GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

Specialised Services
Service Specification: CP73

Hepatobiliary Cancer Surgery

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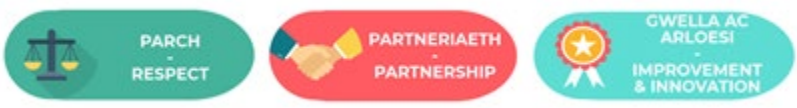

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Description	NHS Wales routinely commission this specialised service in accordance with the criteria described in this document
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Contents

Statement

Welsh Health Specialised Services Committee (WHSSC) commission the service of hepatobiliary cancer surgery for people aged 16 years and older in accordance with the criteria outlined in this specification.

In creating this document WHSSC has reviewed the requirements and standards of care that are expected to deliver this service.

Disclaimer

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

This document 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.

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

1. Introduction

This document has been developed as the Service Specification for the planning and delivery of hepatobiliary cancer surgery for people aged 16 years and older and resident in Wales.

1.1 Background

Hepatobiliary (Liver) Cancer

Liver cancer is a cancer that starts in the liver. It is sometimes called primary liver cancer. A cancer that starts somewhere else in the body and spreads to the liver is called secondary cancer in the liver. There are four main types of cancer that start in the liver:

- Hepatoma, also called hepatocellular carcinoma, or HCC, this is the most common type, seen in nine out of 10 cases.
- Fibrolamellar, a rare form of primary (HCC) liver cancer that affects adolescents[1] and young adults who have no history of liver disease.
- Biliary tree cancer, which includes cholangiocarcinoma (bile duct cancer) and gallbladder cancer.
- Angioscarcoma, a cancer of the inner lining of blood vessels, which may occur in the liver.

Around 5,400 people in the UK are diagnosed with primary liver cancer each year[3]. Some tumours in the liver are not cancerous (benign). They are usually small and are often found by chance. This might happen when a person is having a scan for another reason. Benign tumours do not usually develop into cancer and are not usually removed. However, there are other conditions, such as liver cell adenoma and cystadenoma (that presents as a liver cyst) that are premalignant and require management to prevent them from becoming cancer. These conditions often require treatment in the form of liver resection.

Hepatocellular carcinoma is the most common type of primary liver cancer. This type of liver cancer develops from the main liver cells called hepatocytes. The disease is more likely to develop in men than women and becomes more common in older people.[3]

The progression to secondary cancer of the liver may arise from many primary cancer sites but is common in metastatic colorectal and neuroendocrine cancer.

[1] Note this specification applies to the liver surgery service for people resident in Wales aged 16 years and older.

Epidemiology

There are approximately 300 new cases a year of primary liver cancer in Wales[2]. The incidence of liver cancer has increased from 4 per 100,000 in 1993 to 10 per 100,000 in 2017. 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 females[3].

There are approximately 170 new diagnoses of hepatocellular carcinoma per year in Wales[2] and the number of diagnoses is increasing due to people living with obesity, viral hepatitis and alcohol excess. These factors cause damage and scarring of the liver (known as cirrhosis), which increases the likelihood of hepatocellular carcinoma developing.

It is more difficult to determine the incidence of metastatic disease of the liver. The most common primary cancer that leads to metastatic cancer of the liver is colorectal cancer. In 2017, there were 2315 cases of colorectal cancer in Wales[4].

There are approximately 120 to 130[5] resections being undertaken per annum for the population of Wales for metastatic cancers within the liver. A further 20 to 25[4] resections approximately are undertaken for primary hepatobiliary cancer.

Outcomes

Survival for patients diagnosed with primary liver cancer is relatively poor compared with the majority of other cancer sites. 5 year survival in Wales for patients diagnosed with HCC is approximately 9%[3].

Hepatobiliary (liver) Cancer Surgery

Liver cancer surgery service provides specialist surgical treatment and care for patients with liver cancer. The core patient group for the service will have primary or secondary cancers of the liver and/or biliary tree. Liver surgery for these patients is undertaken with curative intent[6].

Current Service Provision in Wales

Hepatobiliary cancer surgery is provided for the population of Wales by three specialist centres: the University Hospital of Wales University Health Board for people from South-west, Mid and South-east Wales[7], University

[2] WCISU Cancer Incidence in Wales Dashboard (accessed August 2020).
[3] Liver cancer statistics | Cancer Research UK (accessed August 2020)
[4] Welsh Cancer Intelligence and Surveillance Unit (accessed November 2020)
[5] Estimate based on activity in south Wales extrapolated to all Wales on the basis of expected population share.
[6] Palliative liver surgery is not a current standard of practice.
[7] Commissioned by WHSSC.

