out of 54) had progressive disease. The overall response rate was 31% for people with cholangiocarcinoma and 33% for people with secondary malignancies other than ocular melanoma. None of the people with hepatocellular carcinoma had a radiological response. One person with cholangiocarcinoma had a complete response after the first CS-PHP but was lost to follow-up. People with ocular melanoma were more likely to have a response than those with other tumours

(OR 9.26, 95% CI 1.26 to 67.9, p=0.028; Schönfeld 2020). In the retrospective case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases, the overall response rate was 25% and the disease control rate was 75%. After the first CS-PHP, 6% (1 out of 16) of people had a complete response, 18% (3 out of 16) had a partial response, 44% (7 out of 16) had stable disease and 31% (5 out of 16) had tumour progression (Dewald 2023). In the retrospective case series of 33 people with unresectable intrahepatic metastases of uveal melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma or hepatic metastases originating from other primary cancers, the disease control rate of hepatic tumours was 91%. Hepatic complete response was reported for 18% (6 out of 33) of people, hepatic partial response for 36% (12 out of 33) and hepatic stable disease for 36% (12 out of 33). In 6 people, hepatic complete response was achieved after a median of 5 (range 2 to 7) CS-PHP procedures (Veelken 2024). In the prospective single-arm trial of 8 people with unresectable colorectal liver metastases, the overall response rate was 25% (2 out of 8). Partial response was reported for 25% (2 out of 8) of people, stable disease for 38% (3 out of 8) and progressive disease for 38% (3 out of 8; Meijer 2022).

Safety

Uveal melanoma liver metastases

General

Adverse events leading to treatment discontinuation were reported in 15% (6 out of 41) of people and adverse events leading to a dose reduction were reported in 7% (3 out of 41) of people who had CS-PHP in the randomised controlled trial. At least 1 severe treatment-related adverse event was reported in 85% of people in the CS-PHP arm and 34% of people in the BAC arm of the trial (Zager 2025).

Adverse events leading to treatment discontinuation or dose reduction were reported in 18% (17 out of 95) and 14% (13 out of 95), respectively of people who had CS-PHP in the pooled analysis from the randomised controlled trial and single-arm trial (Zager 2024).

Discontinuation of treatment because of toxicity was reported in 10% (8 out of 83) of people in the retrospective case series of 83 people. Dose reduction because of toxicity, interval abnormal liver function tests or filter blockage was reported in 6% (5 out of 83) of people in the same study (Modi 2022).

Haematological events

Severe thrombocytopenia, leukopenia and neutropenia were reported in 56%, 37% and 37% of people, respectively in the CS-PHP arm in the randomised controlled trial. Severe anaemia was reported in 34% and hypophosphatemia in 15% of people in the CS-PHP arm. Serious thrombocytopenia, leukopenia, neutropenia and febrile neutropenia were reported in 20%, 10%, 10% and 7% of people, respectively in the CS-PHP arm. Haematological toxicity was described as transient and manageable with standard supportive care (Zager 2025).

Serious grade 3 or 4 thrombocytopenia, neutropenia, febrile neutropenia and leukopenia were reported in 16% (15 out of 95), 10% (10 out of 95), 6% (6 out of 95) and 5% (5 out of 95) of people, respectively in the pooled analysis from the randomised controlled trial and single-arm trial (Zager 2024).

Grade 3 anaemia, leukopenia, thrombocytopenia and febrile neutropenia were reported after 7%, 9%, 14% and 3% of procedures, respectively in the retrospective case series of 101 people. Grade 4 anaemia, leukopenia and thrombocytopenia were reported after 0.5%, 15% and 14% of procedures respectively (Tong 2022). Grade 3 or 4 anaemia, thrombocytopenia, or neutropenia were reported in 13% (11 out of 83), 12% (10 out of 83) and 13% (11

out of 83) of people, respectively in the retrospective case series of 83 people (Modi 2022). Grade 3 or 4 anaemia, thrombocytopenia, or leukopenia were reported in 26% (17 out of 66), 54% (36 out of 66) and 9% (6 out of 66) of people, respectively in the retrospective case series of 66 people (Dewald 2022). Grade 3 or 4 anaemia (1 event), leukopenia (6 events), thrombocytopenia (3 events) and febrile neutropenia (1 event) were reported within 30 days of CS-PHP in the prospective study of 24 people (Tong 2024). Heparin-induced thrombocytopenia type 2 was reported in 1 person in the retrospective case series of 38 people (Reiner 2025). There were 2 serious events of febrile neutropenia and 1 of febrile neutropenia with mucositis or oesophagitis reported in the prospective single arm trial of 35 people (Meijer 2019 and 2021). Grade 3 or 4 anaemia, thrombocytopenia, leukopenia, neutropenia and lymphocytopenia were reported in 18%, 54%, 76%, 67% and 85% respectively, of people who had at least 1 technically successful CS-PHP (n=33) in the same study.

Vascular injury

Dissection or occlusion of the hepatic artery was reported in 7 procedures in the retrospective case series of 101 people (Tong 2022). Hepatic artery dissection was reported in 1 person in the retrospective case series of 20 people (Vigneswaran 2024).

Bleeding

Vaginal haemorrhage and neck haematoma were each reported after 1 procedure in the retrospective case series of 101 people (Tong 2022). Active bleeding at the puncture site with subsequent haemorrhagic shock and ulcer bleeding were reported in 1 person each in the retrospective case series of 66 people (Dewald 2022). Postprocedural groin haemorrhage was reported in 1 person in the prospective study of 24 people (Tong 2024). Vaginal

haemorrhage with grade 2 anaemia was reported in 1 person in the prospective single arm trial of 35 people (Meijer 2019 and 2021).

Cardiovascular events

Atrial fibrillation with cardioversion was reported after 1 procedure in the retrospective case series of 101 people. Grade 3 stroke was reported after 3% (5 out of 183) of procedures in the same study (Tong 2022). Arrhythmia was reported in 2% (2 out of 83) of people in the retrospective case series of 83 people (Modi 2022). Five major thromboembolic adverse cardiovascular events were reported after CS-PHP in the retrospective case series of 66 people: 1 cerebral artery occlusion, 1 basilar artery thrombosis, 2 minor strokes and 1 central pulmonary embolism. Non-ST-segment elevation myocardial infarction and tachyarrhythmia absoluta were reported in 1 person each in the same study (Dewald 2022).

Periprocedural pseudoaneurysm of the common femoral artery was reported in 1 person in the prospective study of 24 people. Cardiac complications combined with hypothermia, hypotension, and metabolic acidosis were reported in another person in the same study (Tong 2024). Non-ST elevation myocardial infarction, pulmonary embolism, and cerebral artery basilar embolism in conjunction with bilateral pulmonary embolism were reported in 1 person each in the retrospective case series of 38 people (Reiner 2025). Transient cardiac ischaemia, asymptomatic postprocedural hypotension, and asymptomatic postprocedural ECG changes were reported after 1 procedure each and pulmonary emboli were reported after 3% (2 out of 67) of procedures in the prospective single arm trial of 35 people (Meijer 2019 and 2021).

Infection

Vulvar infection and sepsis were each reported after 1 procedure in the retrospective case series of 101 people (Tong 2022). Sepsis was reported in 1 person in the retrospective case series of 66 people (Dewald 2022). Eye infection was reported in 1 person in the prospective study of 24 people (Tong 2024). Sepsis with bacterial pharyngitis and retropharyngeal abscess was reported in 1 person in the prospective single arm trial of 35 people (Meijer 2019 and 2021). Prostatitis was reported in 1 person in the same study.

Liver toxicity

Grade 3 increased AST was reported after 7% (12 out of 183) and grade 4 after 1% (2 out of 183) of procedures in the retrospective case series of 101 people. Grade 3 increased ALT was reported after 5% (10 out of 183) and grade 4 after 1% (2 out of 183) of procedures. Increased bilirubin (grade 3) was reported after 2% (4 out of 183) of procedures (Tong 2022). Grade 3 or 4 AST increase was reported in 17% (11 out of 66) and ALT increase was reported in 15% (10 out of 66) of people, respectively in the retrospective case series of 66 people. Hyperbilirubinemia and hypoalbuminemia were reported in 9% (6 out of 66) of people (Dewald 2022). There was 1 event of increased AST and 2 of increased gamma-glutamyl transferase in the prospective study of 24 people (Tong 2024).

Renal complications

Acute kidney injury was reported after 2% (3 out of 183) of procedures in the retrospective case series of 101 people (Tong 2022). Acute kidney failure was reported in 1 person in the retrospective case series of 66 people (Dewald 2022).

30-day mortality

Some studies reported deaths that happened within 30 days of CS-PHP, but they may not have been directly attributable to the procedure. Two people died within

30 days of CS-PHP in the retrospective case series of 101 people. One person died 3 days after CS-PHP from toxic liver failure, generalised bleeding because of coagulopathy and lactate acidosis. A second person died 12 days after the procedure because of rapid tumour progression and subsequent progressive multiorgan failure (Tong 2022).

Three people died within 30 days of CS-PHP in the retrospective case series of 66 people. One person died from sepsis 3 days after the first CS-PHP and 2 people with high tumour burden died shortly (3 days and 12 days, respectively) after the first CS-PHP caused by tumour lysis syndrome combined with fast tumour progression (Dewald 2022).

Nausea

There were 6 events of grade 3 or 4 nausea within 30 days after CS-PHP in the prospective study of 24 people (Tong 2024). Nausea and vomiting with mild hypokalemia was reported in 1 person in the prospective single arm trial of 35 people (Meijer 2019 and 2021).

Fatigue

There were 5 events of grade 3 or 4 nausea within 30 days after CS-PHP in the prospective study of 24 people (Tong 2024).

Primary or secondary liver cancer, other than metastatic uveal melanoma

Haematological events

The rates of grade 3 or 4 thrombocytopenia, anaemia, and leukopenia during treatment were 80%, 45% and 32%, respectively, in the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers (Schönfeld 2020). Overall, 30% of people

needed platelet transfusion and 32% needed erythrocyte concentrate transfusion. Grade 3 or 4 thrombocytopenia, anaemia and leukopenia were reported after 50%, 26% and 21% of procedures, respectively, in the retrospective case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases (Dewald 2023). Grade 3 or 4 pancytopenia was reported in 2 people in the retrospective case series of 33 people (Veelken 2024). In the same study, 1 person had severe leukocytopenia and thrombocytopenia because of bone marrow infiltration of uveal melanoma. Grade 3 or 4 thrombocytopenia, anaemia, leukocytopenia, lymphocytopenia and grade 4 neutropenia were reported in 6, 3, 7, 8 and 4 people, respectively, in the prospective single-arm trial of 8 people with unresectable colorectal liver metastases (Meijer 2022).

Liver toxicity

Grade 3 or 4 increase in ALT or AST was reported in 27% and 48% of people, respectively and hyperbilirubinemia or hypoalbuminemia were reported in 15% of people each in the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers (Schönfeld 2020). An increase in ALT or AST was reported in 24% and 21% of people, respectively, in the retrospective case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases. Hyperbilirubinemia was reported in 5% of people and hypoalbuminemia was reported in 14% of people (Dewald 2023). Grade 3 increase of AST was reported in 2 people in the prospective single-arm trial of 8 people with unresectable colorectal liver metastases (Meijer 2022).

Cardiovascular events

Cardiovascular events were reported in 5% (3 out of 60) of people in the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers

(Schönfeld 2020). Transient hemiparesis and persistent catecholamine-dependent hypotension were reported in 1 person each in the retrospective case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases (Dewald 2023).

Bleeding

Ulcerous bleeding was reported in 3% (2 out of 60) of people in the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers (Schönfeld 2020).

Discontinuation of treatment

CS-PHP was discontinued because of complications (takotsubo cardiomyopathy or non-catheterisable splenic artery) and in 2 others because of unspecified discomfort at their own choice, in the retrospective case series of 33 people (Veelken 2024).

Other

Generalised oedema, ascites, or pleural effusion because of overhydration or hypoalbuminemia was reported in 22% (13 out of 60) of people in the retrospective case series of 60 people with ocular melanoma, cholangiocarcinoma, hepatocellular carcinoma or other secondary cancers (Schönfeld 2020). Aspiration pneumonia caused by postoperative nausea and vomiting was reported in 1 person in the retrospective case series of 17 people with intrahepatic cholangiocarcinoma or cholangiocarcinoma liver metastases (Dewald 2023).

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about

(anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following anecdotal or theoretical adverse events:

- anaphylaxis
- extracorporeal circuit complications
- anaesthesia related complications
- deep vein thrombosis.

Six professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Adverse events reported by the company

The company submitted a report describing adverse events in 14 people between 2021 and 2025. Most of the types of events have been described in the literature, including pancytopenia, neutropenia, leukopenia, anaemia, infection, haemorrhage and embolic stroke. Single events that have not already been described include anaphylactic shock, acute respiratory distress syndrome, post-embolisation syndrome, tachypnoea, blood pressure decrease, deep vein thrombosis and exertional rhabdomyolysis.

Summary of the evidence considered

Key points

- Most of the evidence is on people with uveal melanoma liver metastases.
- For people with uveal melanoma liver metastases, median overall survival after the procedure ranged from 14.9 months to 29.1 months. Median

progression-free survival ranged from 7.6 months to 13.4 months. The objective response rate ranged from 28% to 72%.

- The randomised FOCUS trial suggests a potential clinical benefit of the procedure in people with unresectable metastatic uveal melanoma compared to BAC, but the trial was closed early because of slow recruitment and people were reluctant to be assigned to the BAC arm. This means all results lacked statistical power.
- In 4 small studies that included a total of 118 people, 69 of whom had liver tumours other than uveal melanoma metastases, median overall survival after CS-PHP ranged from 8 months to 17.3 months.
- There are serious complications associated with the procedure, and haematological toxicity is commonly reported.
- Three studies show quality of life is not reduced over the course of CS-PHP treatment.

Limitations and considerations

- The evidence includes a randomised controlled trial on metastatic uveal melanoma comparing the procedure with BAC, but it was underpowered to show statistically significance because of early termination and small sample size (85 instead of the planned 240).
- There is evidence from the UK (Modi 2022, Vigneswaran 2024).
- The inclusion and exclusion criteria varied between studies, including the presence of extrahepatic disease.
- The number of CS-PHP procedures per person varied between studies. Some study protocols scheduled a maximum of 6 procedures, but others only offered 1 or 2 procedures, depending on the response.
- People may have been offered additional treatments after CS-PHP, and this may have an impact on survival.

- Most of the studies were retrospective. The sample sizes in all 14 studies ranged from 8 to 102 people.
- The study by Meijer (2022) was terminated early because of slow recruitment.
- The FOCUS study was funded by Delcath Systems Inc. (Zager 2024, 2025). Studies by Meijer (2021 and 2022) reported that the study centre received financial support and in kind contributions from Delcath Systems Inc. for conducting studies on CS-PHP. Tong (2024) reported that Delcath Systems Inc. contributed to the study by supplying the kits for CS-PHP. At least 1 author reported consultancy fees, honoraria or a grant from Delcath Systems Inc. in the papers by Modi (2022), Vigneswaran (2024), Schönfeld (2020) and Dewald (2023). In the study by Veelken (2024), 4 authors declared financial support or honoraria from multiple companies.

Ongoing trials

- An Open-label, Randomized, Multi-Center Study to Evaluate the Efficacy and Safety of Induction Treatment With Melphalan/HDS Followed by Consolidation Treatment With Trifluridine-Tipiracil Plus Bevacizumab Versus Trifluridine-Tipiracil Plus Bevacizumab Alone in Patients With Refractory Metastatic Colorectal Cancer With Liver Dominant Disease. ClinicalTrials.gov identifier: NCT06607458). Status: recruiting. Indication: colorectal liver metastases. Estimated n=90. Trial design: randomised controlled trial. Estimated completion date October 2027. Countries: US, Czechia, Germany, Italy, Spain.
- Evaluation of the Safety and Efficacy of Treatment w/High Dose Melphalan Given Directly Into the Liver Followed by Treatment w/Approved Cancer Treatment or Approved Cancer Treatment Alone in Patients w/ Metastatic Breast Cancer w/Liver Dominant Disease. ClinicalTrials.gov identifier: NCT06875128. Status: recruiting. Indication: metastatic breast cancer to the

liver. Estimated n=90. Trial design: randomised controlled trial. Estimated completion date August 2029. Country: US.

