

Title:	SIR-Spheres for the treatment of non-resectable liver tumours
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Reference:	MSAC Application 1082 Assessment report First printed August 2005 ISBN 0 642 82910 1

**Aim:** To assess the safety, effectiveness and cost-effectiveness of SIR-Spheres used alone or in addition to chemotherapy for: i) treating non-resectable, non-ablatable hepatic metastases secondary to colorectal cancer (CLM) compared with hepatic arterial chemotherapy (HAC) or systemic chemotherapy; and ii) treating non-resectable, non-ablatable hepatocellular carcinoma (HCC) compared with transarterial chemoembolisation (TACE) or <sup>131</sup>I-lipiodol.

### Results and conclusions

**Safety:** There is limited comparative evidence for conclusions about the relative safety of SIR-Spheres versus other therapies. Major complications include death and radiation-induced disease (hepatitis, gastritis, pneumonitis, cirrhosis, acute hepatic necrosis and gastrointestinal ulceration). It appears that the doses of radiation delivered to personnel are within recommended ranges.

#### Effectiveness:

i) One randomised controlled trial has reported a statistically significant increase in survival in patients treated with SIR-Spheres and systemic chemotherapy compared to chemotherapy alone (29.4 months vs 12.8 months, HR 0.33; 95% CI 0.12–0.91; P = 0.025), however this trial used systemic chemotherapy regimens that no longer represent current practice. The effectiveness of SIR-Spheres in combination with current chemotherapy regimens is unknown.

ii) Existing evidence is insufficient to draw conclusions about the effectiveness of SIR-Spheres compared to other existing treatments in patients with HCC.

**Cost-effectiveness:** An incremental cost per life-year gained was estimated at \$21,524 (\$12,270–\$88,119) for SIR-Spheres and chemotherapy compared to chemotherapy alone for treatment of CLM. An exploratory economic model analysis of SIR-Spheres and current systemic regimens (FOLFOX6 and FOLFIRI) compared to current chemotherapy regimens alone resulted in a cost per life year gained ranging from \$8,009 to \$133,653.

### Recommendation

i) MSAC recommends that on the strength of evidence pertaining to the treatment of patients with hepatic metastases secondary to colorectal cancer which are not suitable for resection or ablation, interim public funding should be supported for first line treatment by administration of SIR-Spheres in combination with systemic chemotherapy using 5FU and leucovorin, with the collection of survival data. This data should be reported to MSAC within three years.

ii) As there is currently insufficient evidence pertaining to the treatment of non-resectable, non-ablatable hepatocellular carcinoma with SIR-Spheres, MSAC recommends that public funding should not be supported at this time. The Minister for Health and Ageing endorsed these recommendations on 28 November 2005

**Methods:** MSAC conducted a systematic review of the biomedical literature from 1966 to January 2005 to assess safety and effectiveness. Two economic models, a trial-based model and an exploratory model using current chemotherapy regimens, were used to evaluate the cost-effectiveness of SIR-Spheres and systemic chemotherapy in patients with CLM.