NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Selective internal radiation therapy with QuiremSpheres for treating unresectable advanced hepatocellular carcinoma (partial review of 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 QuiremSpheres according to the commercial arrangement (see section 2).

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 technology appraisal guidance on selective internal radiation therapies for treating hepatocellular carcinoma (TA688). This evaluation reviews new evidence submitted by the company. Following the resolution of any appeals on the final draft guidance for this review, the final

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recommendations and relevant discussion will be issued as updated guidance for QuiremSpheres in TA688.

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 QuiremSpheres is as effective as SIR-Spheres and TheraSphere.

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

For all evidence see the committee papers. To see what NICE did for TheraSphere and SIR-Spheres, 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 Directive 90/385/EEC. It is indicated for treating unresectable liver tumours.

Dosage in the marketing authorisation

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, KeV). 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 (Bq). 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. It is the company's responsibility to let relevant NHS organisations know details of the discount.

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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