- Phase 2 Combination of Melphalan/HDS Via PHP + Tebentafusp in Treating Metastatic Uveal Melanoma. ClinicalTrials.gov identifier: NCT07276386. Status: recruiting. Indication: uveal melanoma liver metastases. Estimated n=18. Trial design: single group assignment. Estimated completion date December 2030. Country: US.
- PHP in Combination With IPI1/NIVO3 Compared to IPI3/NIVO1 Only in Patients With Uveal Melanoma Liver Metastases (SCANDIUM-III). ClinicalTrials.gov identifier: NCT06519266. Status: recruiting. Indication: uveal melanoma liver metastases. Estimated n=40. Trial design: randomised controlled trial. Estimated completion date December 2030. Country: Sweden.
- Hepzato Kit and Opdualag for Metastatic Melanoma and Liver Metastasis. ClinicalTrials.gov identifier: NCT07281924. Status: recruiting. Indication: melanoma liver metastases. Estimated n=15. Trial design: single group assignment. Estimated completion date December 2030. Country: US.

Existing assessments of this procedure

An update of UK national guidelines on uveal melanoma was published in 2025 (Carter 2025). This includes the following evidence statement that is relevant to CS-PHP:

'Regional liver-directed treatments (PHP/IHP, SIRT, TACE) can reduce measurable tumour burden. Whilst there is a sparsity of randomised data, outcomes may be improved in selective patients when compared with historic controls. Grade: B' (body of evidence including studies rated as 2++ [high quality systematic reviews of case control or cohort or studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal] directly applicable to the target population, and

demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ [high quality meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials with a very low risk of bias] or 1+ [Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias]).

The guidelines include the following recommendation:

'Liver-directed or systemic treatments should be considered in selected patients with liver predominant disease where resection is not possible. Grade: GPP' (recommended best practice based on the clinical experience of the guideline development group).

Related NICE guidance

Interventional procedures

- 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).
- 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).

Technology appraisals

- 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)
- 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

Professional societies

- British Society of Interventional Radiology
- Royal College of Radiologists – Faculty of Clinical Oncology
- Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
- Association of Cancer Physicians
- British Association of Surgical Oncology - the Association for Cancer Surgery
- Society of Clinical Perfusion Scientists of Great Britain and Ireland
- British Society of Gastrointestinal and Abdominal Radiology.

Evidence from people who have had the procedure and patient organisations

NICE received 1 submission from a patient organisation about melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver.

NICE received 19 questionnaires from people who have had the procedure (or their carers).

The views of people who have had the procedure were consistent with the published evidence and the opinions of the professional experts. See the patient commentary summary for more information.

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 1 completed submission. This was considered during the assessment, and any relevant points have been taken into consideration when preparing this report.

References

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unresectable metastatic uveal melanoma. Journal of Cancer Research and Clinical Oncology 152: 25

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4. Kolb M, Forschner A, Artzner C et al. (2023) Selective Internal Radiotherapy (SIRT) and Chemosaturation Percutaneous Hepatic Perfusion (CS-PHP) for Metastasized Uveal Melanoma: A Retrospective Comparative Study. Cancers 15:4942
5. Meijer TS, Burgmans MC, de Leede EM et al. (2021) Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Ocular Melanoma Metastases Confined to the Liver: A Prospective Phase II Study. Annals of Surgical Oncology 28, 1130–1141

   Meijer TS, Burgmans MC, Fiocco M et al. (2019) Safety of Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Liver Metastases from Ocular Melanoma Using the Delcath Systems' Second-Generation Hemofiltration System: A Prospective Non-randomized Phase II Trial. Cardiovasc Intervent Radiol 42, 841–852
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8. Tong TML, Fiocco M, van Duijn-de Vreugd, JJ et al. (2024) Quality of Life Analysis of Patients Treated with Percutaneous Hepatic Perfusion for Uveal Melanoma Liver Metastases. Cardiovascular and Interventional Radiology 47: 741–750
9. Vigneswaran G, Malalasekera W, Smith V et al. (2024) Quality of life after melphalan percutaneous hepatic perfusion for patients with metastatic uveal melanoma. Melanoma Research 34: 193–197
10. Reiner CM, Schneider MA, Weilert H et al. (2025) Survival Outcome After Percutaneous Hepatic Perfusion with High-Dose Melphalan for Liver-Dominant Metastatic Uveal Melanoma: A 10-Year Single-Center Experience. Cancers 17: 3834

11. Schönfeld L, Hinrichs JB, Marquardt S et al. (2020) Chemosaturation with percutaneous hepatic perfusion is effective in patients with ocular melanoma and cholangiocarcinoma. Journal of Cancer Research and Clinical Oncology 146: 3003–3012

12. Dewald CLA, Becker LS, Meine TC et al. (2023) New perspectives in unresectable cholangiocarcinoma? Evaluation of chemosaturation with percutaneous hepatic perfusion as a palliative treatment option. Clinical and Experimental Metastasis 40: 95–104

13. Veelken R, Ebel S, Schindler A et al. (2024) Hepatic chemosaturation with melphalan in patients with primary or secondary liver tumors with or without extrahepatic tumor manifestation. ESMO Gastrointestinal Oncology 5: 100082

14. Meijer TS, Dieters JHN, de Leede EM et al. (2022) Prospective evaluation of percutaneous hepatic perfusion with melphalan as a treatment for unresectable liver metastases from colorectal cancer. PLoS ONE 17: e0261939

Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver from the medical literature.

Search strategy design and peer review

This search report is informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S).

A NICE information specialist ran the literature searches on 28 January 2026. See the search strategy history for the full search strategy for each database. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in table 4a, taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the Peer Review of Electronic Search Strategies (PRESS) 2015 evidence-based checklist.

Review management

The search results were managed in EPPI-Reviewer version 5 (EPPI-R5). Duplicates were removed in EPPI-R5 using a 2-step process. First, automated deduplication was done using a high-value algorithm. Second, manual

deduplication was used to assess low-probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

Search filters

Limits and restrictions

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material.

The search was limited from 1 January 2020 to 28 February 2026. The new date limits reflect that the prior guidance was last run in 2020.

The limit to remove animal studies in the searches is standard NICE practice, which has been adapted from Dickersin K, Scherer R, Lefebvre C (1994) Systematic Reviews: Identifying relevant studies for systematic reviews. BMJ 309(6964): 1286.

Main search

Table 4a Main search results

Database	Date searched	Database platform	Database segment or version	Number of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	28/01/26	Wiley	Issue 1 of 12, January 2026	10
Cochrane Database of Systematic Reviews (CDSR)	28/01/26	Wiley	Issue 1 of 12, January 2026	0
Embase	28/01/26	Ovid	1974 to 2026 January 27	403
INAHTA International HTA Database	28/01/26	https://database.inahta.org/	-	6
MEDLINE ALL	28/01/26	Ovid	1946 to January 27, 2026	144

Search strategy history

MEDLINE ALL search strategy

1 , Liver Neoplasms/ , 194,836

2 , ((liver or hepatic* or hepatocell*) adj4 (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas*)).tw. , 258,304

3 , Carcinoma, Hepatocellular/ , 118,160

4 , (hepatoma* or cholangiocarcinoma* or hepatocarcinoma* or HCC).tw. , 144,831

5 , Uveal neoplasms/ , 5,700

6 , (uvea* adj4 (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas* or melanom*)).tw. , 7,067

7 , or/1-6 , 356,745

8 , Chemotherapy, Cancer, Regional Perfusion/ , 3,984

9 , ((Percut* or isolate*) adj4 (hepat* or liver*) adj4 (perfus* or chemoperfus*)).tw. , 4,919

10 , CS-PHP.tw. , 16

11 , PHP.tw. , 2,968

12 , PIHP.tw. , 55

13 , Chemosat*.tw. , 40

14 , Melphalan/ , 8,352

15 , Melphalan*.tw. , 8,814

16 , Melphalan hepatic delivery system.tw. , 10

17 , delcath.tw. , 15

18 , hepzato.tw. , 4

19 , ((Hepat* or liver*) adj4 (vein* or venous* or arter* or outflow*) adj4 (isolat* or segregate* or separat*)).tw. , 430

20 , Veno-venous bypass procedure.tw. , 0

21 , VVB.tw. , 102

22 , or/8-21 , 23,318

23 , 7 and 22 , 1,061

24 , animals/ not human/ , 5,384,044

25 , 23 not 24 , 900

26 , limit 25 to ed=20200101-20260228 , 105

27 , limit 25 to dt=20200101-20260228 , 129

28 , 26 or 27 , 144

Embase search strategy

1 , liver tumor/ , 64,177

2 , ((liver or hepatic* or hepatocell*) adj4 (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas*)).tw. , 382,158

3 , liver cell carcinoma/ , 250,102

4 , (hepatoma* or cholangiocarcinoma* or hepatocarcinoma* or HCC).tw. , 217,655

5 , uvea tumor/ , 1,295

6 , (uvea* adj4 (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas* or melanom*)).tw. , 10,092

7 , or/1-6 , 514,183

8 , regional perfusion/ , 13,271

9 , ((percut* or isolate*) adj4 (hepat* or liver*) adj4 (perfus* or chemoperfus*)).tw. , 5,129

10 , CS-PHP.tw. , 36

11 , PHP.tw. , 4,353

12 , PIHP.tw. , 80

13 , Chemosat*.tw. , 92

14 , melphalan/ , 46,947

15 , Melphalan*.tw. , 19,021

16 , Melphalan hepatic delivery system.tw. , 16

17 , delcath.tw. , 185

18 , hepzato.tw. , 7

19 , ((Hepat* or liver*) adj4 (vein* or venous* or arter* or outflow*) adj4 (isolat* or segregate* or separat*)).tw. , 667

20 , Veno-venous bypass procedure.tw. , 0

21 , VVB.tw. , 139

22 , or/8-21 , 70,879

23 , 7 and 22 , 2,359

24 , Nonhuman/ not Human/ , 5,890,375

25 , 23 not 24 , 2,197

26 , limit 23 to dc=20201010-20260228 , 586

27 , limit 23 to dd=20200101-20260228 , 667

28 , 26 or 27 , 668

29 , (conference abstract* or conference review or conference paper or conference proceeding).db,pt,su. , 6,671,734

30 , 28 not 29 , 403

Cochrane Library (CDSR and CENTRAL) search strategy

I#1 MeSH descriptor: [Liver Neoplasms] this term only 3863

#2 ((liver or hepatic* or hepatocell*) near/4 (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas*)):Ti,ab,kw 16229

#3 MeSH descriptor: [Carcinoma, Hepatocellular] this term only 2884

#4 (hepatoma* or cholangiocarcinoma* or hepatocarcinoma* or HCC):Ti,ab,kw 6217

#5 MeSH descriptor: [Uveal Neoplasms] this term only 103

#6 (uvea* near/4 (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas* or melanom*)):Ti,ab,kw 308

#7 #1 or #2 or #3 or #4 or #5 or #6 17902

#8 MeSH descriptor: [Chemotherapy, Cancer, Regional Perfusion] this term only 149

#9 ((percut* or isolate*) near/4 (hepat* or liver*) near/4 (perfus* or chemoperfus*)):Ti,ab,kw 61

#10 CS-PHP 3

#11 PHP 990

#12 PIHP 12

#13 Chemosat* 7

#14 MeSH descriptor: [Melphalan] this term only 850

#15 melphalan 2475

#16 Melphalan hepatic delivery system 6

#17 delcath 38

#18 hepzato 0

#19 ((Hepat* or liver*) near/4 (vein* or venous* or arter* or outflow*) near/4 (isolat* or segregate* or separat*)):Ti,ab,kw 18

#20 Veno-venous bypass procedure 16

#21 VVB.tw 0

#22 #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #17 or #18 or #19 or #20 or #21 3642

#23 #7 AND #22 130

#24 "conference":pt or (clinicaltrials or trialsearch):so 883173

#25 #23 NOT #24 with Cochrane Library publication date Between Jan 2020 and Feb 2026, in Trials 10

INAHTA HTA Database search strategy

1 , "Liver Neoplasms"[mh] , 145

2 , ((liver or hepatic* or hepatocell*) AND (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas*)) , 243

3 , "Carcinoma, Hepatocellular"[mh] , 88

4 , (hepatoma* or cholangiocarcinoma* or hepatocarcinoma* or HCC) , 60

5 , "Uveal Neoplasms"[mh] , 8

6 , (uvea* AND (secondar* or neoplasm* or cancer* or carcinoma* or adenocarcinom* or tumour* or tumor* or malignan* or metastas* or melanom*)): , 12 7 , #6 OR #5 OR #4 OR #3 OR #2 OR #1 , 284

8 , "Chemotherapy, Cancer, Regional Perfusion"[mh] , 10

9 , ((percut* or isolate*) AND (hepat* or liver*) AND (perfus* or chemoperfus*)) , 3

10 , CS-PHP , 3

11 , PHP , 3

12 , PIHP , 0

13 , chemosat* , 2

14 , "Melphalan"[mh] , 9

15 , melphalan , 14

16 , Melphalan hepatic delivery system , 0

17 , delcath , 1

18 , hepzato , 0

19 , ((Hepat* or liver*) AND (vein* or venous* or arter* or outflow*) AND (isolat* or segregate* or separat*)): , 5

20 , Veno-venous bypass procedure , 0

21 , VVB , 0

22 , #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 , 31

23 , 22 AND #7 , 6

Inclusion criteria

The following inclusion criteria were applied to the abstracts identified by the literature search.

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events not available in the published literature.
- People with primary or metastatic cancer in the liver.
- Intervention or test: Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.
- If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in Appendix B: Other relevant studies.

Find out more about how NICE selects the evidence for the committee.

Appendix B: Other relevant studies

Other potentially relevant studies that were not included in the main evidence summary (tables 2 and 3) are listed in table 5 below.

Systematic reviews published before 2020, studies with fewer than 5 people, unless the indication was primary or secondary liver cancer other than metastatic uveal melanoma, and studies using combination therapy, percutaneous isolated hepatic perfusion without melphalan or isolated hepatic perfusion were excluded.

Table 5 additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Abbott AM, Doepker MP, Kim Y et al. (2018) Hepatic progression-free and overall survival after regional therapy to the liver for metastatic melanoma. American Journal of Clinical Oncology: Cancer Clinical Trials 41: 747-753	Retrospective case series n=30 (12 had percutaneous hepatic perfusion) liver metastases from cutaneous or uveal melanoma	Hepatic progression-free survival and progression-free survival were statistically significantly prolonged after PHP compared to chemoembolisation or yttrium-90.	Larger and more recent studies were prioritised for the main evidence.
Bethlehem MS, Katsarelias D, Bagge RO (2021) Meta-analysis of isolated hepatic perfusion and percutaneous hepatic perfusion as a treatment for uveal melanoma liver	Systematic review and meta-analysis n=292 (164 CS-PHP) Uveal melanoma liver metastases	Median overall survival for CS-PHP=15.3 months (range 12.0 to 19.1). Median progression-free survival=7.6 months (range 6.0 to 14.3). Median hepatic progression-free survival=9.1 months (range 6.0 to 11.2).	More recent studies were prioritised. The review includes 5 studies on CS-PHP, all of which are included in the key evidence or table 5 of this report.

metastases. Cancers 13: 4726		The calculated overall survival data show that there is no difference between isolated hepatic perfusion and CS-PHP for patients with liver metastases from uveal melanoma in the long term, but there is a lower risk of complications and mortality following CS-PHP.	
Bruning R, Tiede M, Schneider M et al. (2020) Unresectable Hepatic Metastasis of Uveal Melanoma: Hepatic Chemosaturation with High-Dose Melphalan - Long-Term Overall Survival Negatively Correlates with Tumor Burden. Radiology Research and Practice 2020: 5672048	Retrospective cohort n=19 hepatic metastasis of uveal melanoma	Partial response=53% (n=10), stable disease=47% (n=9). There was no progressive disease and no adverse events exceeding Clavien-Dindo grade 4. Median OS was 16.7 months after the first PHP-M treatment and 26.4 months after initial diagnosis. Low hepatic tumour volume was an independent predictor of favourable OS (HR 0.19, 95% CI 0.04 to 0.89, p<0.05), and females were at a lower risk compared with males (HR 0.15, 95% CI 0.02 to 1.24).	Larger studies were prioritised for the main evidence.
Chandrasekhar S, Perez M, Niaz Z, Ekram J et al. (2024) Troponin Elevation in Patients Undergoing Percutaneous Hepatic Perfusion for Metastatic Uveal Melanoma.	Retrospective study. n=37 people with liver metastases from ocular melanoma. Follow-up: 90 days	The procedure was associated with a transient, asymptomatic troponin elevation perioperatively without major adverse cardiac events at 90 days. The observed troponin elevation is likely secondary to coronary	The main aim of the study was to evaluate the cardiac safety profile of the procedure. Other studies with more people and more safety and efficacy

