NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures

Patient Organisation Submission

Chemosaturation via percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic liver cancer IP1062/2

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.

To help you give your views, we have provided this template. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

About you	
1. Your name	[redacted]
2. Name of organisation	OcuMel UK
3. Job title or position	National Director
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	OcuMel 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. OcuMel UK has also received, sponsorship toward large events such as the Annual Conference and Annual Gala from pharmaceutical companies including Delcath. OcuMel UK has now grown to nearly 600 members with a reach of many more subscribers in the UK and abroad. OcuMel UK also runs several online groups such as the Facebook 'Patient Support' group containing 336 members and the 'Knowledge and Strategy' group containing 191 users which include some clinicians. There is also a family group with 163 users and a stage 4 group with currently 74 users. These groups are fantastically active offering a shared wealth of experience.
5. How did you gather the information about the experiences of patients and carers to help 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.)	

Being a small charity, OcuMel UK gets to know the people and some of the challenges they face which includes needing further treatment and/or needing knowledge regarding further treatment.

[redacted], a liver surgeon from Southampton General Hospital, presented on behalf of his team in 2012 at the 2nd OcuMel UK Annual Conference a talk introducing 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. Both by social media and the helpline, OcuMel 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. The helpline is monitored by either two retired nurses (volunteers) or by the National Director. When issues such as information regarding treatments are brought up, where relevant and with permission, the information shared within the calls are passed on. OcuMel UK is in the process of employing a part-time nurse who will also monitor the helpline two days per week.

In response to the NICE review OcuMel UK opened an online survey to its members (of whom all are either patients or family members of patients) to enquire how patients felt about Chemosat being a 'trial only' drug and whether it should be authorised by NICE.

Since the talk by [redacted], Chemosat has featured in each of our Annual Conferences and can be found on the OcuMel UK YouTube channel. OcuMel UK has constantly remained in contact with patients, carers, clinicians and staff regarding different types of treatment for metastases.

Many calls on the helpline are regarding access to treatment. The issue of Chemosat at this point is that not all patients can join the clinical trial to gain access. A second issue is that they also cannot afford to self-fund or obtain cover through private insurance.

OcuMel UK also joins other patient groups in discussions where issues such as the benefits of Chemosat are discussed. The consensus is that Chemosat should be made available to those in need of it.

Living with the condition

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

Once someone reaches stage 4, time is of the essence as this can be an aggressive cancer and untreated metastasis will mean a very short lifespan.

When someone is stage 1, they are aware it can spread and complexities with prognostication methods means someone can never be sure whether their cancer may progress. This is a difficult time for all patients with the disease as, if it does spread, they know they will need treatment quickly, but they are also aware that there is no clear treatment pathway until a treatment is approved for use on the NHS. Stage 4 patients need clarity and the opportunity to receive treatment as quickly as possible.

Our helpline has shown that in some circumstances the patient does not have the desire or perhaps the skill set to be able advocate on behalf of themselves. This means that it falls to the carer and without a clear treatment path, dilemmas can occur such as:

- People want to ignore the fact that someone has cancer when they look so healthy - this can be either the carer or the patient or both.
- Some patients are not 'ready' to face the issues surrounding UM making difficult for carers to deal with.
- Carers can find looking after a patient either Stage 1 or someone who has progressed to Stage 4 overwhelming.

This is by no means an exhaustive list and once a patient becomes Stage 4, carers and patients have commented that they have experienced a series of 'mixed messages' from clinicians: on the one hand palliative care is offered and at the same time another clinician may offer treatment.

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are?

The treatments offered fall into two groups, local treatments to the liver and systemic full body treatment. A train of thought is that if liver metastasis can be brought under control, a systemic treatment can then be used for longer term benefit. From the systemic treatments available, immunotherapies seem to give the better chance of progression free survival, but this treatment needs time for it to work. Clinicians have suggested to us that they would like to see trials combining two treatments to show if this gives even better results and also Chemosat used as an adjuvant treatment for patients that are at a high risk of metastases.

Another advantage is that although patients need to travel to a specialist centre for treatment, as it's usually at 6 weekly intervals, patients can have a near normal life in between and often report good recovery after each session.

With treatment, a significant number of patients have either had reduction, stability and even a total response. As one of our participants noted, it gave the patient a chance 'to create memories' and another patient noted that with Chemosat the patient received an extra 3 years of life. This in a historically terminal disease is good news indeed.

Disadvantages of the procedure or operation

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

Members of OcuMel UK noted that the main disadvantage of the procedure is the unavailability of the treatment. Slots are often in high demand on trials, and therefore some patients must either pay privately or take a less effective treatment (and subsequently disqualify themselves from the trial at a later date). One survey participant noted that: 'There is no doubt that this operation carries risks, which is why it needs to be carried out by very skilled practitioners.' However, the participant continued saying: 'In their hands the risks are minimalised significantly. My husband very soon bounced back from his operations and had an excellent quality of life for the majority of the time he was terminally ill. He even flew 500 miles to see an ACDC concert four days after one!'

A second disadvantage is that it is not suitable for everybody. One participant thought that it gave 'extra months' of 'very poor quality'. However, the load of the disease plays an important role in the perception of patients and their carers.

Patient population
9. 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. In the paper titled: '*Chemosaturation with percutaneous hepatic perfusion is effective in patients with ocular melanoma and cholangiocarcinoma*' (https://link.springer.com/article/10.1007/s00432-020-03289-5) it was noted that 'patients with OM and low levels of LDH as a surrogate marker of tumour load represent specifically good candidates for CS-PHP' and emphasised that: 'CS-PHP should be carefully discussed in patients with a high tumour burden.'
Equality
10. Are there any potential equality issues that should be taken into account when considering this topic? N/A
Other issues
11. Are there any other issues that you would like the Committee to consider? We would like clarity whether this review is for patients with Uveal Melanoma who have liver metastases, or will it now include other cancers in the liver.
Key messages

12. In no more than 5 bullet points, please summarise the key messages of your submission.

1. Patients experience a high unmet need regarding treatment for metastases.
2. For affected patients who develop this aggressive cancer, time is of the essence and treatments need to be readily available.
3. Although treatment involves travelling to specialist centres, it enables a near normal life in between.
4. The advantage of the treatment, for those with a low load, is it provides life, but it has the disadvantages for some to have to endure grade 3 and 4 side-effects although this is minimal compared to other treatments such as Ipilimumab
5. It has been recognised (in several papers) that this cancer treatment is safe and effective for people with Uveal Melanoma. What we are not sure of is the remit for this NICE review.

Thank you for your time.

Please return your completed submission to ip@nice.org.uk