NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report: Selective internal radiation therapies for treating hepatocellular carcinoma (TA688)

Published: March 2021

Summary

NICE has recommended selective internal radiation therapies (SIRT) for treating hepatocellular carcinoma under certain conditions (see section 1 for further details).

We estimate that around:

- 860 people with unresectable advanced hepatocellular carcinoma are eligible for treatment with selective internal radiation therapies each year. The two recommended selective internal radiation therapies are TheraSphere and SIR-Spheres.
- around 340 people will have selective internal radiotherapy from year 3 onwards once total uptake has reached 40% (20% of each technology) as shown in table 1.

| | 2021/22 | 2022/23 | 2023/24 | 2024/25 | 2025/26 | |
|---|---------|---------|---------|---------|---------|--|
| Uptake rate for TheraSphere (%) | 5% | 13% | 20% | 20% | 20% | |
| Population having TheraSphere each year | 40 | 105 | 170 | 170 | 170 | |
| Uptake rate for SIR- Spheres (%) | 5% | 13% | 20% | 20% | 20% | |
| Population having SIR- Spheres each year | 40 | 105 | 170 | 170 | 170 | |

Table 1 Estimated number of people in England having selective internalradiation therapies

This report is supported by a local resource impact template because the list price of TheraSphere and SIR-Spheres have discounts that are commercial in confidence. The discounted prices of TheraSphere and SIR-Spheres can be put into the template and other variables may be amended.

The technologies are commissioned by NHS England. Providers are NHS hospital trusts.

1 Selective internal radiation therapies

- 1.1 NICE has recommended <u>selective internal radiation therapy (SIRT)</u> <u>SIR-Spheres</u> as an option for treating unresectable advanced hepatocellular carcinoma (HCC) in adults, only if.
 - used for people with Child-Pugh grade A liver impairment when conventional transarterial therapies are inappropriate
 - the company provides SIR-Spheres according to the commercial arrangement.
- 1.2 The <u>SIRT TheraSphere is recommended</u> as an option for treating unresectable advanced hepatocellular carcinoma (HCC) in adults, only if:
 - used for people with Child-Pugh grade A liver impairment when conventional transarterial therapies are inappropriate
 - the company provides TheraSphere according to the commercial arrangement.
- 1.3 Treatment for HCC depends on the stage of the disease and liver function. Treatment options include surgery, ablation, transarterial therapies, chemotherapy (such as sorafenib) and best supportive care. Treatment does not cure the disease for most people.
- 1.4 Stereotactic ablative radiotherapy (SABR) for hepatocellelar carcinoma was approved by an <u>NHS England commisisoning policy</u> in 2020. However there is currently very little data available on the cost and uptake of this procedure. There are blank rows in the accompanying resource impact template that users can populate to reflect any local data available.
- 1.5 SIRTs are small radioactive beads that are injected into the liver's blood supply to treat liver cancer. QuiremSpheres, SIR-Spheres and TheraSphere are the 3 SIRTs considered in the appraisal. The clinical trial data for these SIRTs compared with other treatment Resource impact report: Selective internal radiation therapies for treating hepatocellular carcinoma (April 2021) 3 of 10

options are limited. But compared with sorafenib SIRTs may have fewer and more manageable adverse effects, which can improve quality of life. Please note that QuiremSpheres were not recommended for use in this appraisal.

2 Resource impact of the guidance

2.1 We estimate that around:

- 860 people with unresectable advanced hepatocellular carcinoma are eligible for treatment with selective internal radiation therapies (SIRTs) each year. The two recommended selective internal radiation therapies are TheraSphere and SIR-Spheres.
- around 340 people will have selective internal radiotherapy from year 3 onwards once total uptake has reached 40%. (20% of each technology)
- 2.2 The current treatment and future uptake figure assumptions are based on clinical expert opinion and are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have SIRTs by financial year.

| | 2021/22 | 2022/23 | 2023/24 | 2024/25 | 2025/26 |
|---|---------|---------|---------|---------|---------|
| Uptake rate for TheraSphere (%) | 5% | 13% | 20% | 20% | 20% |
| Population having TheraSphere each year | 40 | 105 | 170 | 170 | 170 |
| Uptake rate for SIR- Spheres (%) | 5% | 13% | 20% | 20% | 20% |
| Population having SIR- Spheres each year | 40 | 105 | 170 | 170 | 170 |

Table 2 Estimated number of people having SIRTs using NICEassumptions.