Cancer Control 31: 10732748241246898		demand-supply mismatch related to procedural hemodynamic shifts, hypotension, and anaemia.	outcomes were prioritised.
de Leede E, Burgmans M, Meijer T et al. (2017) Prospective Clinical and Pharmacological Evaluation of the Delcath System's Second-Generation (GEN2) Hemofiltration System in Patients Undergoing Percutaneous Hepatic Perfusion with Melphalan. Cardiovascular and interventional radiology 40: 1196-1205	n=7 10 PHP procedures done in the first 7 enrolled people, from 2 prospective phase 2 studies in people with hepatic metastases from ocular melanoma or colorectal cancer.	The study analysed pharmacokinetics and toxicity of CS-PHP using the new second generation filter. The analysis of blood samples showed an overall filter efficiency of 86%. Mean filter efficiency decreased from 95% 10 minutes after the start of melphalan infusion to 78% at the end of the procedure (p=0.051). Bone marrow depression was seen after up to 80% of 10 procedures but was self-limiting and mostly asymptomatic.	Study on filter efficiency. Studies with more relevant safety and efficacy outcomes were prioritised.
Deneve JL, Choi J, Gonzalez RJ et al. (2012) Chemosaturation with percutaneous hepatic perfusion for unresectable isolated hepatic metastases from sarcoma. CardioVascular and Interventional Radiology 35: 1480-1487	Case report n=1 unresectable metastatic leiomyosarcoma of the liver	There was a 25% reduction in size of the largest lesion and 16-month hepatic progression-free survival. Toxicity was mild (neutropenia) and manageable on an outpatient basis.	Case report
Dewald CLA, Meine TC, Winther HMB et al. (2019) Chemosaturation	Retrospective study. n=52 (112 CS-PHP) people	2D-perfusion angiography provides a feasible tool for detecting leakages	Study on feasibility of 2D-perfusion angiography (for

Percutaneous Hepatic Perfusion (CS-PHP) with Melphalan: Evaluation of 2D-Perfusion Angiography (2D-PA) for Leakage Detection of the Venous Double-Balloon Catheter. Cardiovascular and interventional radiology 42: 1441-8	were screened for leakage alongside the double-balloon catheter on standard venograms. 18 procedures with visually detected leakage were included. 15 consecutive procedures without leakage served as control.	alongside the cranial portion of the double-balloon catheter used in CS-PHP.	detecting leakage of the double-balloon catheter used for CS-PHP).
Dewald CLA, Becker LS, Maschke SK et al. (2020) Percutaneous isolated hepatic perfusion (chemosaturation) with melphalan following right hemihepatectomy in patients with cholangiocarcinoma and metastatic uveal melanoma: peri- and post-interventional adverse events and therapy response compared to a matched group without prior liver surgery. Clinical and Experimental Metastasis 37: 683-92	Retrospective study. n=7 (21 CS-PHP) people with hemi-hepatectomy and 7 (22 CS-PHP) people without prior surgery.	The severity of adverse events following CS-PHP in people after hemi-hepatectomy was comparable to a matched group without prior liver surgery. The performance of CS-PHP is not substantially compromised by a prior hemi-hepatectomy.	Larger studies were prioritised. Study focussed on the effect of prior liver surgery.
Dewald CLA, Hinrichs JB, Becker LS et al. (2021) Chemosaturation with Percutaneous Hepatic Perfusion: Outcome and Safety	Retrospective study. n=30 hepatic metastatic uveal melanoma	Overall response rate was 42% and disease control rate was 81%. Median OS was 12 months (95% CI 7 to 15), and median	Larger studies were prioritised.

in Patients with Metastasized Uveal Melanoma. RoFo: Fortschritte auf dem Gebiete der Rontgenstrahlen und der Nuklearmedizin 193: 928-936	53% of people had CS-PHP as first-line therapy for the treatment of hepatic metastases, the others had CS-PHP only as a second-to-fifth-line therapy. Follow-up: median 10 months	progression-free survival was 6 months. Adverse events most frequently included haematological toxicities. Less frequent adverse events were hepatic injury extending to liver failure (3%), and cardiovascular events including 1 ischaemic stroke (3%).	
Ebel S, Struck MF, van Boemmel F et al. (2023) Chemosaturation of the Liver - an Update. RoFo: Fortschritte auf dem Gebiete der Rontgenstrahlen und der Nuklearmedizin 195: 30-37	Review	Chemosaturation represents a promising procedure for the treatment of unresectable liver metastases of ocular melanomas and of cholangiocellular carcinomas, which needs close interdisciplinary collaboration. People with a diffuse hepatic involvement with a tumour mass of more than 50% of the liver volume seem to benefit from the therapy.	No meta-analysis. All relevant papers are included in the main evidence or table 5.
Estler A, Artzner C, Bitzer M et al. (2022) Efficacy and tolerability of chemosaturation in patients with hepatic metastases from uveal melanoma. Acta Radiologica 63: 577-585	Case series n=29 hepatic metastatic uveal melanoma	After the initial CS-PHP, partial response=41% (n=11), stable disease=44% (n=12) and progressive disease=15% (n=4); 2 people died before the response was evaluated. After initial treatment, median overall survival=12.9	Larger studies were prioritised.

		months and median progression-free survival=7.1 months. Overall survival after 1 year was 50%. After the second treatment, median progression-free survival=7.9 months. 7 people had a liver tumour burden more than 25%, associated with a statistically significantly shorter overall survival (6.0 versus 12.7 months; p=0.008).	
Facchetti N, Hinrichs JB, Becker LS et al. (2023) Heparin reversal with protamine sulfate after Percutaneous Hepatic Perfusion (PHP): is less more? Cancer imaging: the official publication of the International Cancer Imaging Society 23: 68	Retrospective study. n=92 (192 PHP) people had full unfractionated heparin reversal with protamine; 13 (21 PHP) had a reduced amount of protamine, and 28 (43 PHP) did not have unfractionated heparin reversal with protamine.	There might be a link between the practice of protamine sulphate administration to reverse the full haemodilutive effect of unfractionated heparin after CS-PHP and the post-interventional risk of thromboembolic events as well as clinically significant thrombopenia. Data suggest that the standard use of protamine sulphate after PHP in low-risk individuals without clinical signs of active bleeding should be critically re-evaluated.	Study focussed on potential effect of unfractionated heparin reversal with protamine sulphate on complication rates following CS-PHP, which is not in scope.
Ferrucci PF, Cocorocchio E, Bonomo G et al. (2021) A New Option for the Treatment of Intrahepatic	Review	Considering that the median overall survival in people with liver metastases from cholangiocarcinoma is generally very low, ranging from 6 to	No meta-analysis.

Cholangiocarcinoma :Percutaneous Hepatic Perfusion with CHEMOSAT Delivery System. Cells 10 (no. 1)		8 months irrespective of the treatment chosen, the authors conclude that the reviewed experience with CS-PHP seems to allow for a longer control of the disease. In particular, the procedure could be used earlier in the treatment sequence, to gain time before switching to systemic treatment when disease evolves outside of the liver.	
Fitzpatrick M, Richard Alexander H, Deshpande S et al. (2014) Use of Partial Venovenous Cardiopulmonary Bypass in Percutaneous Hepatic Perfusion for Patients with Diffuse, Isolated Liver Metastases: A Case Series. Journal of Cardiothoracic and Vascular Anesthesia 28: 647-51	Case series n=5 (15 PHPs) people with diffuse melanoma liver metastases.	All people tolerated the procedure well with transient haemodynamic and metabolic changes. In people with diffuse isolated liver metastases, PHP is a well-tolerated procedure that can be performed more than once and is associated with marked anti-tumour activity in some people.	Larger studies were prioritised.
Forster M, Rashid O, Perez M et al. (2014) Chemosaturation with percutaneous hepatic perfusion for unresectable metastatic melanoma or sarcoma to the liver: a single institution experience. Journal	Retrospective study. n=10 people with unresectable metastatic melanoma or sarcoma to the liver treated with PHP.	Median hPFS was 240 days, 9 of 10 participants (90%) demonstrated stable disease or partial response to treatment. At a median follow up of 11.5 months, 4 of 10 (40%) remain alive. There were no perioperative mortalities.	Larger and more recent studies were prioritised.

of Surgical Oncology 109: 434-9.		Myelosuppression was the most common morbidity.	
Ghali H, Dugan MM, Aflatooni S et al. (2024) Hepatic and Overall Progression-Free Survival After Percutaneous Hepatic Perfusion (PHP) as First-Line or Second-Line Therapy for Metastatic Uveal Melanoma. Annals of Surgical Oncology 31: 9150-9158	Retrospective case series n=30 Follow-up: median 14.5 months	CS-PHP for metastatic uveal melanoma to the liver statistically significantly improved hepatic progression-free survival and overall progression-free survival when used as first-line therapy compared with immunotherapy or liver-directed therapy. CS-PHP continued to demonstrate improved progression-free survival when used as second-line therapy compared with second-line immunotherapy or liver-directed therapy.	Studies with more people or longer follow-up were prioritised.
Hofmann H, von Haken R, Werner J et al. (2014) Unresectable isolated hepatic metastases from solid pseudopapillary neoplasm of the pancreas: a case report of chemosaturation with high-dose melphalan. Pancreatology 14: 546-9	Case report n=1 solid pseudopapillary neoplasm of the pancreas and metastases confirmed to the liver	Ten months after initiating treatment, the patient had a good performance status and remained stable.	Case report
Hughes MS, Zager J, Faries M et al. (2016) Results of a Randomized Controlled	RCT n=93 people with ocular (n=83) or cutaneous melanoma (n=10)	Hepatic progression-free survival, progression-free survival, and hepatic overall survival were	Study used earlier version of the technology (first-generation filter).

Multicenter Phase III Trial of Percutaneous Hepatic Perfusion Compared with Best Available Care for Patients with Melanoma Liver Metastases. Annals of surgical oncology 23: 1309-19	with hepatic metastases.	significantly improved with CS-PHP. Median overall survival was not significantly different (CS-PHP 10.6 months versus BAC 10.0 months), likely due to crossover to CS-PHP treatment (57%) from the BAC arm. Most adverse events were related to bone marrow suppression. 4 deaths were attributed to CS-PHP.	A high proportion of people crossed over from BAC to CS-PHP.
Ini' C, Foti PV, Farina R et al. (2025) Percutaneous Locoregional Therapies for the Treatment of Liver Metastases from Uveal Melanoma: A Systematic Review. Technology in Cancer Research & Treatment 24: 15330338251343144	Systematic review n=955 (26 studies) uveal melanoma with liver metastases 9 studies (n=497) focused on CS-PHP. Search date: November 2024	The median overall survival was available for all studies and it was 16 months (sd 6.7), while the mean overall survival was 16.4 months. The median progression-free survival was available for 22 studies and it was 8.2 months (sd 2.9), while the mean progression-free survival was 8.1 months. The median overall response rate was 39% (sd 0.2), and the mean overall response rate was 38%. The median overall survival was higher for laser-induced thermotherapy procedure (32 months). The median overall response rate was higher for CS-	Only 9 studies were included on CS-PHP, all of which are already in the main evidence or table 5.

		PHP procedures (53%).	
Karydis I, Gangi A, Wheater MJ et al. (2018) Percutaneous hepatic perfusion with melphalan in uveal melanoma: A safe and effective treatment modality in an orphan disease. Journal of Surgical Oncology 117: 1170-1178	Retrospective cohort study n=51 hepatic metastatic uveal melanoma Follow-up: median 367 days	Partial response=43% (n=22), complete hepatic response=6% (n=3). In 17 (33%) additional people, the disease stabilised for at least 3 months, for a hepatic disease control rate of 82%. Median overall progression-free survival and hepatic progression-free survival was 8.1 and 9.1 months, respectively and median overall survival was 15.3 months. There were no treatment related fatalities. Non-haematologic grade 3 to 4 events were seen in 19 (38%) people and were mainly coagulopathic (n=8) and cardiovascular (n=9).	Larger or more recent studies were prioritised.
Kirstein M, Marquardt S, Jedicke N et al. (2017) Safety and efficacy of chemosaturation in patients with primary and secondary liver tumors. Journal of cancer research and clinical oncology 143: 2113-21	Case series. n=29; 19 had unresectable hepatic metastases from solid tumours (ocular melanoma, n=11; colorectal carcinoma, n=2; pancreatic adeno-carcinoma, n=2; periampular carcinoma, n=2; breast and	Second-generation CS-PHP seems to be effective and tolerable. Patient selection based on tumour volume and entity is of importance. Particularly, people with ocular melanoma and hepatobiliary tumours represent promising candidates for CS-PHP.	All participants are included in the Schönfeld (2020) study (study 11).

	endometrial cancer each, n=1) and 10 were diagnosed with hepatocellular or cholangio-carcinoma.		
Laukhuf J, Wiens L, Grozinger G et al. (2025) Characterization of long-term survivors with liver metastases from uveal melanoma diagnosed between 2005 and 2021. International Journal of Cancer	Retrospective cohort n=33 people with uveal melanoma and liver metastases who had survived at least 3 years from initial diagnosis of liver metastases (17 had chemosaturation)	Most of the long-term survivors (85%, 28/33) had had immune checkpoint inhibitors at some point. Median overall survival of the 17 people who had CS-PHP was 37.4 months and the median progression-free survival was 10.3 months. Most people (16/17; 94%) who had CS-PHP also had immune checkpoint inhibitor therapy. All 13 people who had CS-PHP as the first liver-specific therapy had disease control. The best response in 9 of the 13 people was partial response, while 3 of them had stable disease.	Larger studies were prioritised.
Ludwig J, Haubold J, Heusner T-A et al. (2021) Lactate Dehydrogenase Prior to Transarterial Hepatic Chemoperfusion Predicts Survival and Time to Progression in Patients with Uveal Melanoma Liver	Retrospective case series n=56 uveal melanoma liver metastases	Median overall survival=9.4 months. Elevated pretreatment serum lactate dehydrogenase is a robust predictor of overall survival and time to hepatic progression, potentially allowing for the	Study focused on serum lactate dehydrogenase as a pretreatment prognostic factor.

Metastases. RoFo Fortschritte auf dem Gebiet der Rontgenstrahlen und der Bildgebenden Verfahren 193: 683		identification of people benefiting most from transarterial hepatic chemoperfusion.	
Ludwig JM, Haubold J, Bauer S et al. (2021) Predictive impact of the inflammation-based indices in uveal melanoma liver metastases treated with transarterial hepatic chemoperfusion. Radiology and Oncology 55: 347-353	Retrospective case series n=54 uveal melanoma liver metastases	Median overall survival of the study cohort was 7.7 months. People with 1, 2, 3 elevated significant multivariate-analysis factors survived a median of 14.9, 7.7, and 3.9 months, respectively (p=0.0001). Pretreatment inflammatory markers and aspartate aminotransferase were independent prognostic survival markers.	Study focused on inflammatory markers as pretreatment prognostic factors.
Marquardt S, Kirstein MM, Bruning R et al. (2018) Percutaneous hepatic perfusion (chemosaturation) with melphalan in patients with intrahepatic cholangiocarcinoma: European multicentre study on safety, short-term effects and survival. European Radiology 29: 1882–92	Retrospective case series n=15 Cholangio-carcinoma	Overall response rate=20%, disease control=53% after the first CS-PHP. Median overall survival=26.9 months from initial diagnosis and 7.6 months from first CS-PHP. Median progression-free survival and hepatic progression-free survival were 122 and 131 days, respectively. Haematological toxicity was common, but manageable. No grade 3 or 4 adverse events occurred during the procedures.	Results from the same cohort of people are included in Dewald (2023).

Marquardt S, Kirstein M, Vogel A, Wacker F. (2016) Percutaneous hepatic perfusion with Melphalan (Chemosaturation) in patients with hepatic metastasis of ocular melanoma: Experience in 11 patients. CardioVascular and Interventional Radiology 39 (no. 4supplement): 392	Retrospective study. n=11 people with hepatic metastasis from ocular melanoma	Complications from bone marrow suppression were common but controllable. 2 people with a tumour load exceeding 70% of liver volume died shortly after first and second CS-PHP respectively because of acute liver failure. After an average follow-up of 2 months stable disease or partial response was observed in 10 people.	Larger studies were prioritised.
Meijer TS, de Geus-Oei L-F, Martini CH et al. (2019) Embolization of variant hepatic arteries in patients undergoing percutaneous hepatic perfusion for unresectable liver metastases from ocular melanoma. Diagnostic and Interventional Radiology 25: 451-8	Retrospective study. n=12 people with unresectable liver metastases from ocular melanoma.	Flow redistribution in liver segments by coil-embolisation of variant hepatic arteries is a feasible technique that does not seem to compromise tumour response in people having CS-PHP.	Larger studies were prioritised.
Metze M, Zimmermann S, Kirsten H et al. (2025) Effects of Protamine Reversal on Coagulation Parameters After High-Dose Heparin Administration in Percutaneous Hepatic Chemosaturation.	Retrospective study. n=31	Results suggest that protamine contributes to the normalisation of the activated partial thromboplastin time, international normalised ratio, prothrombin time, and fibrinogen levels. Further prospective studies should be conducted to	Study on protamine administration for heparin reversal after CS-PHP, which is not in scope.

