NHS approves funding in 10 hospitals for life-extending liver tumour radiotherapy

Selective Internal Radiation Therapy (SIRT) is first treatment available through new NHS policy to improve access to innovative therapies

London, 20 November 2013. NHS England today published a list of 10 NHS hospitals that will now offer life-extending SIRT to eligible patients with liver cancer that has spread from the bowel, and bile duct cancer. SIRT is the first treatment to be funded under the new NHS 'Commissioning through Evaluation' (CtE) policy that is hoped will improve the availability of cutting-edge treatments.

Since April 2013, NHS patients in England have been unable to receive SIRT after it was removed from the Cancer Drugs Fund creating inequalities to treatment for these aggressive forms of cancer. The only way patients could be treated was if SIRT was paid for privately or if an application was made for its use under exceptional circumstances, a process that can take many months and at a time when patients may only have a short time to benefit from treatment. Today's announcement means that there will be fair and equitable access for eligible patients across England to this cancer therapy.

"This announcement marks a major milestone in widening access to specialist cancer treatment. It's a step in the right direction in breaking down inequalities where only those that can afford private care can benefit from pioneering treatments", said Mark Flannagan, Chief Executive from the charity Beating Bowel Cancer. "Patients in England with liver cancer that has spread from the bowel, and who have exhausted other treatments, now have access to a therapy which can extend their survival so that they can spend extra time with their loved ones and enjoy more of life".

Treatment with SIRT will be available to eligible patients by referral from local specialist consultants at NHS hospitals in Birmingham, Cambridge, Leeds, London, Manchester, Newcastle, Nottingham, Oxford and Southampton. At present SIRT will only be funded for patients where all other routine approaches, such as surgery and chemotherapy, have been unsuccessful. In the first year, around 220 patients are expected to be treated.

"On behalf of our patients who have been waiting for several difficult months for this news, we are delighted by this announcement," said Dr Ricky Sharma, Consultant Oncologist at the Oxford University Hospitals NHS Trust. "The list of centres published today means that we can offer SIRT to a large number of eligible patients. Some of these patients have no other treatment options available. This represents a significant advance for the NHS in England. In the future, I hope the Commissioning through Evaluation programme will be extended to include patients with primary liver cancer."

The SIRT procedure is a form of radiotherapy in which millions of tiny radioactive beads are injected into the artery that supplies the cancer, direct into the site of the liver. SIRT using SIR-Spheres microspheres (Yttrium-90 resin microspheres) has been shown to significantly improve survival by about five months in patients with bowel cancer that has spread to the liver and who have failed prior chemotherapy[1,2]

The new policy allows approved hospitals to offer innovative treatments like SIRT, where initial effectiveness and safety has been shown and supported by guidance from the National Institute for Health and Care Excellence (NICE), but where further proof on clinical and cost effectiveness is required for routine NHS use. The outcomes of the use of SIRT under the CtE policy will be evaluated over the next two years.

"Sirtex welcomes the improved availability of SIRT on the NHS. We will work closely with the approved treatment centres to ensure that our SIR-Spheres technology, which is used in SIRT procedures, will be made available to those patients that meet the right criteria", 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.

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NHS centres that are approved to use SIRT

North: Leeds Teaching Hospitals NHS Trust, Newcastle upon Tyne Hospitals NHS Trust, The Christie NHS Foundation Trust

South: Oxford University Hospitals NHS Foundation Trust, University Hospital Southampton NHS Foundation Trust

Midlands and East: University Hospitals Birmingham NHS Foundation Trust, Nottingham University Hospitals NHS Trust, Cambridge University Hospitals NHS Foundation Trust

London: King's College Hospital NHS Foundation Trust, The Royal Free London NHS Foundation Trust

About SIRT

Selective internal radiation therapy (SIRT) is an innovative treatment for liver metastases (the spread of cancer from other parts of the body to the liver). It involves millions of very tiny 'beads' (microspheres) being injected into the major blood vessel that supplies the liver with oxygen and nutrients. Each bead is small enough to reach the tiny blood vessels in and around the active tumours, where they give out concentrated doses of direct radiation specifically to these tumour cells. The treatment is then active within the liver for about two

[1] Seidensticker R *et al*. *Cardiovasc Intervent Radiol* 2012; 35; 1066–1073.
[2] Bester L *et al*.. *J Vasc Interven Radiol* 2012; 23: 96–105.

weeks of continuous treatment. Because internal radiation is delivered directly to the tumours, patients may receive radiation doses many times greater than is possible with external beam radiation.

About bowel cancer that has spread to the liver

In the UK, bowel cancer is the second biggest cancer killer and the fourth most common cancer[3]. In 2010, 40,695 people in the UK were diagnosed with bowel cancer[4]. Cancer of the bowel can spread to other parts of the body but typically spreads to the liver first. About a quarter of people who are diagnosed with bowel cancer will already have cancer that has spread to the liver. A further 25-30% of patients will go onto develop liver cancer[5].

About bile duct cancer

The bile ducts are narrow tubes that carry bile, a fluid made in the liver, to the bowel where it helps digest fats. Bile duct cancer (cholangiocarcinoma) is rare, with around 1,000 new cases each year in the UK[6].

About Commissioning through Evaluation

Commissioning through Evaluation (CtE) is particularly relevant to specialised services and treatments that treat smaller numbers of patients, because there is typically less evidence available in these areas to support the development of a full NHS funding policy. This new policy will lead to a bank of high quality information that will help to inform either future funding policies or NICE decisions. Each of the CtE services and treatments will be funded for between 1-2 years whilst new evidence is gathered.

About SIR-Spheres microspheres

SIR-Spheres microspheres (Yttrium-90 resin microspheres) can improve survival by about five months in patients with bowel cancer that has spread to the liver and who have failed prior chemotherapy.[1,2] They can sufficiently downsize tumours to enable potentially curative surgery or ablation[7,8,9] SIR-Spheres microspheres are well tolerated[10].

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 liver tumours that are unable to be removed through surgery. 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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[3] Beating Bowel Cancer. www.beatingbowelcancer.org/facts-and-figures. Accessed 3 Nov 2013.

[4] Cancer Research UK. www.cancerresearchuk.org/cancer-info/cancerstats/types/bowel. Accessed 3 Nov 2013.

[5] Sirtex. www.sirtex.com/eu/patients/about-cancer/colorectal-cancer-in-the-liver. Accessed 3 Nov 2013.

[6] MacMillan. www.macmillan.org.uk/cancerinformation/cancertypes/bileduct/bileductcancer.aspx. Accessed 4 Nov 2013.

[7] Van den Eynde *et al. Clin Nucl Med* 2008; 33: 697–699.

[8] Cosimelli M et al. *Br J Cancer* 2010; 103: 324–331.

[9] Hadaki M et al. *BMJ Case Reports* 2011; DOI:10.1136/bcr.01.2011.3793

[10] Coldwell D et al.. *Am J Clin Oncol* 2011; 34: 337–341.