NICE National Institute for Health and Care Excellence

NICE guidance

Selective internal radiation therapy with QuiremSpheres for treating unresectable advanced hepatocellular carcinoma

Technology appraisal guidance
Published: 3 July 2024

www.nice.org.uk/guidance/ta985

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance partially replaces TA688.

1 Recommendations

1.1 The selective internal radiation therapy (SIRT) QuiremSpheres is recommended as an option for treating unresectable advanced hepatocellular carcinoma (HCC) in adults, only if it is:

- used for people with Child–Pugh grade A liver impairment when conventional transarterial therapies are inappropriate, and
- the company provides it according to the commercial arrangement.

1.2 This recommendation is not intended to affect treatment with QuiremSpheres that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

Why these recommendations were made

This evaluation is a partial review of NICE's technology appraisal guidance on selective internal radiation therapies for treating hepatocellular carcinoma (TA688). This evaluation reviews new evidence submitted by the company.

Treatment depends on the stage of HCC and liver function. Treatment options include surgery, transarterial therapies (including SIRT with SIR-Spheres and TheraSphere), chemotherapy and best supportive care. Treatment does not cure HCC for most people. QuiremSpheres is another treatment option that could be used instead of SIR-Spheres and TheraSphere.

Clinical trial evidence for QuiremSpheres is limited. It has not been directly compared with SIR-Spheres and TheraSphere. But the results from an indirect comparison suggest that it is as effective as SIR-Spheres and TheraSphere.

A cost comparison suggests QuiremSpheres has similar costs to SIR-Spheres and TheraSphere. So, QuiremSpheres is recommended.

For all evidence see the committee papers. To see what NICE did for SIR-Spheres and TheraSphere, see the committee discussion section in NICE's technology appraisal guidance on selective internal radiation therapies for treating hepatocellular carcinoma.

2 Information about QuiremSpheres

CE mark for QuiremSpheres

2.1 QuiremSpheres (Terumo) received its CE mark in April 2015. It is classified as an Active Implantable Medical Device by Council Regulation (EU2017/745). It is indicated for treating unresectable liver tumours.

Dosage in the CE mark for QuiremSpheres

2.2 QuiremSpheres is given through a catheter to the hepatic artery. The product is supplied as a customised, patient-specific dose. The maximum range of the emitted beta particles in tissue is 8.7 mm with a mean of 2.5 mm. Also, holmium-166 emits primary gamma photons (81 kilo electronvolt). The half-life is 26.8 hours, which means more than 90% of the radiation is given in the first 4 days after the procedure. At the moment of treatment, the activity per microsphere is 200 to 400 Becquerel. The number of particles implanted depends on the targeted liver volume and ranges, on average, from 10 to 30 million.

Price

2.3 The company has stated that the acquisition cost of QuiremSpheres is £12,000 for a single treatment. The company has a commercial arrangement. This makes QuiremSpheres available to the NHS with a discount. The size of the discount is commercial in confidence.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication. Because QuiremSpheres has been recommended through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.

3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has hepatocellular carcinoma and the healthcare professional responsible for their care thinks that QuiremSpheres is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the chair and the vice chair of committee C.

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

Chair and vice chair

Stephen O'Brien and Richard Nicholas
Chair and vice chair, technology appraisal committee C

NICE project team

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

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