Intervention Clinics and Practice 15: 38		determine optimal dosing ratios.	
Ocal O, Eldem G, Karagoz AH et al. (2021) Initiation of Chemosaturation With Percutaneous Hepatic Perfusion Program in Interventional Radiology Department. Cureus 13: e17880	Retrospective case series n=3 (2 uveal melanoma, 1 colorectal carcinoma)	Grade 3 and 4 complications were seen after 50% and 33% of procedures, respectively. Two people had a partial response, and the other person had stable disease after procedures. Mean hepatic progression-free survival was 10.8 months. Overall survival from the first procedure was 14.8 months.	Larger studies were prioritised.
Padia SA, Modi S, Wehrenberg-Klee E et al. (2026) Treatment of Liver Metastases from Uveal Melanoma with Percutaneous Hepatic Perfusion. Journal of Vascular and Interventional Radiology 37: 107887	Review	Clinical data show encouraging survival and disease control with manageable haematological toxicity and rapid recovery. Research into improved filtration, optimised dosing, and immunotherapy integration may further improve outcomes.	No meta-analysis. All relevant papers are included in the main evidence or table 5.
Rehn P, Tan B, Turra J et al. (2024) Peri-Interventional Hemodynamic Management Strategies for Percutaneous Chemosaturation of the Liver in Metastatic Cancer. Cancers 16 (no. 21)	Case series n=66 procedures	Advanced hemodynamic management ensures low peri-interventional mortality and morbidity. High-dose vasopressors, including vasopressin and the preferred use of balanced crystalloids, are sufficient to stabilize circulatory function during CS-PHP.	Study on peri-interventional haemodynamic management strategies, which is not in scope.

Struck MF, Werdehausen R, Kirsten H et al. (2023) Prognostic Factors for Postoperative Bleeding Complications and Prolonged Intensive Care after Percutaneous Hepatic Chemosaturation Procedures with Melphalan. Cancers 15: 3776	Retrospective study n=31 (90 CS-PHP)	Results suggest a restrictive perioperative fluid regime to be beneficial and support the use of protamine for heparin reversal after CS-PHP.	Study on arterial branch embolisation and prolonged intensive care, which is not in scope.
Struck MF, Kliem P, Ebel S et al. (2021) Percutaneous hepatic melphalan perfusion: Single center experience of procedural characteristics, hemodynamic response, complications, and postoperative recovery. PloS one 16: e0254817	Retrospective case series n=16 (11 uveal melanoma, 3 cholangio-carcinoma, 1 hepatocellular carcinoma, 1 tonsillar carcinoma) Follow-up to discharge from intensive care unit.	There were 84 procedure related complications, including 9 grade 3 and 4 complications. Complications included airway constriction), vascular catheterisation issues, and renal failure that needed haemodialysis. There were no procedure-related fatalities.	Studies with more people or longer follow-up were prioritised.
Veelken R, Maiwald B, Strocka S et al. (2022) Repeated percutaneous hepatic perfusion with melphalan can maintain long-term response in patients with liver cancers. Cardiovascular and Interventional Radiology 45: 218-222	Retrospective case series. n=10 people who had repeat treatments (8 unresectable intrahepatic metastases of ocular melanoma, 1 cholangio-carcinoma, 1 hepatocellular carcinoma)	Median hepatic progression-free survival was 336 days (range 0 to 354) for ocular melanoma, 251 days for the person with cholangiocarcinoma and 256 days for person with hepatocellular carcinoma. At the end of observation, 6 out of 10 people were still	Larger studies were prioritised.

	Follow-up 153 to 701 days	alive. Adverse events were mostly haematologic, grade 1 to 4, and self-resolving.	
Vogel A, Ochsenreither S, Zager JS et al. (2023) Chemosaturation for primary and secondary liver malignancies: A comprehensive update of current evidence. Cancer Treatment Reviews 113: 102501	Review	A global phase 3 study and several cohort studies have provided compelling evidence that CS-PHP is an effective salvage treatment for liver-dominant metastatic uveal melanoma in institutions with appropriate expertise.	No meta-analysis.
Vogl TJ, Koch SA, Lotz G et al. (2017) Percutaneous Isolated Hepatic Perfusion as a Treatment for Isolated Hepatic Metastases of Uveal Melanoma: Patient Outcome and Safety in a Multi-centre Study. Cardiovascular and Interventional Radiology 40: 864-872	Retrospective cohort n=18 isolated hepatic metastases of uveal melanoma	Initial treatment resulted in partial response in 8, stable disease in 7 and progressive disease in 3 people. After second treatment (n=9), there were 8 partial responses and 1 progressive disease. After third treatment (n=6), there were 5 partial responses and 1 stable disease. Two people had a fourth treatment with progressive disease in both. Median overall survival was 9.6 months (range 1.6 to 41.0 months). Median progression-free survival time was 12.4 months (range 0.9 to 41.0 months) with 1-year survival of 44%. Most common grade 3 and 4 adverse events	Larger studies were prioritised.

		were temporary leukopenia (n=11) and thrombocytopenia (n=8). Patients' self-assessments showed good ratings for overall health and quality of life with only slight changes after the procedure, and a high degree of satisfaction.	
Vogl TJ, Zangos S, Scholtz JE et al. (2014) Chemosaturation with percutaneous hepatic perfusions of melphalan for hepatic metastases: experience from two European centers. RoFo: Fortschritte auf dem Gebiete der Rontgenstrahlen und der Nuklearmedizin 186: 937-44	Cohort study n=14 ocular (n=8) or cutaneous melanoma (n=3), breast cancer (n=1), gastric cancer (n=1) and cholangio-carcinoma (n=1). All people, except for 1, had metastases confined to the liver.	There was 1 complete response (cholangiocarcinoma), 6 partial responses (ocular, n=3 or cutaneous melanoma, n=3), 5 people had stable disease (ocular melanoma, n=3; breast cancer, n=1; gastric cancer, n=1). Mild to moderate filter-related toxicity was seen immediately after the procedure. Grade 3 or 4 melphalan-related pancytopenia developed after 1 to 2 weeks. All haematological events were managed with transfusions or other supportive measures. The new high-efficiency filter showed milder toxicity and faster recovery. CS-PHP was abandoned prematurely in 1 person because of heparin-induced vaginal bleeding, and 1 person died because of retroperitoneal	Larger or more recent studies were prioritised.

		haemorrhage from heparin anti-coagulation.	
Wiens L, Grözinger G, Dittmann H, et al. (2024) Melanoma-specific survival of patients with uveal melanoma and liver metastases diagnosed between 2005 and 2021. Therapeutic Advances in Medical Oncology 16: 1–12	Retrospective case series. n=167; 28 had CS-PHP. Follow-up period not reported.	The melanoma specific survival was significantly better for people who developed liver metastases between 2016 and 2021 compared to the period between 2005 and 2015. First-line liver-directed therapy was associated with better survival than first-line systemic therapy.	Outcomes were not reported separately for CS-PHP.

NICE National Institute for Health and Care Excellence

HealthTech Programme

IPG10448 (IP1062/3) - Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver (provisional title)

Patient organisation submission

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

Information on completing this submission

- You do not have to answer every question — they are there as prompts.
- The text boxes will expand as you type, your response should not be longer than 10 pages.
- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.

Information about your organisation	
Organisation name	Ocular Melanoma UK
Contact person's name	Jo Gumbs
Role or job title	Chief Executive
Email	[redacted]
Telephone	[redacted]

Brief description of the organisation, such as:

- **Who funds it?**
- **How many members does it have?**
- **What region your organisation represents**

Ocular Melanoma UK is a registered charity supporting those affected by ocular melanoma. It aims to help patients and their families by providing accurate, up-to-date information and emotional support via website, helpline and online forums. The vision is a world where ocular melanoma patients are given the information, support and treatment they need.

Funding is primarily driven by members, their families and friends who donate or fundraise on OcuMel UK's behalf. OcuMel UK receives some funding from trusts and businesses known to its members. Ocular Melanoma UK has also received, funding toward our annual conference and support services, including our helpline from pharmaceutical companies including Delcath.

Ocular Melanoma UK has now grown to over 1000 members with a reach of many more subscribers in the UK and abroad.

Ocular Melanoma UK also runs several online groups such as the Facebook 'Patient Support' group, a separate group for people who have metastatic disease, and another for family and loved ones. These groups are fantastically active offering a shared wealth of experience.

Ocular Melanoma UK represents patients and families across the whole of the United Kingdom, advocating at national level, the devolved nations and has representation in EU schemes and research projects.

Declarations

Do you have any conflicts of interest? Please let us know if you have a question on the NICE policy on declaring and managing interests.

Ocular Melanoma UK receives annual charitable sponsorship from Delcath Systems (the manufacturer) along with other pharmaceutical companies working in this space. This funding contributes to costs associated with our patient support services (including the helpline) and our annual conference. Delcath has no role in our governance, service delivery, editorial control, policy positions, or decision making, and has had no involvement in the preparation of this submission. We manage this relationship through agreed boundaries and transparency, and can provide further detail on the nature and approximate level of support if requested by NICE.

How did you gather information about the experiences of patients and carers to include in your submission? (For example, information may have been gathered from one-to-one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature)

Ocular Melanoma UK gets to know the people we support and some of the challenges they face which includes needing further treatment and/or needing knowledge regarding further treatment.

[redacted] a retired liver surgeon from [redacted], presented on behalf of his team in 2012 at our second Annual Conference and introduced this procedure to the community. Since then, the topic of chemosaturation (in its various names: i.e. Delcath, Chemosat, PHP) has been discussed in the support groups.

It should be noted that approximately 50% of all Uveal Melanoma patients will develop Stage 4 disease and 90% of these patients will have liver disease. This makes Stage 4 treatments a significant part of our helpline work. Ocular Melanoma UK not only helps to remove isolation but also shares knowledge on coping with vision loss, treatment effects and other related concerns such as treatments.

Information included in this submission has been gathered through a range of ongoing engagement activities, including one to one discussions with patients and carers, the charity's national helpline, moderated online peer support forums, patient surveys, and direct feedback from individuals who have undergone the procedure outside the NHS. The organisation also draws on long standing relationships with clinicians and previously submitted patient evidence to NICE and NHS England.

Are you willing for this submission to be shared on our website?	Yes ☒ No ☐
We may invite you to a committee meeting where this procedure or operation is to be discussed. Would a member of your	Yes ☒ No ☐

organisation be willing to join such a meeting (this may be in person or virtually)?	
Does the organisation have any direct or indirect links with, or funding from, the tobacco industry?	Yes ☐ No ☒

Impact of the symptoms, condition or disease on patients and / or family and carers

1. What is it like to live with the condition? What do carers experience when caring for someone with the condition?

Living with metastatic ocular melanoma is physically and emotionally devastating. Many patients feel well, even once liver metastases are detected through surveillance, but throughout their diagnosis they would have lived with the constant anxiety knowing the disease is life limiting and treatment options are extremely limited.

As the disease progresses, patients may experience fatigue, pain, liver related symptoms and rapid deterioration. Carers often experience significant emotional distress, anticipatory grief and a heavy practical burden as clear treatment pathways do not exist. People frequently balancing caring responsibilities with work and family life but also have to advocate for their loved one in a short window before they progress and begin to experience symptoms. The lack of NHS treatment options intensifies feelings of helplessness and inequity.

About the procedure or operation being assessed

2. What do patients (or carers) think the advantages of the procedure or operation are? Why do you consider it be to be innovative?

Patients and carers value Chemosat because it directly targets liver metastases, where the disease most commonly and critically progresses. It is seen as innovative because it delivers high dose chemotherapy to the liver while limiting systemic exposure, offering meaningful tumour control where systemic treatments often fail. Patients consistently describe it as providing hope, time and, for some, significantly reducing or eliminating their tumours or giving them much needed stability and improved quality of life.

Patients (and their carers) report feeling general well after treatment. A loved one commented, “The side effects for him were minor, lack of appetite and he felt tired for a few days, but he soon picked up again.” Another patient said, “The treatments themselves are quite intense, and I felt tired for a week or so afterwards. The initial day of recovery is quite trying with having to lie flat on back, constant monitoring etc. BUT that bit is very short-term and I quickly felt well between treatments, so quality of life is excellent. Side effects are minimal (bit of tiredness, small wounds to dress).”

3. Does this procedure have the potential to change the current pathway or patient outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes. Chemosat is very likely to significantly change the current pathway for patients with liver dominant metastatic ocular melanoma. It may improve disease control, extend survival, delay progression and reduce reliance on less effective systemic therapies. For some patients, it can reduce the frequency of hospital visits related to disease complications and allow them to maintain independence and daily activities for longer.

A patient said, I feel very strongly that this treatment should be available to all patients that could benefit from it. After failed immunotherapy I was left with no options for treatment. After approaching the team at [redacted] I was able to have treatment privately. I have had 3 treatments to date with good effect. Smaller tumours have disappeared and at last scan largest tumours are less than half size. I have had no side effects for the treatments”. Another said, “I think he would have benefited from starting this treatment sooner. It took almost 6 months to start the trial which is too long for someone with metastatic malignant ocular melanoma. I feel if this had been readily available it may have been able to be contained for longer in the liver and given him a longer life with us.

Ocular/uveal melanoma has historically been incredibly difficult to successfully treat and carried a high mortality rate once it spread. This treatment was the first treatment that began to change the course for people and is well tolerated by patients.

We are confident when this is available routinely to this rare cancer cohort of patients, real-world evidence will show it is even more effective than the clinical trial data, as many of the patients on the clinical trial, had long waits before they were seen by the clinical trial team and for treatment to start, as clear referrals pathways were only just beginning to form in the years the trial was recruiting.

Another benefit would be the psychological impact of trying to live with a cancer that spreads for 50% of people, that is known to have very limited effective treatment options. Tebentafusp began to change this for some patients, but more is needed as that treatment is unsuitable for all patients who need treatment.

4. What do patients (or carers) think the disadvantages of the procedure or operation are?

Patients recognise that the procedure is intensive, requires specialist centres, and involves hospital admission and recovery time. There can be short term side effects, including fatigue and blood count changes, but in the years since this treatment became available, we have not known of anyone experiencing long-term side effect or any that significantly affected them.

Travel to specialist centres can also be burdensome, particularly for those living far away or with limited support, but generally people would opt for treatment as it does not require daily or weekly visits to hospitals, and people are aware the alternative choices are less effective and sparse.

5. What are the uncertainties about how well this procedure works and how safe it is?

Patients understand that ocular melanoma is rare and that evidence shows it is a safe and effective treatment. This in a cancer with such a high unmet need, is incredibly important.
While the procedure is generally viewed as acceptable in terms of safety, patients recognise that there are risks and that ongoing data collection and audit are important, and many would opt for treatment as alternatives are lacking.

Equality issues

6. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.

Chemosat should be available to all eligible patients based on clinical need. Decisions about suitability should be made case by case, with appropriate specialist assessment and supportive care.
For many patients, including those of working age or with caring responsibilities, the potential for disease control and improved quality of life is especially important.

7. Are there any groups of people that might need further consideration in using the technologies (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)?

Patients living in remote or rural areas, those on low incomes, and those without strong support networks may face additional barriers due to travel, time off work and accommodation costs. These factors should be considered to avoid unequal access.

8. Are there any potential equality or health inequality issues that should be taken into account when considering this topic?

The current lack of NHS access creates clear health inequalities, as only patients who can self-fund or travel abroad can access Chemosat currently. This disproportionately disadvantages patients with lower incomes and increases inequity in outcomes for a rare cancer population.

Additional information

9. Please include any additional information you believe would be helpful in assessing the procedure or operation.

Ocular Melanoma UK strongly encourages that patient reported outcomes and lived experience are considered alongside clinical data. For ultra rare cancers, real world evidence, expert clinician involvement, and patient perspective are particularly important in understanding meaningful benefit.

Key messages

In up to 5 bullet points, please summarise the key messages of your submission.

- Ocular melanoma is a rare aggressive cancer with limited effective treatment options once metastatic
- Chemosat addresses the dominant site of disease and is highly valued by patients
- Current lack of NHS access creates significant health inequality
- Patients generally feel there are low levels of risk and uncertainty as the data supports treatment and there is a high unmet need in terms of alternatives
- Patient experience, real world evidence and clinical expertise are crucial in assessing this procedure correctly and fairly.

Thank you for your time. Please return your completed submission to IP@nice.org.uk

Did you know NICE meetings are held in public? You can register on the NICE website to attend a meeting up to 20 working days before it takes place. Registration will usually close 10 days before the meeting takes place.