Hospitals Birmingham NHS Foundation Trust for people from Mid-Wales[8], and Royal Liverpool & Broadgreen NHS Trust for people in North Wales[9].

1.2 Aims and Objectives

The aim of this service specification is to define the requirements and standard of care essential for delivering hepatobiliary (liver) cancer surgery for people with primary or secondary liver cancer. This specification should be read in conjunction with the wider service specification Tertiary Hepato-Pancreato-Biliary Surgical Service[10] for people Resident in Wales (Wales Cancer Network).

The objectives of this service specification are to:

- details the specifications required to deliver surgery for hepatobiliary cancer for people who are resident in Wales
- ensure minimum standards of care are set for the hepatobiliary cancer surgical service
- ensure equitable access to hepatobiliary cancer surgery
- identify centres that are able to provide hepatobiliary cancer surgery for Welsh patients
- improve outcomes for people accessing hepatobiliary cancer surgery services.

1.3 Relationship with other documents

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

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).
  - Welsh Government. National Standards for Colorectal Cancer Services, 2005
  - Welsh Government. National Standards for Upper Gastrointestinal Cancer Services, 2005
  - Welsh Cancer Networks, MDT Working Charter, 2014.
  - Service Specification for Tertiary Hepato-Pancreato-Biliary Surgical Service for People Resident in Wales, Wales Cancer Network (In development)

[8] Commissioned by WHSSC.
[9] Commissioned by BCUHB for its resident population.
[10] In Development

- **WHSSC policies and service specifications**
  - Positron Emission Tomography, CP50a, August 2020.
  - Transarterial Chemobolisation (TACE) Drug Eluting Doxyrubicin (DEBOX) for the Management of Unresectable, Metastatic Liver Disease, CP68, December 2012.

- **National Institute of Health and Care Excellence (NICE) guidance**
  - NICE Guideline, Colorectal Cancer (NG151). January 2020.
  - NICE Quality Standard (QS20), Colorectal Cancer. January 2020
  - NICE Technology Appraisal Guidance, Regorafenib for previously treated advanced hepatocellular carcinoma (TA555). January 2019.
  - NICE Technology Appraisal Guidance, Lenvatinib for untreated advance hepatocellular carcinoma (TA551). December 2018.
  - NICE Technology Appraisal Guidance, Sorafenib for treating advanced hepatocellular carcinoma (TA474). September 2017.
  - NICE Technology Appraisal Guidance, Cetuximab and panitumumab for previously untreated metastatic colorectal cancer. (TA439). September 2017

- **Relevant NHS England policies**
  - NHS England Improving Quality, 2013. National Peer Review Programme HPB Cancer Measures.
  - Department of Health. Guidance on Commissioning Cancer Services: Improving Outcomes in Upper Gastrointestinal Cancers, London 2001

- **Other published documents**
  - Association of Upper Gastrointestinal Surgeons, 2010. Guidance on minimum surgeon volumes.
  - Association of Upper Gastrointestinal Surgeons, 2016. The Provision of Services for Upper GI Surgery.

2. Service Delivery

The Welsh Health Specialised Services Committee commission the service of hepatobiliary cancer surgery for people aged 16 years and older in-line with the criteria identified in this specification. This service will be delivered in the context of the wider standards and pathway set out in the service specification Tertiary Hepato-Pancreato-Biliary Surgical Service[11] for people resident in Wales (Wales Cancer Network).

It is expected that all patients will have access to an appropriate cancer clinical nurse specialist. Support from a specialist dietitian with knowledge and skills in gastrointestinal disease, oncology and management of nutrition in surgical patients, and local prehabilitation services, should be available to optimise patients prior to treatment and rehabilitation services for post treatment recovery.

2.1 Access Criteria

The service is for people in Wales aged 16 years and older with primary or secondary cancer within the liver referred via the hepatobiliary multi-disciplinary team to the liver cancer surgery service. It is acknowledged that a minority of patients will be found to have benign tumours following further pathological investigation after surgery.

2.2 Service description

In addition to the standards required within the Contract, specific quality standards and measures will be expected. The provider must also meet the standards as set out below.

Facilities and equipment

The operations and acute post-operative care of the surgical centre should all be carried out at the same hospital which should have ITU and HDU on site.