2.3 This report is supported by a local resource impact template.

TheraSphere and SIR-Spheres have commercial arrangements

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(simple discount patient access schemes) which makes them available to the NHS with a discount. The size of the discounts are commercial in confidence. The discounted prices of TheraSphere and SIR-Spheres can be put into the template and other variables may be amended. It is the company's responsibility to let relevant NHS organisations know details of the discount.

2.4 Providers may need to consider the impact on their infrastructure of the administration of TheraSphere and SIR-Spheres requiring a pre-treatment work up as well as radio-embolisation and the delivery of a fraction of interstitial radiotherapy.

Savings and benefits

2.5 SIRTs may have fewer and more manageable adverse effects, which can improve quality of life in comparison to existing treatments such as sorafenib.

3 Implications for commissioners

- 3.1 The technologies are commissioned by NHS England. Providers are NHS hospital trusts.
- 3.2 Selective internal radiation therapies fall within the programme budgeting category 02-C, Cancers and Tumours, Cancer, Lower GI.

4 How we estimated the resource impact

The population

4.1 Around 4,900 adults were diagnosed with cancer of liver and intrahepatic bile ducts in England in 2018 (<u>Cancer registration</u> <u>statistics for England, 2018</u>). Table 3 shows the details of the population with unresectable advanced hepatocellular carcinoma who are be eligible for treatment with selective internal radiation therapies.

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| Population | Proportion of previous row (%) | Number of people | | | | |
|---|--------------------------------------|---------------------|--|--|--|--|
| Total population | | 56,286,961 | | | | |
| Adult population | | 44,263,393 | | | | |
| Incidence of cancer of liver and intrahepatic bile ducts in adults ¹ | 0.01 | 4,900 | | | | |
| Incidence of liver cell carcinoma ² | 55.3 | 2,710 | | | | |
| Proportion of people with hepatocellular carcinoma that is unresectable ³ | 82 | 2,220 | | | | |
| Proportion of people with Child-Pugh grade A liver impairment ⁴ | 77 | 1,710 | | | | |
| Proportion of people who are fit for surgery or treatment ⁵ | 80 | 1,370 | | | | |
| Total number of people that are eligible for transarterial embolisation (TAE) or transarterial chemoembolisation (TACE) ⁶ (conventional treatments) | 37.5 | 510 | | | | |
| Total number of people that are ineligible for TAE or TACE ⁶ (conventional treatments) | 62.5 (of 1,370) | 860 | | | | |
| Total number of people estimated to have TheraSphere each year from year 3^6 | 20 | 170 | | | | |
| Total number of people estimated to have SIR-Spheres each year from year 3^6 | 20 (of 860) | 170 | | | | |
| ¹ Source: Cancer registration statistics England 2018 | | | | | | |
| ² Source: Cancer registration statistics England 2017 | | | | | | |
| ³ Source: <u>https://pubmed.ncbi.nlm.nih.gov/25921660/</u> | | | | | | |
| ⁴ Source: <u>https://pubmed.ncbi.nlm.nih.gov/27964898/</u> | | | | | | |
| ⁵ Source: Clinical expert opinion | | | | | | |
| ⁶ Source: Average estimate from company submissions, verified by clinical experts | | | | | | |

Table 3 Number of people eligible for treatment in England

Assumptions

- 4.2 The resource impact template assumes that:
 - TheraSphere is provided in a dose of between 80-150 gy (SI unit of absorbed radiation), the cost of this does not vary according

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to dose size and it includes the single use accessory kit and reusable administration kit.