IP Survey IP1062

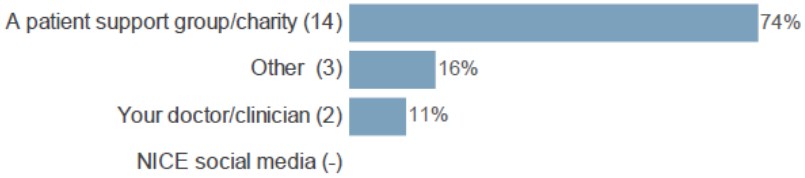
This report was generated on 07/04/26. Overall 19 respondents completed this questionnaire. The report has been filtered to show the responses for 'All Respondents'. A total of 19 cases fall into this category.

The following charts are restricted to the top 12 codes. Lists are restricted to the most recent 100 rows.

I have read the information above which explains the purpose of the project and how any information I provide will be used

I consent (agree) to NICE using the information I have given in the ways described above

How did you hear about this survey?



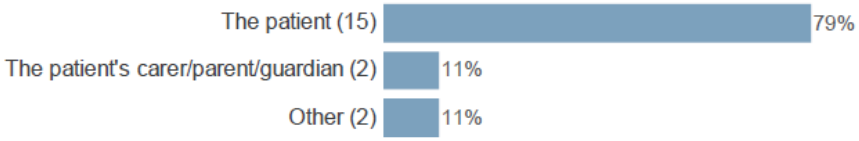
If other, please specify

OCUMEL UK

On a Facebook group

Fb

Are you (the person completing the questionniare)



If other, please specify

Sister of the belated brother

Friend

Your age

54	78	64	39	40	65
62	81	59	40	62	46
54	38	46	40	45	57
67					

In years

6	5	1
1	1	1
9	0	2
0		

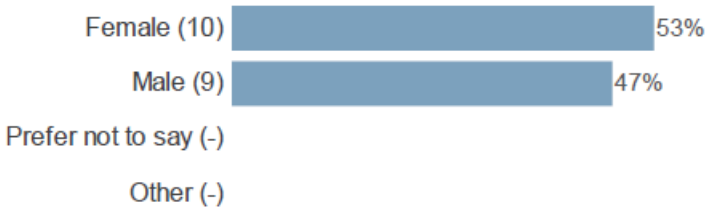
In months

8	10	1
4	6	14
37	2	4
10		

in weeks

4
29
10
3

To which gender identity do you most identify?



What other treatment options did you consider, and why did you choose this one?

Best option and have tried immunotherapy

this was the only treatment available to me as immunotherapy only had a 1% chance of working on my type of cancer at that time

None

It was the most successful one for my brother

Other drugs, as part of a trial.

No other treatment options available with acceptable proven results and minimal acceptable side effects. Unfortunately, private funding is the primary obstacle for most patients.

Non available at that time

It was the only option available privately and had good success rate

Ipi nivo

Clinical trial (IDE196) and standard NHS immunotherapy (Ipi / Nivo / Pembro) - chose chemosaturation for better quality of life, fewer side effects and documented efficacy. Response rate of chemosaturation far in excess of the NHS offered immunotherapy which have very poor response rates in Bap1 negative uveal melanoma

Immunotherapy. I asked my consultant which one he would choose. He said chemosaturation.

Only this as best chance of survival

This is the only treatment available for the type of cancer

IDE 196 trial

Only available treatment that might be beneficial

Much more accurate for uveal melanoma in liver

Tebentafus and one other treatment which didn’t work

Did the procedure work?

Yes (13)

Somewhat (5)

No (1)

68%

26%

5%

If somewhat or no, please provide further details along with information about whether symptoms later reoccurred.

Not sure yet as too early

I had 4 rounds which resulted in shrinkage of liver mets and inactivity of those that remained.

Unfortunately, the cancer regrow at a later date within the liver

It worked for 8 months

After four treatments the results are showing as stable. Doctors would like to get patient in for another round but we don’t have the funds

I dud 2 treatments and the liver was clear for 8 months Latest scan shows that it has returned and I have done a third treatment

Already had liver lesions and received to procedures of delcath

Did you have any side-effects following your procedure?

No (12)

Yes (7)

63%

37%

If yes, please provide further details along with information about whether

symptoms later reoccurred.

A very little bit of fatigue!

My brother had 4 in focus trial very successfully results then 2 years later it had come back so he had Another 4 in [redacted] around 14 months later it was back again so he went back to [redacted] for Another 2 on The Eighth Cycle my brother had A chemical reaction From treatment And died intheatre for 43 minutes My brother was in hospital 3 months in [redacted] was a miracle that he made it back My brother lived twelve month after this happen And made a full recovery.But without this treatment , my brother wouldn't have had Nine wonderful years that this treatment Had given him,it should be on the NHS for everybody. Because it is a very good treatment and should be easy. Access, rather than people worrying that they've got to find the money to fund this treatment at 40.000 pound ago.

Some tiredness and nausea, but not too serious. Drop in haemoglobin concentration. Drop in RBC.

Mild nausea and tiredness. Fully recovered within 7-10 days and back to normal life after that.

Slightly nauseous and tired for a few weeks

Bruising on one occasion to leg. Small abdominal bleed on one occasion Inflammation around liver and gall bladder - had 10 days of steroids, on one occasion Fatigue for a few weeks following each treatment

After the 2nd procedure there was a slight leak with the chemo saturation which caused sickness for a few days

How long did it take you to recover from the procedure?

1/2 weeks

i recovered straight away i was hungry sitting up eating and drinking i had to lie flat for couple of hours then i was up and about not even paracetamol needed for me

4-5 days

Every time my brother at this treatment, he recovered very well .

Back to almost normal in a few days. Several months to restore iron concentration.

Full recovery of liver function took a few weeks at home. Only two nights post procedure spent in hospital.

7-10 days and then felt fully normal

2 or 3 weeks

About a week to 10 days

Very quick recovery - walking day after proceedure and as an example I hiked 25 miles in the lake district 2 weeks after procedure 1 and cycled 125 miles between [redacted] and [redacted] to raise funds for treatment 3 weeks after procedure 3. I've kept very active and could eat completely normally, I continued to run my daughter to school and enjoy life. I was able to have lovely holidays to France and New York between treatments.

Less than one week

1 week

Three to four weeks

How long did it take you to recover from the procedure?

2-3 weeks

4 weeks

7-10 days . Only minimal side effects including tiredness and a bit of chemorash

2 days

Unfortunately she passed away

How did the procedure positively affect your condition and/or your quality of life?

Please consider things such as:

Your physical symptoms

Your ability to perform daily activities

Your quality of life, lifestyle and/or social life

Your state of mind, emotional health and/or wellbeing

The effect on family, friends and others

Have only had 1 treatment so too early to tell. However it provides hope and this is positive for mental well being.

with out this treatment i was given 6-12 months this was back in 2019 we are in 2026 and i am still here living my life. After treatment i was back to normal within couple days doing my chores when back home. family members and friends could not believe how good i was

I was physically fit before & after treatment & could perform my daily duties fine! Regarding my emotional health it was a very big relief that I had finally had some treatment for my Ocular Melanoma & a massive relief to my family this treatment occurred! [redacted]

This treatment gave my brother his life for 9 years. My\n Brother always recovered well apart from the eighth go when he had a chemical reaction to the treatment. But apart from that, he recovered wonderful

I felt perfectly normal before the procedure. It was if we were meerly treating the MRI and CT scans, successfully. Day to day life good before and after the procedure. Accepting that life is finite, death eventually inevitable. My adult daughter is sad but very supportive.

Dramatic and wholly positive impact as my prognosis without the procedure was six to nine months. Quality of life post procedure was no different to that prior to metastasis.

After the short recovery period, I was able to fully get on with my life as normal. Considering the treatment caused the disease to shrink/become inactive, this bought me another 12-18 months with my young children, before we had to start more systemic treatment for my metastic uveal melanoma. It greatly improved my quality of life, it gave me hope and optimism and it gave me memories with my children, and more importantly gave them more time with me. The burden on my family and friends was the huge fundraising effort required for this treatment

It went well. I was given a year to live and I'm still here five years later. Quality of life good, friends and family really pleased at the success of this treatment. State of mind is normal

There weren't any side effects once you recovered from the operation and although that was invasive

it gave you a good 2 and a half months of no treatment and feeling really good. I almost felt a fraud telling people I was terminal

I lived very normal For 8 months my liver remained clear and I went about my daily life Emotionally I was very positive

How did the procedure positively affect your condition and/or your quality of life?

Please consider things such as:

Your physical symptoms

□Your ability to perform daily activities

□Your quality of life, lifestyle and/or social life

□Your state of mind, emotional health and/or wellbeing

□The effect on family, friends and others

Having a treatment which has not only stopped the tumours growing but shrunk them over 42% has been fantastic. The benefit to my mental health has in some ways been most significant, I've been given a plan when there are no others available on the NHS. The fact that I've recovered so quickly and been able to enjoy every moment in between treatments with my family has been very special, I've really been able to maximise that time and not be in hospital or bed. My family have been superb and all interested and engaged in this treatment. The team at [redacted] are so passionate about what they do and the benefits of the chemosaturation procedure that their confidence radiates onto the patient. They have supported me so well and encouraged me to actively enjoy life. The routine blood testing after procedures also very easy and give total piece of mind. In some ways I was sad to get to my 4th treatment and know that we would pause there for more scans.

This disease has never given me one day of being poorly so this is a tricky one to answer. Chemosaturation has allowed this to continue to happen. The procedure has allowed me to relax and enjoy time precious time with my family. Although the stress of finding the funds for my 4 procedures has caused immeasurable stress.

Only symptom from procedure was recovery from anaesthetic and a few bruises from cannula sites. After a few days rest I was back to normal with home duties. Life went back to normal pretty quick as I have young children and last procedure was just before Christmas. I felt positive after treatment that it was working and extending my life expectancy as did my family and friends. My only worry was finding the funds for my next procedure.

The cancer has been quiet in regards to symptoms but knowing the treatment is keeping it steady is good. The treatment has given the patient more time with family and friends that they otherwise wouldn't have had. It’s a really tough situation for any family to go through and the financial pressure only adds to that.

Reduced nausea Didn’t really affect ADLs Made me feel very positive and hopeful Family felt very positive and hopeful too

Stable disease at 14 months past my last chemosaturation. I had 4 treatments in 2024. Positive State of mind knowing there is a treatment. Effect on family and friends minimal. I handled the treatments very well

I am currently living a normal life and feel the fittest I've felt for a long time both mentally and physically

No physical symptoms Started daily activities within the week Quality of life is the same and mental health was better as I felt good to do normal stuff

Unfortunately it was a last resort and probably too late but it was the only chance so we had to be positive but it was very stressful financially

How did the procedure negatively affect your condition and/or your quality of life?

Please consider things such as:

Your physical symptoms

Your ability to perform daily activities

Your quality of life, lifestyle and/or social life

Your state of mind, emotional health and/or wellbeing

The effect on family, friends and others

It took a week to fully recover from the treatment but otherwise there were no side effects.

i didn’t experience any of the above obviously i was a little anxious about having cancer but the worst part about all of this was having to fund raise so much money to pay privately knowing i had Axa health care cover yet they have always refused to pay due to the wording on NICE Guidance yet other big insurances are paying out. This was so traumatic for me having to keep fighting them when i was fighting to live

Had no negative impact on my day to day life, I was able to carry out my day to day activities! Physically it had no impact on me apart from a little fatigue that last approx 4-5 days after treatment. My state of mind was good, but I was relieved treatment had finally taken place…even at a cost of £125k to me & my family! Family & friends were also relieved.

My brother recovered really well from this treatment.Within 2 weeks, 3 weeks, he was back to himself As a family , this always gave us hope and gave us all a very good peace of mind that without this treatment, my brother would have not lived the life he lived. My brother passed Away In [redacted]

No evident physical symptoms. General age related issues had greater negative impact.

For a few days after the treatment I felt nauseous and tired. This was a mild impact of quality of life and for family life as I couldn't be as active with the kids. Other than that, the main stress and effect it had was the huge pressure to fundraise the massive amount needed. We could see after 2 rounds it was having a positive effect but to continue, needed to raise anothrr £80,000.

No negative affects

It only affected me directly after the operation when I healed up. The only emotional concerns I had was wether I’d had enough money to pay for the upcoming treatments

It never effected me negatively

Immediately after the procedure I felt the effects of the general Anesthetic and operation, particularly the first round. However the ability to stand unaided and

walk so soon after really helped. I was aware of what I ate for 2 or 3 days after returning from hospital but completely back to normal 7 days after the procedure. The hardest part has been raising funds for treatment from friends and family without them knowing how the procedure might work for me. I have had to launch a GoFundMe page and complete 125 mile cycle ride. I've also felt guilty as friends have completed charity events on my behalf to pay for it. The other hardest part mentally is coming to the end of treatment and having so few options on the NHS. But I feel so glad I've been able to have this treatment, had no other time in hospital and been able to enjoy so much time with my wife and Daughter.

No negative effects whatsoever. Only the stress of finding the funds to pay for the procedure four times.

The financial burden is hard, family and friends are doing all they can to support and raise the money but the cost is so high it’s hard to get the money inline with when the doctors want to do the treatment - for example the doctors want to treat the patient this month but we only have £6000 in the pot. Asking people to donate and raise money is an ongoing full time commitment and it’s a strain on everyone involved. This is the only treatment available for the patient, we have no other option and if we don’t raise the money the outcome is unthinkable.

There wasn’t really any negative effects of the treatment, apart from reduced energy levels, which I felt was a small price to pay

Sore for a week Rested for 2 weeks Back to work after 3 weeks light duties

How did the procedure negatively affect your condition and/or your quality of life?

Please consider things such as:

Your physical symptoms

Your ability to perform daily activities

Your quality of life, lifestyle and/or social life

Your state of mind, emotional health and/or wellbeing

The effect on family, friends and others

Not applicable

Nothing negative Just always hoping for good scans

It didn't really affect the situation because we had no choice but to try the treatment even though it gave a negative feeling because of the cost

Did you require anymore treatment, including procedures or surgery after this procedure?

Yes (11)

No (8) 42%

58%

If yes, please provide further details.

I will do another 1-3 treatments if is it effective.

Laparoscopic surgery two years later for a single "stubborn" lesion has resulted in my being NED for ten months to date.

Yes, I've required immunotherapy

I had three in total

I went on Tebe when it became available on the NHS. I could no longer afford chemosaturation

2 x Delcath And after 8 months another delcath

I was offered immunotherapy along side chemosaturation in January.

Doctors would like the patient to have another treatment this month, and have said she may need six or more.

I had four rounds of Delcath. I had a hospital admission following one of the treatments for the abdominal bleed

Surgery 14 months later to remove a tumour from lymph node spread

I did ipi nivo which didn't work as I had bone Mets too

Would you recommend this procedure to another patient with your condition?

Yes (19)

No (-)

100%

If yes, what might you tell them?

It is intensive but if you are otherwise healthy then it is a small time of physical recovery for potentially significant results.

Absolutely 100% i has lived after this treatment for almost 7 years and i hope to live a lot longer with the help of trying to get this treatment passed. Like i spoke out in parliment i deserve the chance to live like other cancer patients who have a treatment for them. I spoke with [redacted] who also agreed with me. This treatment has saved my life i live a good life i just want to be around to see my twin grandsons grow up

Yes definitely recommend this treatment as it is classed as the gold standard of treatment for Uveal Melanoma that has metastasised to the liver.

As I am the patient sister , My brother is not here to speak for himself. As I said, he passed away in [redacted], but I can tell you one thing without this treatment. Being available to him, my brother always used to say this treatment should be available to everybody and not have the Worry about trying to find the money to fund the treatment.he would have not lived these wonderful years Today he would definitely say yes, I would definitely recommend this treatment to anybody

It's not painful. It's not dramatic. It's life changingly expensive.

It works!

It had a positive effect and shrunk and stopped the tumours in my liver for a year. Especially if combined with immunotherapy (which is now being considered), this is the most powerful and effective treatment as it stands for metastic uveal melanoma

To get it done as early as possible it saves lives

It’s the best option available and give you really good quality of life in between

It’s not painful and the only negative part is lying down for 24 hours in the ICU

This is a very well understood procedure with very manageable recovery. It truly gives you the best chance of slowing tumour growth in your liver with a quality of life that means you enjoy more precious time with your family.

This procedure is nothing to be frightened of. Yes it is invasive however the staff make you feel at ease the whole way and I wouldn’t hesitate to have it done again.

The cost of the procedure places this treatment out of the reach of some patients but if there is any way they can raise the funds I would encourage them to find a way!

The treatment is proving to work from the results and the staff and surgeons are incredible. However the pressure of the cost in a daily worry to everyone involved especially the patient and their kids.

I would say it works

It works abd gives you stable disease

That it works!

It works . It’s the best treatment out there for people with this disease

If you can get the treatment early after diagnosis I believe it could work

If the procedure had an impact on any other areas of your life that are not covered by the questions above please tell us about them here.