The specialist surgical centre should provide the following infrastructure in order to ensure timely and efficient services:

- Theatres
- Access to intensive care (ITU/HDU) facilities
- Ward beds
- Outpatient clinics
- Remote/networked access to diagnostics and results
- Access to CT, MRI and PET scanning services[12].

[11] In Development

[12] Patients may access diagnostics locally but reports should be available for review at the specialist centre.

Specialist Multi-Disciplinary Team

The liver cancer surgery service will consist of the following specialist team:

- Consultant led care by hepatobiliary surgeons
- Hepatobiliary surgical trainees
- Consultant anaesthetists with hepatobiliary expertise
- Theatre staff with hepatobiliary expertise
- Specialist ward staff
- Nurse specialist support
- Radiology (inc. interventional radiology)
- Specialist pathology
- Dietetics
- Physiotherapy
- Pain control
- Access to palliative care

Specialist service

The following treatments and care should be available to support delivery of the specialist liver surgical service:

- All tumour resective surgery (this should only be carried out in the host hospital of the specialist team)
- Assessment and investigation of patients using relevant modalities such as pathology, radiology, nuclear medicine, PET-CT, liver MRI, endoscopic ultrasound and endoscopy
- Portal vein embolisation to enable surgery in patients that might not otherwise be operable
- Spyglass procedure to confirm malignancy and avoid unnecessary surgery
- Other treatments that surgical patients may require in the course of their treatment pathway (subject to NHS Wales commissioning policies) including:
    - microwave ablation
    - transarterial chemoembolisation (TACE)
    - endoscopic stenting and other endoscopic treatment of biliary tumours
    - Stereotactic Ablative Radiotherapy
    - Systemic anticancer therapies including chemotherapy, immunotherapy and multikinase inhibitors.

Diagnosis

- Local services should be available to meet the agreed standards adopted by NHS Wales for the Single Cancer Pathway. Patients should be referred in line with the single cancer pathway for primary cancers. There is currently no defined guidelines for the management of secondary cancer.
- Assessment of patients with suspected primary liver tumours involves a combination of imaging modalities, pathology services and specialised surgical and medical expertise. Complex imaging modalities may be required, e.g. liver magnetic resonance imaging (MRI) with special contrast agents, and careful case selection for these modalities is required to achieve optimal results.
- Colorectal cancer (CRC) secondary tumours in the liver are one of the most common of liver tumours. Imaging, such as computed tomography (CT) and MRI, is performed in most local hospitals, but decisions on surgery and interventional radiology will be taken by the tertiary centre multidisciplinary teams in line with NICE guidance on colorectal cancer[13] and NICE quality standards for colorectal cancer[14]. Chemotherapy can be given locally according to cancer network guidelines.
- Neuroendocrine tumours (NET) require specialist imaging, particularly involving nuclear medicine and specialist pathology, which will be provided at the specialist centre through established neuroendocrine cancer pathways.
- The service shall work to network agreed assessment and referral guidelines that have been developed with the lead clinicians of the HPB diagnostic teams.
- All patients who are diagnosed with liver cancer (or suspected of having the disease) should be referred to the hepatobiliary MDT prior to any proposed treatment. Treatment that does not require tertiary input should be provided locally.
- Liver surgeons are core members of the Hepatobiliary MDT.

Treatment

- The treatment of liver cancers is limited by performance status and the degree of underlying liver disease. An effective AHP led prehabilitation service to enable optimisation of patients and medical management of liver disease can improve quality of life and liver function allowing a greater range of treatment options including potentially curative interventions.

[13] https://www.nice.org.uk/guidance/ng151
[14] https://www.nice.org.uk/guidance/qs20

- The liver surgery service will deliver evidence based treatment depending on the personal circumstances of the individual and in line with agreed and published standards and guidelines.
- Ensure treatment is provided consistently and equitably to all individuals independent of social circumstances, behaviour and lifestyle choices.
- Ensure the establishment of appropriate shared care arrangements between specialties for the management of co-morbidities directly associated with patients' diseases / conditions.
- Ensure integration of patient care between the specialist centres and local services through the use of standardised shared-care protocols.
- Enable patients to have access to clinical trials as appropriate.

Out of hours provision: post-operative patients

- The specialist surgical centre should provide a rota of consultant core surgical members to ensure that one is available for telephone advice and potential face to face patient assessment and intervention, 24 hours per day, 365 days a year for post-operative patients.

Patient information and co-production

- The service will ensure each patients is involved in decisions about their care plan and is offered a written copy.
- Each patient will be provided with appropriate information regarding all aspects of liver malignancies, treatments and outcomes.

