



## **NHS England makes SIRT (Selective Internal Radiation Therapy) first treatment available through new Commissioning through Evaluation initiative**

**NHS revision of Clinical Policy Commissioning Statement on SIRT will allow patients in England with metastatic colorectal cancer (mCRC) and intrahepatic cholangiocarcinoma (ICC) who may benefit from SIR-Spheres® microspheres to get treatment in specialist NHS centres**

**London, 1<sup>st</sup> October 2013** -- NHS England has issued an interim Clinical Commissioning Policy Statement that updates its policy on Selective Internal Radiation Therapy (SIRT) for use in treating eligible patients with metastatic colorectal cancer (mCRC) and intrahepatic cholangiocarcinoma (ICC). As a result of the NHS announcement, which can be found at [www.england.nhs.uk/2013/09/26/com-through-eval/](http://www.england.nhs.uk/2013/09/26/com-through-eval/), SIR-Spheres microspheres are now one of the first medical technologies that will be made available in specialist NHS centres through a new NHS England initiative called Commissioning through Evaluation (CtE). The CtE initiative allows specialist NHS centres to use services like SIRT, whose initial safety and efficacy has been shown and supported by guidance from the National Institute for Clinical Excellence (NICE), but still require further evidence of relative clinical and cost effectiveness to support routine commissioning.

The CtE statement on SIRT was developed by NHS England in collaboration with the Clinical Reference Groups for Radiotherapy, Hepatobiliary and Pancreas, and Interventional Radiology. The outcomes of the use of SIRT under CtE will be evaluated in 2014.

“This announcement brings a moment of very good news to the large number of patients with liver metastases from colorectal cancer who have previously received chemotherapy and biological treatments, many of whom have been waiting for several difficult months in anticipation of this announcement,” said Dr Ricky Sharma, Consultant Oncologist at the Oxford University Hospitals NHS Trust. “It is also excellent news for patients with cholangiocarcinoma, a rare and aggressive form of liver cancer for which there are very few treatments available. Enabling suitable patients across the whole of England to have access to SIRT in this important evaluation process represents a significant advance for the NHS.”

“The NHS deliberations that led to today’s announcement demonstrate that NHS England, medical experts and healthcare companies can collaborate together to provide appropriate access to innovative therapies for patients who stand to benefit measurably from them,” said Nigel Lange,

Chief Executive Officer of Sirtex Medical Europe, which developed and continues to study new uses of SIR-Spheres microspheres in the treatment of liver tumours.

### **What is SIRT?**

Selective Internal Radiation Therapy (SIRT) is a non-surgical procedure, in which an interventional radiologist uses a catheter directed through an incision in the patient's femoral artery to deliver a treatment comprising millions of radioactive microspheres (more than 30 million resin microspheres coated in radioactive Yttrium-90 in the case of SIR-Spheres microspheres) directly into branches of the hepatic (liver) artery. The microspheres are carried by the blood flow through the arteries into the small vessels that nourish tumours in the liver, where they ultimately become trapped due to their size and deliver high doses of beta-radiation directly to the tumours. Because internal radiation is delivered directly to the tumours, patients may receive radiation doses many times greater than possible with external beam radiation.

### **NHS Policy for SIRT in mCRC**

Colorectal cancer (CRC) is the third-most prevalent cancer in the world. It is also a cancer that too often spreads (or metastasizes) to other organs in the body, most commonly the liver. Despite increased emphasis on colorectal cancer screening, patients will often present with mCRC at initial diagnosis.

The NHS commissioning statement recognises that SIRT should not routinely be used in the initial treatment of mCRC, for which chemotherapy and biological therapy are the current standards of care. However, the NHS commissioning statement also recommends that eligible mCRC patients be offered enrolment in a UK clinical trial called FOXFIRE, where SIR-Spheres microspheres are administered concomitantly with first-line chemotherapy and biologic agents to determine if an additive treatment benefit exists from first-line use of SIRT.

In addition, the new NHS statement language notes that mCRC patients who are chemo-refractory (no longer responsive to chemotherapy or biological therapy) may be offered SIRT at NHS specialist centres under the CtE process, or encouraged to enrol in other SIRT clinical trials if applicable.

### **NHS Policy for SIRT in ICC**

Intrahepatic cholangiocarcinoma (ICC) is a cancer that arises in the epithelium or wall of the liver's bile ducts. It is a relatively rare cancer that is becoming somewhat more common, suggesting that occurrence may be linked to changes in diet or lifestyle.

The NHS recognises that few proven treatments exist for ICC and recommends that SIRT may now be offered to chemo-refractory patients at NHS specialist centres under the new CtE process.

## **NHS Policy on Patient Selection Criteria for SIRT**

In addition to the use of SIRT in treating patients with liver tumours due to mCRC and ICC, NHS England is looking into whether they should employ a similar scheme of CtE for patients with hepatocellular carcinoma following recent NICE guidance supporting SIRT in HCC. To be eligible for SIRT for treating any of these forms of liver tumours, NHS states that patients must have or be:

- Not amenable to surgical resection of the liver
- Not suitable for treatment with radio-frequency ablation (RFA)
- WHO performance status 0-1
- Disease that is predominantly located in the liver, with no life-threatening disease outside of the liver
- Adequate liver function
- Less than 60% of the liver involved by tumour
- No ascites or other signs of liver failure
- A life expectancy of greater than 3 months
- Not pregnant

### **About SIR-Spheres microspheres:**

Manufactured by Sirtex Medical Limited, SIR-Spheres microspheres are approved for use in Australia, the European Union (CE Mark), New Zealand, Switzerland, Turkey and several other countries for the treatment of unresectable liver tumours.

SIR-Spheres microspheres are also fully PMA FDA-approved and are indicated in the U.S. for the treatment of non-resectable metastatic liver tumours from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using floxuridine.

SIR-Spheres® is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd.

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Downloadable images, background information, a mode-of-action video and further supporting materials are available online at [www.SIRTnewsroom.com](http://www.SIRTnewsroom.com).

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