None

Without this treatment I was told life expectancy was 11-14mths without treatment!!!

Seriously affected my financial security. Awkward to choose between self preservation and financial future of daughter and grand daughter, but daughter very supportive.

I am so grateful that I could have this procedure. Friends and family have been astounded how well I look and sound post treatment. I truly hope more people can benefit from this. I also believe decath chemosaturation has potential for treating other liver cancers and in combination with other drugs to increase efficacy even further still.

I cannot stress enough the hardship of trying to fund these procedures myself. It is unnecessary and cruel for NHS cancer patients to decide which treatment they can have depending on their bank balance. I'm a private person who would have preferred to of dealt with this battle behind closed doors. Instead I had to advertise my life via TV, radio and a social media and beg strangers for money to help me have longer with my family. When my 10 year old son offered to sell his toys to help and when his friends are bringing their penny boxes to school to help fund my treatment is truly heartbreaking. Especially when the [redacted] (less than 5 miles from my front door) is fully equipped for chemosaturation and ready to treat me with a trained team.

When you're faced with a terminal diagnosis everything in your life is impacted. Then told there is a procedure, albeit not funded by NHS, that could extend your life you but will cost approx £300,000 for x6 treatments you see a faint light at the end of the tunnel. After my first treatment my scan was very positive and lead me to fund raise for the next three with similar results. I don't

know if I can raise enough for further treatments but I know I am already living beyond the prognosis of 12-14 months without this treatment. It works!!!!!

The cost of the treatment causes stress on the patient, their family and friends. The treatment its self has given the patient precious time with their kids they wouldn't have had without it however that time is spent worrying about the next payment. As a friend of the patient, myself and others are working our usual jobs and dealing with our own personal lives while also coming together to find ways to raise the funds needed. The pressure and strain on us all is hard, being told this is the only treatment currently that will give the patient more time but that comes with a cost is totally heartbreaking. We are scared to see the donations slow down on our fund raising site because no funds means no treatment and no treatment puts the patient back in the boat of the initial prognosis of less than twelve months to live. The patient has a husband and two children and family and friends that have all been effected by the strain of the cost, it's like it's being put in our hands when it's no one's fault the patients cancer is this rare type. It feels unfair to put someone, anyone in a situation where your life depends on finding £46,000 over and over again. The staff and surgeons have been amazing, the treatment is an incredible thing and shows how amazing our medical teams are at finding ways to treat these awful deceases but the cost being put on the patient and their family's feels unfair. I hope this can change soon, we are praying for all the patients health and a break from the stress of the cost.

Not applicable

Obviously time of work and the stress of raising funds through charity events

View results

Respondent

81 Anonymous

72:30
Time to complete

1. Project Number and Name - (Can be found on email) *

Routine Review: IP1062/3 - Overview | Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver | Guidance | NICE

Your information

2. Name: *

Fenella Welsh

3. Job title: *

Consultant Hepatobiliary & General Surgeon

4. Organisation: *

Hampshire Hospitals NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Association of Upper Gastrointestinal Surgery (AUGIS)

7. Nominated/ratified by (if applicable):

Iain Cameron, President of AUGIS

8. Registration number (e.g. GMC, NMC, HCPC) *

3664447

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

We do not currently use it in my Trust.

I believe it is available privately in Southampton and in London. It was previously additionally being used on a trial basis in Liverpool and Manchester.

It is an interventional radiology procedure, so elements of the technique will be used by interventional radiologists, for other procedures.

In my Trust, we would refer patients with metastatic uveal melanoma to the Regional Melanoma MDT. Consideration for chemosaturation would be part of that MDT discussion, if funding could be secured (either from an insurance company, self-pay or on a named patient / compassionate basis)
We would not refer patients with other conditions for this treatment.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] I attend national and international meetings, where this procedure may be on the Agenda for discussionnat

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

The title of the Guidance is appropriate, to cover all indications

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

The procedure is not novel, being described for 10+ years. It has not been widely adopted, due to funding constraints and paucity of high quality evidence. So to answer Q17 below, it is neither new, nor established practice across the UK.

17. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

This would serve as an addition to standard of care, in very highly selected patients.

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Since 2021, there has been at least three case series, and one single-arm multi-centre study, as below. This is balanced against novel systemic treatments which can offer similar OS, such as the Phase 3 trial of Tebentafusp in metastatic uveal melanoma (OS at 1 year 73%) published in NEJM 2021, 385(13): 1196-1206. Nathan P et al.

FOCUS Trial – 22 sites
Single-arm, multi-national, multi-centre open-label study to evaluate the efficacy, safety, and pharmacokinetics of melphalan/ HDS treatment in patients with hepatic-dominant ocular melanoma
JS Zager et al Ann Surg Oncol 2024; 31(8):5340-5351.
102 patients Metastatic uveal melanoma enrolled
Treatment attempted in 95 patients
Treatment received in 91 patients.
Median PFS 9 months
Median OS 20.5 months, with OS of 80% at 1 year

Chemosaturation with percutaneous hepatic perfusion of melphalan for metastatic uveal melanoma. Modi S Gibson T, Vigneswaran G et al. Melanoma Research 2022; 32(2) 103-111.
Retrospective 2012 – 2020.
250 procedures in 81 patients, median 3 per patient
Overall response rate of 60.5%
Median PFS 8.4 months, OS 14.9 months
27% of patients experiences a G3/4 TRAE, improved over time.

Percutaneous hepatic perfusion with melphalan in liver dominated metastatic uveal melanoma: the German experience. Dewald CLA et al. Cancers (Basel). 2021, 14(1):118.
N=66, Median OS 18.3(7-24.6)months. Grade 3& 4 TRAE in 24.8%.

Hepatic chemosaturation with melphalan in patients with primary or secondary liver tumours with or without extrahepatic tumour manefestation. Veelken R et al. ESMO Gastrointest. Oncol 2024, 5:1-11. Case series. N=33 patients. 2016-2023. 97 treatments. Uveal Melanoma(n=19), CCA(n=8), HCC (n=2).

21. Do you think the guidance needs updating?

I think the current evidence-base needs updating, but the crux of the Recommendations from 2021 should remain the same.

Current management

22. Please describe the current standard of care that is used in the NHS.

Multi-disciplinary Team discussion, relevant to the Primary Tumour

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

    No

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

    There may be a small improvement in overall survival in very highly selected patients, balanced against the cost per treatment (median of 3 required) and the 25% grade 3 & 4 treatment-related adverse effects.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

    The bulk of the evidence is in patients with metastatic uveal melanoma.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Not really

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    A modern interventional radiology suite and a skilled interventional radiologist and team, working within an MDT

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Like any interventional radiology or indeed surgical procedure, skill will improve with volume.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Phase 3 Trial of Chemosaturation vs best available care for patients with melanoma liver metastases MS Hughes, J Zager, Faries M et al. Ann Surg Oncol 2016; 23:1309-1319.
Small numbers n=93.
PFS 5.4 months vs 1.6 months for BAC, with no difference in OS 10.6 v 10 months.
4 treatment related deaths

Chemosaturation with percutaneous hepatic perfusion of melphalan for metastatic uveal melanoma. Modi S Gibson T, Vigneswaran G et al. Melanoma Research 2022; 32(2) 103-111.
Retrospective 2012 – 2020.
250 procedures in 81 patients, median 3 per patient
Overall response rate of 60.5%
Median PFS 8.4 months, OS 14.9 months
27% of patients experiences a G3/4 TRAE, improved over time.

Percutaneous hepatic perfusion with melphalan in liver dominated metastatic uveal melanoma: the German experience. Dewald CLA et al. Cancers (Basel). 2021, 14(1):118.
N=66, Median OS 18.3(7-24.6)months. Grade 3& 4 TRAE in 24.8% (Haematological toxicity 24.8%, hepatic toxicity 7.6%, ischaemic stroke 2.8%, PE 0.7%). .

30. Please list the key efficacy outcomes for this procedure/technology?

Progression-free and overall survival

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Risks of treatment-related adverse events are documented in the literature, and appear to be less over time, with experience.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Only suitable for very highly selected patients

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ○ A minority of hospitals, but at least 10 in the UK.
- ◉ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    As already cited above.

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    Not that I am aware of.

36. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    10 - 20 people per annum - rough estimate

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Treatment-related adverse events
    Patient reported outcome measures/ quality of life
    Progression-free and overall survival

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    Ideally use the Common Terminology Criteria for Adverse Events (CTCAE) V6, but should include
    Catheter-related complications
    Haematological toxicity (bone marrow suppression)
    Hepatic toxicity (transaminase rise)

    with 90 day follow up from the procedure, for short-term outcome data.

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

I have concerns about the cost per procedure, about which I am unclear, but historically I have been told of the order of £20,000. This may be entirely incorrect.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

My interest are ongoing and professional, to help provide a balanced view, to benefit patients and the wider NHS.

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Fenella Welsh

45. Date: *

17/03/2025

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1062/3 Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic liver cancer (IPG691)**

Your information

Name:	Dr Joseph Sacco
Job title:	Reader and Honorary Consultant in Medical Oncology
Organisation:	University of Liverpool
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Physicians
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	GMC 6061663

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

X I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am familiar with the technology. I collaborated with colleagues in a neighbouring acute NHS trust (Aintree) to set PHP up locally over ten years ago. We treated 5 patients, doing 6 procedures through compassionate access with provision of the filters from the company and with support from Aintree hospital. We then participated in the phase III FOCUS study and recruited a couple of patients. I also proposed (and prepared a synopsis for) an investigator led study, which was not however funded. Due to lack of funding we have not been able to provide this procedure for the last several years.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	The procedure is not widely used in the NHS at the moment, due to lack of funding. The main centre that provides it is Southampton, although this is performed in the private sector; mostly for self-funded patients. Centres in Manchester and London also provide the procedure in private. There is however, a significant desire to offer the procedure (due to its efficacy and lack of other options), and those currently running the procedure in private also work in the NHS and would be able to set the procedure up rapidly within the NHS. However, this would logically be only a small number of centres (~3-5), at least in the first instance.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	The procedure itself involves a multidisciplinary team including interventional radiologists, anaesthetists and a perfusionist. Oncologists (such as myself) oversee patient selection and follow up afterwards, but also toxicity (which is mainly due to the chemotherapy agent).
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients. I have published this research.
3	Does the title adequately reflect the procedure?	Yes The evidence to date predominantly relates to metastatic uveal melanoma. While there has been some work on other indications, there is much less data at present
	Is the proposed indication appropriate? If not, please explain.	The only indication with strong evidence is uveal melanoma; however, from a technical point of view the approach can be used for other malignancies affecting the liver, and there is some evidence to support its use in other cancers. My expertise relates to UM.
	Does this have a multi-indication?	It is a very different approach to the standard of care for metastatic uveal melanoma; which is usually systemic therapy. The only drug that is specifically licenced in uveal melanoma is tebentafusp, but this is only appliable to patients with HLA A0201 allele ie ~50%. Most (if not all) patients ultimately progress on tebentafusp underpinning the need for alternative therapies. However currently available treatments such as immune checkpoint inhibitors and chemotherapy have very low efficacy. There are other liver directed therapies that have been trialed (ie TACE, SIRT etc) and that are used in other coutries, but none of these has the amount of evidence that PHP does and are not widely used in the UK.
	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	
	Which of the following best describes the procedure (please choose one):	None of below points completely described the procedure, below is closest Established practice and no longer new. *However, with recent publication of a phase III trial (leading to FDA approval) and increasing evidence to support it*

4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It is likely to be a mix, in some patients it would be the only line of therapy, but hopefully in more patients will provide another option (albeit displacing current used therapies to later line). For liver predominant UM I would expect it would be first line for those who are HLA A0201 negative and second line in most with HLA A0201 positive status, with some of those with HLA A0201 having PHP first (if rapidly progressing disease).
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	None recently (and since last NICE review). Yes- there has been a Phase III international study which completed recruitment and which is now published. (doi: 10.1245/s10434-025-17231-x. https://doi.org/10.1245/s10434-024-15293-x) There have also been a number of series published from the UK, Germany, US etc. These studies support the efficacy of the procedure and have not shown new safety concerns.

Current management

6	Please describe the current standard of care that is used in the NHS.	Oligometastatic UM may be managed by resection or ablation, but in the main the standard of care for metastatic uveal melanoma in the UK is usually systemic therapy. The only drug that is specifically licenced in uveal melanoma is tebentafusp, but this is only appliable to patients with HLA A0201 allele ie ~50%. Most (if not all) patients ultimately progress on tebentafusp underpinning the need for alternative therapies. However the other available treatments such as immune checkpoint inhibitors (ICI) and chemotherapy have very low efficacy. For example, response rate to ICI is approximately 5-12% depending on agent and combination; and in contrast to skin melanoma, responses when these occur are not durable.

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Not really. There are other liver directed therapies such as SIRT or immune/chemo/bland embolisation which have been used but these are not readily available on the NHS and do not have a strong evidence backing. What evidence we have suggests PHP is better (but head to head)

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Increased patient survival. Across studies I would estimate this to be around 6 months median, although the OS comparison in the phase III was not statistically significant and based on only small numbers due in part to withdrawals from the best alternative care arm which also led to early cessation of randomisation. Notably from experience some patients have very long benefit from treatment, sometimes with control of several years.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Liver only metastatic UM (with mets not in excess of >50% of liver volume), potentially patients with minimal extrahepatic disease as well.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	It would lead overall to improved outcomes. It does involve fewer visits (ie only 3-6 cycles of treatment) with big breaks between treatments in contrast to other treatments (eg tebentafusp which involves weekly treatments). However, it is complex to deliver for each treatment cycle.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Facilities for this are mostly in place, with existing networks of clinicians in the pre-existing centres (or those involved in the trial previously). In certain centres, we would need to obtain services of a perfusionist and equipment involved in this.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes- but the company (Delcath) provide excellent mentoring and would provide relevant traners for this

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	The procedure is now well established and relatively well tolerated. No treatment deaths have been reported since the use of the current generation filter (which has been in use for over 10 years). The following peri-procedural TEAEs were reported 20 % or more of the patients: anemia (56.0 %), thrombocytopenia (50.5 %), nausea (41.8 %), international normalized ratio (INR) increased (30.8 %), vomiting (29.7 %), prolonged activated partial thromboplastin time

	Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	(PTT) (28.6 %), fatigue (23.1 %), aspartate aminotransferase (AST) increased (23.1 %), and ALT increased (22.0 %). https://pmc.ncbi.nlm.nih.gov/articles/PMC11249544/ Most toxicity is haematological with nadirs about 2 weeks after treatment, and reversible Considering the extensive experience now with the modality, it is unlikely new toxicity will emerge.
14	Please list the key efficacy outcomes for this procedure/technology?	Is the phase 3 trial, the main outcomes were an object tive response rate of 36%, duration of response of 14 months and median overall survival of 20.5 months.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	I don't believe any; if the procedure is limited to major centres and appropriate training is carried out as part of setup where the team is new to the procedure
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The procedure is complex and requires an appropriate multidisciplinary team with post-procedural care in HDU/ITU. This has generated some concern, but is related to lack of familiarity. We have a centre in the UK (Southampton) that has among the most experience globally providing appropriate guidance and mentoring for new centres.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are	I think most of the key work has been published now; including that presented at conferences last year.

	only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	No major trials; although there are combination studies ongoing (CHOPIN- https://clinicaltrials.gov/study/NCT04283890) Delcath have/had a registry for patients treated with PHP (I don't have details as to status) More generally, I am involved in an international registry for patients with uveal melanoma (as it is a rare disease), which we hope will allow analysis of PHP efficacy in comparison to other treatments. (https://ascopubs.org/doi/10.1200/JCO.2022.40.16_suppl.TPS9610)
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	In the UK would estimate around 100 per year. Overall incidence of UM is about 500; with about 40-50% developing metastasis. Considering fitness, liver only disease etc, would expect about half of those with metastatic disease to be eligible
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement	Beneficial outcome measures: Overall survival, Response rate, Progression free survival are all key indicators. QOL measures can be considered but would need additional support (as this would need questionnaires etc).

	for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: Toxicity is almost all in the early phase, I think we would want to monitor changes in haematological indices in the 2-3 week window post treatment, as well as any LFT changes and any admissions due to toxicity. I don't think there is need to monitor much more than a month after treatment (ie could be self reported)

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Member of advisory boards, IDMC committees, PI on clinical trial and grant funding (for OMNI registry) for Immunocore (manufacturer of tebentafusp which is the only systemic therapy licenced and funded in uveal melanoma). All paid to institution.	**Ongoing**	
Direct - financial	Member of TMG, PI on clinical trial, and member of advisory board for Replimune (which is developing an oncolytic virus for use in uveal melanoma). Paid to institution	**Ongoing**	
Direct - financial	Speaker fee for an educational session at SMR last year (which sponsored by Replimune).	**12/10/2024**	**12/10/2024**

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Joseph Sacco**
Dated:	**24/04/2025**

View results

Respondent

3 Anonymous

53:30
Time to complete

This questionnaire is only to be completed and submitted by Health and care practitioners

This questionnaire should be completed by those whose role is, or is directly related to, one of the specialisms below. For each assessment, we engage with professionals with expertise relevant to the topic under evaluation. By completing this questionnaire, you acknowledge and consent to being considered for the role of professional expert on this assessment.
Please indicate which option best describes your area of expertise. If there is no option which you feel relates to your role, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment.
For expressions of interest and/or to share your lived experience please email pip@nice.org.uk

Note:
Please ensure all necessary edits or amendments are completed on your questionnaire before the portal close date. A final submission pull will be conducted after closure, and the portal will then be locked. Any changes made after the closing date will not be included in the final submission.
https://techcommunity.microsoft.com/blog/microsoftformsblog/you-can-now-save-and-edit-your-survey-responses/3865033

1. Which option below best relates to your own role? You will be asked to supply your job title and organisation in the next section.
If your role is not listed but you feel it ought to be included, please select 'Other' and let us know your role and why you think we should include your knowledge and expertise on the assessment.

