NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

QuiremSpheres for treating unresectable advanced hepatocellular carcinoma (Partial review of TA688)

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of QuiremSpheres within its approved indication for treating unresectable advanced hepatocellular carcinoma.

Background

Hepatocellular carcinoma (HCC) is the most common form of liver cancer in England.[1] It is commonly associated with cirrhosis (scarring of the liver), which can be caused by viral infections such as hepatitis B or C, excessive alcohol intake, or other diseases that result in chronic inflammation of the liver. In England, between 2016 and 2018, on average 5,148 people were diagnosed with liver cancer every year, and there were 3,537 diagnoses of HCC. HCC accounted for 67% of diagnoses in men and 37% of diagnoses in women.[1]

Treatment for HCC depends on the location and stage of the cancer, and how well the liver function is preserved. Treatment options include surgical resection and liver transplantation, radiotherapy, and systemic treatments.

For people with advanced disease, NICE recommends selective internal radiation therapy (SIRT), a locoregional transarterial therapy:

- SIR-Spheres or TheraSphere as an option for treating unresectable advanced HCC only for adults with Child-Pugh grade A liver impairment when conventional transarterial therapies are inappropriate (TA688).

NICE also recommends systemic treatments for advanced disease:

- cabozantinib as an option for treating advanced HCC only for adults who have had sorafenib, have Child-Pugh grade A liver impairment and an ECOG performance status of 0 or 1 (TA849).

- atezolizumab plus bevacizumab as an option for treating advanced or unresectable HCC only for adults who have not had previous systemic treatment and have Child-Pugh grade A liver impairment and an ECOG performance status of 0 or 1 (TA666).

- regorafenib as an option for treating advanced unresectable hepatocellular carcinoma only for adults who have had sorafenib, have Child-Pugh grade A liver impairment and an ECOG performance status of 0 or 1 (TA555).

- lenvatinib as an option for untreated, advanced, unresectable HCC only for adults with Child-Pugh grade A liver impairment and an ECOG performance status of 0 or 1 (TA551).

- sorafenib as an option for treating advanced HCC only for people with Child-Pugh grade A liver impairment (TA474).

QuiremSpheres received a negative recommendation in TA688 evaluating SIRTs in advanced HCC. This scope is a part review of TA688 and focuses only on adults with unresectable advanced hepatocellular carcinoma with Child-Pugh grade A liver impairment when conventional transarterial therapies are inappropriate, a population for which SIR-Spheres and TheraSphere are recommended.

The technology

QuiremSpheres (Terumo) received its CE mark in April 2015. It is classified as an Active Implantable Medical Device by Council Directive 90/385/EEC. It is indicated for treating unresectable liver tumours.

Intervention(s)	QuiremSpheres
Population(s)	Adults with unresectable advanced hepatocellular carcinoma with Child-Pugh grade A liver impairment when conventional transarterial therapies are inappropriate
Comparators	• SIR-Spheres • TheraSphere
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • time-to-progression • response rates • rates of liver transplant or surgical resection • adverse effects of treatment • health-related quality of life

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.
Other considerations	Guidance will only be issued in accordance with the CE marking. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** 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. Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma (2020) NICE technology appraisal guidance 666. Regorafenib for previously treated unresectable hepatocellular carcinoma (2019) NICE technology appraisal guidance 555. Lenvatinib for untreated advanced hepatocellular carcinoma (2018) NICE technology appraisal guidance 551. Sorafenib for treating advanced hepatocellular carcinoma (2017) NICE technology appraisal guidance 474. **Related interventional procedures:** Living-donor liver transplantation (2015) NICE interventional procedure guidance 535

	Selective internal radiation therapy for primary hepatocellular carcinoma (2013) NICE interventional procedure guidance 460 Ex-vivo hepatic resection and reimplantation for liver cancer (2009) NICE interventional procedure guidance 298 Microwave ablation of hepatocellular carcinoma (2007) NICE interventional procedure guidance 214 Radiofrequency-assisted liver resection (2007) NICE interventional procedure guidance 211 Laparoscopic liver resection (2007) NICE interventional procedure guidance 135 Radiofrequency ablation of hepatocellular carcinoma (2003) NICE interventional procedure guidance 2
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) chapter 131 (page 357): Specialist services for complex liver, biliary and pancreatic diseases in adults.

Questions for consultation

Where do you consider QuiremSpheres will fit into the existing care pathway for unresectable advanced hepatocellular carcinoma?

- Which treatments are considered to be established clinical practice in the NHS for hepatocellular carcinoma with Child-Pugh grade A liver impairment when conventional transarterial therapies are inappropriate?
- Are SIRT SIR-Spheres and TheraSphere routinely used in the NHS and what is the proportion of patients receiving these treatments?
- Are atezolizumab with bevacizumab, cabozantinib, lenvatinib, regorafenib and sorafenib appropriate comparators for this population?

Would QuiremSpheres be a candidate for managed access?

Do you consider that the use of QuiremSpheres can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which the treatment is licenced;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE is considering evaluating this technology through its cost comparison evaluation process.
Please provide comments on the appropriateness of appraising this topic through this process.
(Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?

- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.

- Will the intervention be used to treat the same population as the comparator(s)?

- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?

- Would it be appropriate to use the cost-comparison methodology for this topic?

References

1. Cancer Research UK (2021) Liver cancer incidence statistics Assessed November 2023.