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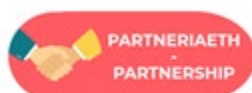
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Specialised Services Policy Position PP227

Selective internal radiation therapies for treating adults with hepatocellular carcinoma

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) commission selective internal radiation therapies (SIRT) for adults with hepatocellular carcinoma (HCC) in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the relevant guidance issued by National Institute of Health and Care Excellence (NICE)¹ and has concluded that selective internal radiation therapies should be made available.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy position statement.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy position statement.

¹ [Overview | Selective internal radiation therapies for treating hepatocellular carcinoma | Guidance | NICE](#)

1. Introduction

This Policy Position Statement has been developed for the planning and delivery of selective internal radiation therapies (SIRT) for adults with hepatocellular carcinoma (HCC) resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain language summary

Hepatocellular carcinoma (HCC) is also called hepatoma. It is the most common type of primary liver cancer. This type of liver cancer develops from the main liver cells called hepatocytes. It is more common in people with cirrhosis. Cirrhosis means scarring of the liver due to previous damage, and can be caused by:

- long term infection with a virus such as hepatitis B or C
- long term alcohol drinking
- inherited diseases such as iron overload disorder (haemochromatosis) and alpha 1 antitrypsin deficiency
- non-alcoholic fatty liver disease
- primary biliary cirrhosis (PBC).

Therefore, people with HCC are a heterogeneous population and their disease is characterised by both stage of cancer and liver function.

QuiremSpheres, SIR-Spheres and TheraSphere are selective internal radiation therapies (SIRTs). These are small radioactive beads that are injected into the liver's blood supply to treat liver cancer. The 3 SIRTs are medical devices with CE marks for their indications. QuiremSpheres is indicated for treating unresectable liver tumours, SIR-Spheres for treating advanced inoperable liver tumours and TheraSphere for treating hepatic neoplasia. SIRTs are available in some specialist centres in the UK for other cancers (such as metastatic colorectal cancer)².

1.2 Aims and Objectives

This Policy Position Statement aims to define the commissioning position of WHSSC on the use of SIRTs for people with HCC.

The objectives of this policy are to:

- ensure commissioning for the use of SIRTs is evidence based
- ensure equitable access to SIRTs
- define criteria for people with HCC to access treatment
- improve outcomes for people with HCC.

² [Overview | Selective internal radiation therapies for treating hepatocellular carcinoma | Guidance | NICE](#)

1.3 Epidemiology

HCC is the most common form of primary liver cancer. The disease is more common in males than females and the risk of developing the disease increases with age, with the peak rate of incidence being in people aged between 85 – 89 years of age³. Liver cancer incidence rates are projected to rise by 38% in the UK between 2014 and 2035 and this includes a larger increase for males than for females⁴.

In 2017, there were 289 cases of liver cancer in Wales⁵. Of the 289, 169 had HCC. The majority of patients present with non curable disease and survival has been poor as a consequence.

1.4 Current Treatment

Treatment for HCC depends on the location and stage of the cancer, and how well the liver is functioning. Treatment for HCC depends on the stage of the disease and liver function. Treatment options include ablation and transplant in early disease, and conventional transarterial therapies (CTT) such as transarterial chemoembolisation (TACE) or transarterial embolisation (TAE) in intermediate disease. In advanced disease, treatment options are chemotherapy or systemic therapy with Atezolizumab and Bevacizumab. For some people the aim of treatment might be to reduce the tumour size ('downstaging') to potentially allow subsequent transplantation that could cure the disease.

1.5 Proposed Treatment

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 covered by this policy. The clinical trial data for these SIRTs compared with other treatment options are limited. But, compared with sorafenib, SIRTs may have fewer and more manageable adverse effects, which can improve quality of life.

1.6 What NHS Wales has decided

WHSSC has carefully reviewed the relevant guidance issued by National Institute of Health and Care Excellence (NICE). We have concluded that selective internal radiation therapies, should be made available within the criteria set out in section 2.1.

³ [Cancer Research UK](#)

⁴ [Liver cancer statistics | Cancer Research UK](#)

⁵ [WCISU Cancer incidence in Wales dashboard](#)

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of selective internal radiation therapies for adults with hepatocellular carcinoma, in-line with the criteria identified in the policy.

2.1 Inclusion Criteria

- The selective internal radiation therapy (SIRT) SIR-Spheres is recommended 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 **and**
 - the company provides SIR-Spheres according to the commercial arrangement⁶.
- The SIRT TheraSphere is recommended as an option for treating unresectable advanced HCC in adults, only if:
 - used for people with Child–Pugh grade A liver impairment when conventional transarterial therapies are inappropriate **and**
 - the company provides TheraSphere according to the commercial arrangement⁶.
- These recommendations are not intended to affect treatment with SIR-Spheres, TheraSphere and QuiremSpheres that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

2.2 Exclusion Criteria

- The SIRT QuiremSpheres is not recommended for treating unresectable advanced HCC in adults.

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating

⁶ There are simple discount patient access schemes for SIR-Spheres and for TheraSphere. Contact UK_access@sirtex.com for SIR-Spheres and CustomerServiceEMEA@btgplc.com for TheraSphere

healthcare professional. However, SIRT is typically provided as a one-off treatment.

2.4 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i)

Patients should be referred by local hepatology services to the regional hepatocellular carcinoma MDT. The decision to refer a patient for SIRT will be made by the HCC MDT. Patients will be followed up by the HCC MDT.

2.6 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

2.7 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

Reported outcomes will include:

- Overall survival
- Progression free survival
- Patient reported outcome and experience measures.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

2.8 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinician considering treatment should:

- discuss all the alternative treatment with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Documents which have informed this policy

The following documents have been used to inform this policy:

- **WHSSC policies and service specifications**
 - The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for patients with Hepatocellular carcinoma or Cholangiocarcinoma, Commissioning Policy (CP124). In Development
 - [Hepatobiliary Surgery Service Specification](#)⁰, (CP73). November 2021
- **National Institute of Health and Care Excellence (NICE) guidance**
 - [Selective internal radiation therapies for treating hepatocellular carcinoma](#), NICE Technology appraisal guidance [TA688], March 2021.

This document should be read in conjunction with the following documents:

- **NHS Wales**
 - All Wales Policy: [Making Decisions in Individual Patient Funding requests](#) (IPFR).

4. Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

5. Putting Things Right

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for [NHS Putting Things Right](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

6. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex ii Codes

Code Category	Code	Description
ICD-10	C22.0	Liver cell carcinoma

Annex iii Abbreviations and Glossary

Abbreviations

CTT	Conventional transarterial therapies
HCC	Hepatocellular carcinoma
IPFR	Individual patient funding request
PBC	Primary biliary cirrhosis
SIRT	Selective internal radiation therapies
TACE	Transarterial chemoembolisation
TAE	Transarterial embolisation
WHSSC	Welsh Health Specialised Services Committee

Glossary

Child-Pugh score

A scoring system used to assess liver disease.

Cirrhosis

Describes the damage and scarring of the liver. Cirrhosis can be caused by a number of factors including hepatitis infections and excessive alcohol consumption.

Hepatitis

A term used to describe inflammation of the liver. Hepatitis is usually caused as a result of a viral infection or drinking alcohol.

Hepatocellular carcinoma (HCC)

The most common form of primary liver cancer, originating from hepatocytes.

Hepatocytes

The most common type of cell in the liver. These cells account for 65 – 75% of the tissue in the liver and are responsible for protein synthesis.

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Surgical Resection

A surgical procedure used to remove the cancer or tumour.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.