- ○ Consultant hepatobiliary surgeon
- ○ Consultant hepatologist
- ◉ Consultant in medical oncology
- ○ Consultant in clinical oncology
- ○ Consultant in surgical oncology
- ○ Interventional radiologist
- ○ Consultant in anaesthesia and critical care
- ○ Upper gastrointestinal surgeon
- ○ Other

2. Topic Title

Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver

3. Name: *

Matthew Wheater

4. Job title *

Consultant Medical Oncologist

5. Organisation

University Hospital Southampton

6. Email Address

[redacted]

7. Professional organisation or society membership/affiliation

Royal College of Physicians, Association of Cancer Physicians

8. Nominated/ratified by (if applicable)

9. Registration number (e.g. GMC, NMC, HCPC) *

GMC 4520577

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Please note: if consent is not given, you will not be eligible for the role of professional expert on this assessment.

For more information about how we process your data please see our privacy notice.

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below: *

- [x] Yes, I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above.
- [ ] No, I do not give my consent for the information in this questionnaire to be used and it may not be published on the NICE website as outlined above.
- [ ] Other

11. If you do not consent to us publishing your response, please explain why below:

Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

12. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure/technologies?
- Have you used it or are you currently using it? If so, please indicate your experience with this.
- Do you know how widely this procedure/technology is used in the NHS? Is this procedure/technology performed/used by clinicians in specialities other than your own?

I have extensive experience of the supervision of patients undergoing PHP for metastatic uveal melanoma. I was local principle investigator in Southampton for the Focus Trial comparing Melphalan-PHP to best alternative care. I have been involved in the supervision of over 100 patients undergoing this treatment, predominantly in private care, but with some treated in the NHS via trials or individual funding approval. Very few patients receive this treatment in the NHS due to lack of funding. Treatment involves the co-ordinated input of an oncologist, an interventional radiologist, an anaesthetist and a perfusionist.

13. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- [ ] I have done bibliographic research on this procedure or technology
- [ ] I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure or technology.
- [ ] Other

Interventional procedure related questions ONLY

Please skip 12 - 16 - if a DG/EVA/MTAC/LSA topic (information can be found on your email invite)

14. Does the title adequately reflect the procedure?

Yes. The most common description for the treatment is Melphalan-Percutaneous Hepatic Perfusion (M-PHP)

15. Is the proposed indication appropriate? If not, please explain.

There is now an established evidence base for M-PHP in the treatment of uveal melanoma. There is very little evidence in primary liver tumours, or liver metastases from other primary sites, although clinical trials are ongoing. I think the use of M-PHP should be assessed separately to other indications.

16. Does this have a multi-indication?

The original review looked at multiple tumour indications, however the majority of the evidence is specific to uveal melanoma.

17. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No major changes since the last review.

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes, a large international multi-centre trial has been completed and published.

19. Do you think the guidance needs updating?

Yes. There is now significantly more evidence supporting the safety and efficacy of melphalan-PHP specifically in metastatic uveal melanoma. It is now regarded as standard of care for this indication in many healthcare settings.

Current management

20. Please describe the current standard of care that is used in the NHS

For patients with HLA*A201 (about 40% of the population) and who are fit enough to receive it, then treatment with tebentafusp, a novel immunotherapeutic, would be regarded as standard of care. For patients without this HLA type, then checkpoint inhibitor immunotherapy is offered. The evidence base for this is limited and is largely done on the basis of studies in cutaneous melanoma, from which uveal melanoma patients were excluded.

21. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? Where would the technologies/procedure fit in the care pathway?

For patients with HLA A201 this treatment would likely be offered after treatment with tebentafusp. For patients without this HLA type it would likely be offered in advance of checkpoint inhibitors.

22.

- What are the main aims of these procedures or technologies?
- How innovative are they?
- Can you name any technologies which are available in the UK and have this function/mode of action?
- Are there any competing or alternative procedures available to the NHS which have a similar function/mode of action to this?
- If so, how do these differ from the technology/procedure indicated here?

Melphalan-PHP aims to reduce the tumour burden of uveal melanoma metastases in the liver, and as a consequence defer the onset of symptoms and extend life expectancy. This is a highly innovative treatment, with only 4 UK centres with experience of delivery and only 2 of these in the NHS. There are no other treatments able to deliver whole liver anti-cancer therapy. Other liver specific interventions (Chemo-embolisation, Radio-embolisation) tend to be embolic and poorly suited to the miliary pattern of liver involvement associated with uveal melanoma. There are therefore no other directly competing procedures with a similar mode of action.

23. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

There were 481 registrations of newly diagnosed cancer of the choroid and 59 registrations of cancer of the ciliary body in England in 2017 (Office of National statistics, 2017). Though there is no registered data, one paper suggests that the iris represents only 4% of all uveal melanomas (Cherkas et al, 2024); approximately 23 individuals. Approximately 50% of patients with a new diagnosis of uveal melanoma will relapse with metastatic spread, equating to 282 new metastatic cases annually. 80% of these would be anticipated to present with liver only or liver dominant metastatic disease and 75% of those would be expected to be eligible for treatment on the basis of performance status and co-morbidity giving a potential eligible population of 170 patients per year. With the introduction of tebentafusp for those patients who are HLA-A*02:01-positive, a proportion of patients will receive this as first line therapy and either not be fit for, or no longer have appropriate metastatic disease for, percutaneous hepatic perfusion M-PHP. It is anticipated that 126 patients annually would be eligible for treatment.

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Delayed cancer symptoms and improved life expectancy

25.
- Are there any groups of patients who would particularly benefit from this procedure/technology?
- Are there any groups in which the technology would be less effective or would be less likely to benefit?
- Are there any potential equality issues that should be considered for this condition and procedure/technology?

Patients with liver dominant metastatic uveal melanoma would particularly benefit from this treatment. I think it is currently less clear whether other primary tumour types would benefit although clinical trials are ongoing.
In terms of equality of access, the only current access is in the private sector, either through insurance or self funding. This has led to a significant equality issue with only patients of significant financial means able to access treatment.

26.
- What do you consider to be the potential benefits to the system from using this procedure/technology?
- Could it lead, for example, to a reduced number of appointments, improved care pathway, more efficient NHS staff time use?

Melphalan-PHP requires a 1 night hospital stay and is delivered 6-8 weekly up to 6 times. This compares to tebentafusp which requires weekly treatment until progression, with the first four treatments given as an inpatient, or to checkpoint inhibitors given every 2-6 weeks until progression with 20% of patients requiring hospital admission for toxicity management. Therefore although the procedure itself is more complex, the overall burden of treatment visits and drug cost is significantly lower.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/implement this technology safely?

An engaged multi-disciplinary team including an oncologist, interventional radiologist, anaesthetist and perfusionist is key to the implementation of treatment. An appropriate IR suite and the ability to make up melphalan chemotherapy on or close to the site of the procedure is also required.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

The team as described above should be appropriately trained and mentored in delivering this treatment safely.

Safety and efficacy of the procedure/technologies

29. What are the potential harms of the procedure/technology?

- Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:
- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Most patients will experience transient cytopaenias after treatment. For most these are self limiting, however patients should undergo weekly blood test monitoring for neutropaenia and thrombocytopaenia for 4 weeks after treatment, and should be given growth factors to minimise the risk of neutropaenia and infection.
There are rarely reported procedural adverse events of hepatic artery dissection and thrombo-embolic events.
(references Zager et al 2024 and 2025)

30. Please list the key efficacy and safety outcomes for this procedure/technology? Please suggest the most appropriate method of measurement for these outcomes and the timescales over which these should be measured (where appropriate) and if there are any challenges in collecting key outcomes.

The key efficacy outcomes are response rate, progression free survival and overall survival. Response should be measured radiologically after each 2 procedures up to a maximum of 6.
Toxicity data should be collected including incidence of neutropaenic infection, transfusion requirements for anaemia or thrombocytopaenia and any symptomatic toxicities.

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

The Focus trial comparing melphalan-PHP to best alternative care in metastatic uveal melanoma was established as a randomised controlled trial. Unfortunately due to poor accrual, predominantly in the US, the trial was modified to a single arm study. This has resulted in a relatively limited evidence base compared to other cancer interventions. With a rare cancer, and with PHP well established in the US and Europe, it is unlikely that another large randomised study will be completed in uveal melanoma.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

There is some controversy as to the robustness of the clinical data, however there is widespread acceptance in the melanoma oncology community that this is an effective treatment which is safe when delivered by a team with appropriate expertise.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):

- [ ] Most or all district general hospitals
- [ ] A minority of hospitals, but at least 10 in the UK
- [x] Fewer than 10 specialist centres in the UK
- [ ] Cannot predict at present

34. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

Cost (predominantly the kit and staff costs) and staff resource (predominantly availability of a perfusionist)

35. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of for this topic.
Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email.

Zager et al Ann Surg Oncol 2024 Efficacy and safety of the melphalan/hepatic delivery system in patients with unresectable metastatic uveal melanoma: Results from an open-label, single arm multicenter phase 3 study
Zager et al Ann Surg Oncol 2025 An Open-Label, Randomised study of melphalan/hepatic delivery system versus best alternative care in patients with unresectable metastatic uveal melanoma
Kapiteijn et al ESMO 2025 Combined percutaneou hepatic perfusion with ipilimumab plus nivolumab in metastatic uveal melanoma (CHOPIN): A single-center, open-label, randomised phase II study

36. Is there any research that you feel would be needed to address uncertainties in the evidence base?

A sequencing trial of tebentafusp followed by PHP vs the reverse order of treatment would be informative but is unlikely to be done.

37. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

- Beneficial outcome measures - These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.
- Adverse outcome measures - These should include early and late complications. Please state the post procedure timescales over which these should be measured.

Outcome measures: Response rate, overall survival
Adverse outcome measures: registry of acute complications such as bleeding or embolic events. Readmission rates for neutropaenic infection. Use of blood product support.

Further Comments

38. Please add any further comments on your particular experiences or knowledge of the procedure/technology.

Contact confirmation

Please indicate if you would like to opt in to NICE contacting you regarding other technologies/treatments in the future for your advice, or if you would only like to be contacted regarding this specific technology:

39. Please select what NICE may contact you about: *

- (●) NICE can use my details to contact me for advice on this and future assessments.
- ( ) NICE can use my details to contact me for advice on this topic only, but not for others.

40. Date *

09/12/2025

View results

Respondent

2 Anonymous

66:04
Time to complete

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- ○ Consultant hepatobiliary surgeon
- ○ Consultant hepatologist
- ○ Consultant in medical oncology
- ○ Consultant in clinical oncology
- ○ Consultant in surgical oncology
- ○ Interventional radiologist
- ○ Consultant in anaesthesia and critical care
- ○ Upper gastrointestinal surgeon
- ◉ Clinical Perfusionist

2. Topic Title

Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver

3. Name: *

Mona Dave

4. Job title *

Manager Clinical Perfusion Science Liver Perfusion

5. Organisation

King's College Hospital NHS Trust

6. Email Address

[redacted]

7. Professional organisation or society membership/affiliation

Society of Clinical Perfusion Scientists of Great Britain and Ireland

8. Nominated/ratified by (if applicable)

SCPS

9. Registration number (e.g. GMC, NMC, HCPC) *

431-PAE-06

Consent to publish response

How NICE will use this information: The information that you provide on this form may be used to develop guidance on this topic.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Where relevant your name, job title, organisation and your responses, along with your declared interests may be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Please note: if consent is not given, you will not be eligible for the role of professional expert on this assessment.

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- [x] Yes, I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above.
- [ ] No, I do not give my consent for the information in this questionnaire to be used and it may not be published on the NICE website as outlined above.
- [ ] Other

11. If you do not consent to us publishing your response, please explain why below:

Experience

Please answer the following questions as fully as possible to provide further information about the procedure/technologies and/or your experience

12. Please describe your level of experience with the procedure/technologies, for example:

- Are you familiar with the procedure/technologies?
- Have you used it or are you currently using it? If so, please indicate your experience with this.
- Do you know how widely this procedure/technology is used in the NHS? Is this procedure/technology performed/used by clinicians in specialities other than your own?

Yes familiar with the technology. Have used VVBYPASS used in this technology for over 21yrs now. I have a vast experience in all kinds of perfusion technology used in liver surgery. Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver is not widely used in the NHS but the technology used to facilitate this treatment which is called VVBYPASS is used widely in nhs trusts and not just for liver cancer but for liver transplant procedures and some specific cardiac procedures too.

13. Please indicate your research experience relating to this procedure or technology (please choose one or more if relevant): (Please highlight your choice(s))

- [ ] I have done bibliographic research on this procedure or technology
- [ ] I have done research on this procedure or technology in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure or technology involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure or technology.
- [ ] Other

Interventional procedure related questions ONLY

Please skip 12 - 16 - if a DG/EVA/MTAC/LSA topic (information can be found on your email invite)

14. Does the title adequately reflect the procedure?

My suggestion would be to use the term "VVBYPASS" as it gives more clarity about the technology used to facilitate Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver

15. Is the proposed indication appropriate? If not, please explain.

Yes

16. Does this have a multi-indication?

No

17. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

I am not aware of any

19. Do you think the guidance needs updating?

If this treatment becomes more widely used in the UK, I am sure the guidance will need updating at a later stage, depending on the further evidence and experience

Current management

20. Please describe the current standard of care that is used in the NHS

Because of the variety of liver cancers and metastatic disease from different primary tumours, the choice depends on tumour type, number and location of lesions, liver function, whether disease is confined to liver, overall patient health, and other factors. This particular treatment is only currently offered in one nhs trust in the UK

21. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? Where would the technologies/procedure fit in the care pathway?

Additional

22.
- What are the main aims of these procedures or technologies?
- How innovative are they?
- Can you name any technologies which are available in the UK and have this function/mode of action?
- Are there any competing or alternative procedures available to the NHS which have a similar function/mode of action to this?
- If so, how do these differ from the technology/procedure indicated here?

The main aims are to deliver a very high, organ-directed dose of chemotherapy (melphalan) to the liver while limiting systemic exposure by isolating hepatic venous outflow and filtering the blood,to control or shrink hepatic tumours (particularly unresectable liver metastases, notably from uveal/ocular melanoma) when other local therapies are not suitable and to provide a repeatable locoregional option for liver-dominant disease to prolong disease control, palliate symptoms or bridge to other treatments.
Technically innovative as a whole-organ locoregional therapy, it combines endovascular hepatic arterial infusion with temporary hepatic isolation and an extracorporeal filtration circuit to remove drug from venous blood before it returns systemically, using veno-venous bypass, permitting much higher local doses than systemic chemo but it is not a brand new concept.
CHEMOSAT® / Hepatic CHEMOSAT Delivery System (Delcath)are the clinically used system for melphalan PHP, it has been used in some UK centres offering this treatment.
Alternative - TACE, SIRT / TARE,HAI and Percutaneous image-guided ablation (radiofrequency / microwave) and surgical resection.

Chemosaturation treats the whole liver (saturates organ), useful for diffuse or multifocal disease not amenable to focal therapy.

23. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Approx 50-70

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

This can provide better control of liver-only or liver-dominant metastases, particularly in conditions like uveal melanoma where the liver is the primary site of progression. It may delay liver tumor progression compared to other technology. Because the drug is isolated within the hepatic circulation and filtered before returning to systemic circulation, patients may experience less whole-body toxicity than with conventional IV chemotherapy of equivalent doses. It is a therapeutic alternative when surgery, ablation, or systemic therapy are unsuitable or ineffective.

25.

- Are there any groups of patients who would particularly benefit from this procedure/technology?
- Are there any groups in which the technology would be less effective or would be less likely to benefit?
- Are there any potential equality issues that should be considered for this condition and procedure/technology?