- According to the company submission that the average number of doses is 1.2 per person per year.
 - The administration costs of TheraSphere include a pretreatment element which is Percutaneous Transluminal Embolisation of Peripheral Blood Vessel (YR54A-C), the average cost for planned procedures based on the activity in the national cost collection 18-19 and the national tariff 20/21 gives a cost of £2,616.
 - The administration of TheraSphere involves 2 procedures: a Percutaneous, Chemoembolisation or Radioembolisation, of Lesion of Liver (YR57Z) and Deliver a Fraction of Interstitial Radiotherapy (SC28Z). These attract a tariff of £3,606 and £14,228 respectively (national tariff 20/21).
- SIR-Spheres is provided in a dose containing 3 GBq (Gigabecquerel (GBq) is a SI-multiple of a derived metric measurement unit of radioactivity) of yttrium-90 with 5 mL water.
- According to the company submission the average number of doses is 1.11 per person per year.
 - The administration cost of SIR-Spheres include a pretreatment element which is Percutaneous Transluminal Embolisation of Peripheral Blood Vessel (YR54A-C), the average cost for planned procedures based on the activity in the national cost collection 18-19 and the national tariff 20/21 gives a cost of £2,616.
 - The administration of SIR-Spheres involves 2 procedures: a Percutaneous, Chemoembolisation or Radioembolisation, of Lesion of Liver (YR57Z) and Deliver a Fraction of Interstitial Radiotherapy (SC28Z). These attract a tariff of £3,606 and £14,228 respectively (<u>national tariff 20/21</u>).

- Sorafenib is an oral medication provided in the form of 200mg tablets. The daily dose is 400mg twice per day and it is assumed that:
 - an average month will require 1 packet of sorafenib containing 112 x 200mg tablets.
 - Based on expert clinical opinion the average number of cycles is 5.78 cycles. Therefore, a total of 5.78 packets will be required.
 - a cycle is 28 days
 - The administration of sorafenib is SB11Z Deliver Exclusively
 Oral Chemotherapy which attracts a tariff of £129 per cycle (national tariff 20/21).
 - There is VAT to be included on top of the price of sorafenib due to it being prescribed but not administered by secondary care.
- Lenvatinib is an oral medication, provided in the form of 4 mg capsules. The recommended dose is 12mg once daily for body weight of 60kg and above. The <u>average body weight in England</u> is assumed to be 78.4kg and therefore the average daily dose is 12mg. It is assumed that:
 - an average cycle will require 2.8 packets of 4mg lenvatinib tablets.
 - a cycle is 28 days
 - Based on expert clinical opinion the average number of cycles is 9. Therefore, a total of 25.2 packets of 4mg capsules will be required.
 - The administration of lenvatinib is SB11Z Deliver Exclusively
 Oral Chemotherapy which attracts a tariff of £129 per cycle (national tariff 20/21).
 - There is VAT to be included on top of the price of lenvatinib due to it being prescribed but not administered by secondary care.

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- Regorafenib is an oral medication, provided in the form of 40mg capsules. The recommended dose is 160mg daily for 21 days of a 28-day cycle. It is assumed that:
 - an average month will require 1 packet of regorafenib.
 - Based on expert clinical opinion the average number of cycles per person is 4, therefore a total of 4 packets will be required per treatment cycle.
 - The administration of regorafenib is SB11Z Deliver
 Exclusively Oral Chemotherapy which attracts a tariff of £129
 per cycle (national tariff 20/21).
 - There is VAT to be included on top of the price of regorafenib due to it being prescribed but not administered by secondary care.

About this resource impact report

This resource impact report accompanies the NICE guidance on <u>selective</u> <u>internal radiation therapies for treating heaptocellular carcinoma</u> and should be read with it.

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