The procedure is most likely to benefit highly selected patients with liver-only or liver-dominant metastatic disease, especially when other treatments are limited, like the ones with metastatic uveal (ocular) melanom,patients with preserved liver function or unsuitable for surgical resection or thermal ablation.
The technology would be less effective or inappropriate for patients with extensive extra-hepatic metastatic disease or severe hepatic impairment, where the risks outweigh potential benefit.
Potential equality issues to consider- Chemosaturation can only be delivered in a very small number of high-expertise centres.

26.

- What do you consider to be the potential benefits to the system from using this procedure/technology?
- Could it lead, for example, to a reduced number of appointments, improved care pathway, more efficient NHS staff time use?

By targeting liver-dominant disease in a single, organ-focused procedure, it can potentially reduce the need for multiple sequential treatments (e.g., repeated systemic chemotherapy cycles) in selected patients. It may allow centralization of care in specialist centres, creating a coordinated, multidisciplinary approach (interventional radiology, oncology, anaesthesia, perfusion)
Although it is resource-intensive for a single procedure (requires perfusionist, IR suite, anaesthetic support), it may reduce cumulative staff time compared with multiple cycles of systemic therapy or repeated local interventions in eligible patient. Since the procedure is delivered under NICE "special arrangements" or within research protocols, its use supports systematic data collection and audit, which can improve future service planning and inform commissioning decisions.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/implement this technology safely?

The procedure can only be delivered safely in specialist tertiary centres with advanced interventional radiology, critical care support, perfusion capability, and a multidisciplinary team trained in hepatic isolation chemotherapy. Existing facilities may require modifications for perfusion equipment, staff training, and governance system.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes, definitely. This is not a standard interventional procedure, it requires specialist multidisciplinary training across interventional radiology, perfusion, anaesthesia, oncology, and nursing.

Safety and efficacy of the procedure/technologies

29. What are the potential harms of the procedure/technology?

- Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:
- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Haemodynamic instability, Bleeding / vascular injury, Extracorporeal circuit complications,anaesthesia related complications, Myelosuppression / neutropenia / thrombocytopenia,Transient liver enzyme elevation, Pulmonary embolism / deep vein thrombosis .

Serious complications are rare but potentially life-threatening, especially in patients with poor baseline health or extensive liver involvement.

Careful patient selection, specialist staff, and monitoring are essential to minimise harm

30. Please list the key efficacy and safety outcomes for this procedure/technology? Please suggest the most appropriate method of measurement for these outcomes and the timescales over which these should be measured (where appropriate) and if there are any challenges in collecting key outcomes.

Efficacy: Focus on tumour response, liver-specific control, progression-free survival, overall survival, QoL, and symptom improvement.
Safety: Focus on haematologic, hepatic, renal toxicities, procedure-related complications, systemic toxicity, and peri-procedural mortality.
Measurement: Imaging (CT/MRI), lab tests, standardized toxicity grading (CTCAE), validated QoL questionnaires, clinical records.
Timescales: Baseline, immediately post-procedure, weekly for 2–4 weeks, then at 1–3 months and every 2–3 months for longer-term outcomes.
Challenges: Small patient numbers, variability in imaging/assessment, multi-disciplinary reporting, and long-term follow-up.

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Efficacy uncertainties relate mainly to limited trial evidence, long-term outcomes, and optimal patient selection.Safety uncertainties relate to serious but rare complications, variability between centres, and long-term organ toxicity.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

controversial due to limited high-quality evidence, small eligible population, procedural complexity, and uncertainty about long-term benefits.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):

- [ ] Most or all district general hospitals
- [ ] A minority of hospitals, but at least 10 in the UK
- [ ] Fewer than 10 specialist centres in the UK
- [x] Cannot predict at present

34. Are you aware of any additional issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.

Probably costs and staffing considering the current ongoing scenarios in every NHS trusts in the UK

35. Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of for this topic.
Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email.

36. Is there any research that you feel would be needed to address uncertainties in the evidence base?

CHOPIN

37. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

- Beneficial outcome measures - These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.
- Adverse outcome measures - These should include early and late complications. Please state the post procedure timescales over which these should be measured.

Beneficial outcomes: tumour response, hepatic/overall PFS, OS, QoL, symptom control, time to next therapy.
Adverse outcomes: haematologic, hepatic, renal, procedural complications, systemic toxicity, serious/life-threatening events, late complications.
Measurement methods and timescales: baseline, peri-procedure, early post-procedure (days–weeks), medium-term (1–3 months), long-term (≥6–12 months).

Further Comments

38. Please add any further comments on your particular experiences or knowledge of the procedure/technology.

I am still helping develop this technology in some private centres in London si nothing to add

Contact confirmation

Please indicate if you would like to opt in to NICE contacting you regarding other technologies/treatments in the future for your advice, or if you would only like to be contacted regarding this specific technology:

39. Please select what NICE may contact you about: *

- (●) NICE can use my details to contact me for advice on this and future assessments.
- ( ) NICE can use my details to contact me for advice on this topic only, but not for others.

40. Date *

02/12/2025

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1062/3 Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic liver cancer (IPG691)**

Your information

Name:	Sanjay Gupta
Job title:	Consultant in Anaesthesia and Critical Care
Organisation:	University Hospital Southampton
Email address:	[redacted]
Professional organisation or society membership/affiliation:	FRCA RCOA
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4067931

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have been the anaesthetic lead and sole anaesthesia provider in the UK for many years. My first case was in 2012 and I have provided perioperative care for over 500 cases since and therefore have the largest case series experience as single provider world-wide. I am also a senior member of the proctoring team providing training internationally. Currently due to lack of NHS reimbursement, the treatment is only available in a private setting and I currently provide this at Spire Hospital Southampton on a regular basis.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	The technology requires specialist anaesthesia and interventional radiology training with support from a perfusionist. Patient selection is important and their ability to withstand potential haemodynamic instability eg very high dose vasopressors, total venous occlusion of the IVC, severe SIRS response during the filtration phase causing dysrhythmia requires patients to be free from ischaemic heart disease and be PS1 and at least ASA 3. Anaesthesia training and experience is essential in managing these patients.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research as co-author Other (please comment)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	YES YES There is growing evidence that non-melanoma metastases patients would also benefit from this treatment. Completely different: isolated liver and whole of liver treatment rather than systemic; minimally invasive and very well tolerated; requires GA and bypass circuit support Established practice and no longer new. In experienced centres the procedure is routine, safe and has efficacy

4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Most patients progress to systemic disease and require systemic treatment though the outcomes at this stage are quite poor
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	NO NO

Current management

6	Please describe the current standard of care that is used in the NHS.	Systemic therapy with tebentefusp / immunotherapy
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	NO

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Well tolerated, shows efficacy, quick recovery and good quality of life in between treatments.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Non-resectable liver metastases currently from ocular melanoma
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	YES as explained above. Patients could have this done with an overnight stay in hospital and only return 6-8 weeks later for subsequent treatments. Median number of treatments ion the trial was around 4.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Dedicated team in a centre to undergo training to provide treatment and followup
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	YES

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Immediate: cardiovascular complications (dysrrythmias – common, MI and stroke rare, bleeding (rare), anaphylaxis (rare), severe hypotension (common but treatable) Intermediate after a few days: myelosuppression (mild), hair loss Annecdotal severe: anaphylaxis to protamine in one patient and melphalan in another leading to cardiac arrest with subsequent full recovery

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Disease control / disease remission
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Essential that this is carried out in well trained and experienced centres that must remain current or undergo refresher training. I would suggest to remain current a centre must do at least one treatment per month
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not to my knowledge
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 5 specialist centres in the UK.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a	

	comprehensive reference list but it will help us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Please seek this information from oncology
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: 1. Quality of life and time interval to normal activity 2. Patient reported outcome on side-effects and tolerability 3. Degree of myelosuppression following treatment 4. Degree of organ dysfunction (hypotension related) following treatment (eg renal / hepatic) 5. Each treatment would be performed every 6-8 weeks. An audit could be done following each treatment Adverse outcome measures: myelosuppression 2 weeks, nausea 24 hours

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Proctor for Delcath as company trainer for which a fee is charged and expenses paid.	**Last 10 years**	
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Sanjay Gupta**
Dated:	**1 April 2025**

NICE National Institute for Health and Care Excellence

Interventional Procedures Advisory Committee: Committee Interests Register

Topic: IPG10448 (IP1062/3) - Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver

NICE's declaration of interest policy can be accessed here

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Rick Body	Standing Committee Member (Chair)	Financial	Nil	N/A	10/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	10/03/2026	N/A	No further action
		Indirect	Nil	N/A	10/03/2026	N/A	No further action
Simon Bach	Standing Committee Member (Vice-Chair)	Financial	Nil	N/A	27/05/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	27/05/2026	N/A	No further action
		Indirect	Nil	N/A	27/05/2026	N/A	No further action
Angus McNair		Financial	Nil	N/A	23/03/2026	N/A	No further action

	Standing Committee Member	Non-financial professional and personal	Nil	N/A	23/03/2026	N/A	No further action
		Indirect	Nil	N/A	23/03/2026	N/A	No further action
Augusto Azuara-Blanco	Standing Committee Member	Financial	Nil	N/A	09/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	09/03/2026	N/A	No further action
		Indirect	Nil	N/A	09/03/2026	N/A	No further action
Christopher Adams	Standing Committee Member	Financial	Nil	N/A	11/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	11/03/2026	N/A	No further action
		Indirect	Nil	N/A	11/03/2026	N/A	No further action
Conrad Harrison	Standing Committee Member	Financial	Nil	N/A	06/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	06/03/2026	N/A	No further action
		Indirect	Nil	N/A	06/03/2026	N/A	No further action
Dawn Lee		Financial	Nil	N/A	09/03/2026	N/A	No further action

	Standing Committee Member	Non-financial professional and personal	Nil	N/A	09/03/2026	N/A	No further action
		Indirect	Nil	N/A	09/03/2026	N/A	No further action
Mahmoud Elfar	Standing Committee Member	Financial	Nil	N/A	25/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	25/03/2026	N/A	No further action
		Indirect	Nil	N/A	25/03/2026	N/A	No further action
Marwan Habiba	Standing Committee Member	Financial	Nil	N/A	06/04/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	06/04/2026	N/A	No further action
		Indirect	Nil	N/A	06/04/2026	N/A	No further action
Noemi Muszbek	Standing Committee Member	Financial	I do not have a conflict of interest in primary or metastatic cancer in the liver, however Visible Analytics, where I am Partner (part-owner) and HE Director provides consultancy services to Aura Biosciences, a project that I am also involved in, in early uveal melanoma.	27/08/2025	16/04/2026	Ongoing	No further action
		Non-financial professional and personal	Nil	N/A	09/03/2026	N/A	No further action

		Indirect	Nil	N/A	09/03/2026	N/A	No further action
Paddy Storrie	Standing Committee Member	Financial	Nil	N/A	09/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	09/03/2026	N/A	No further action
		Indirect	Nil	N/A	09/03/2026	N/A	No further action
Patrick Farrell	Standing Committee Member	Financial	Nil	N/A	18/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	18/03/2026	N/A	No further action
		Indirect	Nil	N/A	18/03/2026	N/A	No further action
Sandeep Singh Randhawa	Standing Committee Member	Financial	Nil	N/A	17/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	17/03/2026	N/A	No further action
		Indirect	Nil	N/A	17/03/2026	N/A	No further action
Stuart Smith	Standing Committee Member	Financial	Nil	N/A	09/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	09/03/2026	N/A	No further action

		Indirect	Nil	N/A	09/03/2026	N/A	No further action
Suvitesh Luthra	Standing Committee Member	Financial	Nil	N/A	09/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	09/03/2026	N/A	No further action
		Indirect	Nil	N/A	09/03/2026	N/A	No further action
Tim Kinnaird	Standing Committee Member	Financial	Nil	N/A	10/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	10/03/2026	N/A	No further action
		Indirect	Nil	N/A	10/03/2026	N/A	No further action
Veena Soni	Standing Committee Member	Financial	Nil	N/A	09/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	09/03/2026	N/A	No further action
		Indirect	Nil	N/A	09/03/2026	N/A	No further action
Joseph Sacco	Professional Expert	Financial	Paid involvement in an educational meeting on PHP (co-chair and speaker). Income £1,250.	Aug-25	19/12/2025	23 March 2026 (further meeting planned)	No further action
		Financial	Delcath advisory board meeting. Received personal income of £1,700	May-18	19/12/2025	May-18	Declare and participate

		Non-financial professional and personal	I recently participated in a Delcath sponsored advisory board with a group of experts in the field in which we sought to come to consensus statements around the use of the PHP in uveal melanoma. This has not been finalized or published; in the event publication I will highlight the publication to the committee.	Nov-25	19/12/2025	Nov-25	Declare and participate
		Indirect	I was local PI for a delcath sponsored trial which was published last year	2017	19/12/2025	2024	Declare and participate
		Indirect	I have attended advisory boards for delcath with payments to institution rather than to self	Nov-25	19/12/2025	Nov-25	Declare and participate
		Indirect	I have also attended advisory boards for other companies with trials or treatments in uveal melanoma space, including Immunocore, BMS, Replimune	~2014	19/12/2025	Ongoing	No further action
		Indirect	I am or have been local PI on a number of clinical trials in uveal melanoma sponsored by other companies (including Immunocore and Replimune in particular)	~2015	19/12/2025	Ongoing	No further action
Matthew Wheater	Professional Expert	Financial	Attendance at ESMO Conference 2025 Support (flights to Berlin and hotel accomodation) from Delcath systems	16/10/2025	15/12/2025	20/10/2025	Declare and participate
		Financial	Consultancy fees Delcath systems - £500	04/11/2025	15/12/2025	04/11/2025	Declare and participate
		Non-financial professional and personal	Senior author UK Occular melanoma guidelines	01/10/2025	15/12/2025	01/10/2025	No further action

		Non-financial professional and personal	PPP (Preliminary policy proposal) lead on CPAG application for melphalan-PHP for liver dominant metastatic uveal melanoma	01/01/2025	15/12/2025	Ongoing	Declare and participate
		Indirect	Nil	N/A	15/12/2025	N/A	No further action
Mona Dave	Professional Expert	Financial	Nil	N/A	10/03/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	10/03/2026	N/A	No further action
		Indirect	Nil	N/A	10/03/2026	N/A	No further action
Sanjay Gupta	Professional Expert	Financial	Private practice: providing anaesthesia and critical care service for private and NHS patients	2012	24/11/2025	Ongoing	No further action
		Financial	International proctor: I provide proctorship and training to new centres principally in Europe and USA. This is reimbursed by the company (Delcath Inc (HQ Ireland)	01/07/2013	24/11/2025	Ongoing	Declare and participate
		Financial	I provide clinical advice at Ad board meetings to direct future progress of the service (approximately £1200 per year or less)	01/07/2013	24/11/2025	Ongoing	Declare and participate
		Non-financial professional and personal	Nil	N/A	24/11/2025	N/A	No further action
		Indirect	Nil	N/A	24/11/2025	N/A	No further action

Stephen Mackworth-Green	Patient Expert	Financial	Nil	N/A	25/02/2026	N/A	No further action
		Non-financial professional and personal	Nil	N/A	25/02/2026	N/A	No further action
		Indirect	Nil	N/A	25/02/2026	N/A	No further action
Jo Gumbs	Patient Expert	Financial	Nil	N/A	23/03/2026	N/A	No further action
		Non-financial professional and personal	Chief Executive of Ocular Melanoma UK, a patient advocacy charity supporting individuals affected by uveal melanoma. The organisation provides patient support services, contributes to policy discussions, and advocates for improved access to treatments. This role includes representing the patient perspective in discussions relevant to ocular melanoma treatments.	October 2009	23/03/2026	Ongoing	Declare and participate
		Non-financial professional and personal	Regular engagement with patients who have undergone treatments including Chemosat, providing insight into lived experience and outcomes which may inform my contributions.	Ongoing	23/03/2026	Ongoing	No further action
		Indirect	Ocular Melanoma UK, the charity I work for, received funding of £20,000 from Delcath Systems This funding supports activities such as patient conferences and community support initiatives.	July 2025	23/03/2026	Ongoing	Declare and participate

			We also received other grants from pharmaceutical companies and I receive no personal financial benefit. While my role involves representing the patient community, the charity maintains independence in its activities and advocacy, and funding is not linked to specific positions taken in policy or advisory settings.				
		Indirect	Delcath Systems are covering reasonable expenses for my attendance at clinical meetings and will make a payment to Ocular Melanoma UK for my time at two events so that clinicians can hear more about the patient experience. This payment is made at fair market value to the organisation, with no personal financial benefit to me. The charity retains full independence in its activities and advocacy, and this arrangement does not determine the views I present.	September 2025	23/03/2026	March 2026	Declare and participate