2.3 Interdependencies with other services or providers

- The hepatobiliary cancer surgery service should be co-located with Interventional radiology[15]. The interventional radiology service should provide a consultant rota to ensure availability of advice and potential face to face patient assessment and intervention (24 hours per days, 365 days per year).
- The hepatobiliary cancer surgery service should also be co-located with full radiology, endoscopy and oncology support, and tertiary hepatology.
- The hepatobiliary surgical service will require appropriate access to core clinical support services including haematology, pathology, pharmacy and blood and blood products.

[15] Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland, Provision of Services for Upper GI Surgery (2016)

2.4 Exclusion Criteria

Surgery for patients with non cancer hepatobiliary conditions, and surgery for patients under the age of 16 years, is outside the scope of this specification.

2.5 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.

2.6 Patient Pathway (Annex i)

- All patients with suspected primary liver or biliary tree cancer should be referred in accordance with the Single Cancer Pathway and National Optimum Pathways.
- All patients who proceed to surgery for suspected liver or biliary tree cancers (primary and secondary) should have been assessed and considered by the regional hepatobiliary MDT or the Hepatocellular Carcinoma MDT.
- Referring cancer units from the surrounding district hospitals should have easy access to the liver cancer centre for advice about complex cases and early transfer of patients where appropriate should be facilitated.
- Electronic imaging transfer facilities are vital for the effective function of any liver cancer centre and district hospitals should have access to robust systems of image transfer for decision making at the liver cancer centre MDT meetings.
- Liver cancer centres should have at least weekly MDT meetings and all referring units should have access on a weekly basis to decision making from the specialist team. This allows patients to either start their treatment as soon as possible or continue along their cancer pathway in a timely manner.
- Out-patient appointment with the liver surgeon and pre-admission assessment. Additional diagnostics if required (including PET scan to confirm suitability for surgery).

Admission for surgery

- Follow up will be provided in accordance with guidelines. Some patients may need to continue receiving follow up from the specialised service but it is expected the majority will be able to receive follow up locally. The provider will need to ensure effective hand over of care and/ or work collaboratively with other agencies to ensure patients have follow up plans appropriate to their needs.

- Post operatively patients should continue to have access to dietetics and on-going rehabilitation in accordance with their needs.

2.7 Service provider/Designated Centre

- University Hospital of Wales
  Cardiff & Vale University Health Board
  Heath Park
  Cardiff
  CF14 4XW

- Liverpool University Hospitals NHS Foundation Trust
  Liverpool
  Precott Street
  Liverpool
  L7 8XP

- University Hospitals Birmingham NHS Foundation Trust
  13 Oak Tree Lane
  Selly Oak
  Birmingham

2.8 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, 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

3. Quality and Patient Safety

The provider must work to written quality standards and provide monitoring information to the lead commissioner. The quality management systems must be externally audited and accredited.

The centre must enable the patients, carers and advocates informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

3.1 Quality Indicators

Minimum volumes

- Liver surgeons should each perform at least 15 liver surgical procedures per year for neoplastic disease, at least 10 of which should be major (3 or more segments).
- Liver resections include intrahepatic bile duct resections.
- If two surgeons share the surgery of a given case, this would count as a case for each in relation to this standard.

Patient Outcome and clinical quality indicators

The service will measure and report the following outcomes:

- Mortality
  - intraoperative deaths
  - early post operative deaths including deaths in ITU
  - deaths in hospital prior to discharge
  - deaths up to 90 days (at home or in another hospital)
- Open and close rate
- Complication rates, including:
  - Clavien Dindo score (% level 3 and above)
  - Blood loss
  - Requirement for blood transfusion
- Length of stay

Patient experience

- Patient/carer satisfaction - questionnaire survey
- Access to support groups and education - questionnaire survey plus patient/carer participation

3.2 National Standards

The provider will participate in national UK audit in order to ensure the best possible clinical outcomes. All audits should take into account the results of all surgeons in the centre.

3.3 Other quality requirements

- the provider will have a recognised system to demonstrate service quality and standards
- the service will have detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site
- the quality system and its treatment protocols will be subject to regular clinical and management audit
- the provider is required to undertake regular patient surveys and develop and implement an action plan based on findings

4. Performance monitoring and Information Requirement

4.1 Performance Monitoring

WHSSC will be responsible for commissioning services in line with this policy. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this policy the following approach will be adopted:

- Service providers to evidence quality and performance controls
- Service providers to evidence compliance with standards of care (see 3.1)

WHSSC will conduct performance and quality reviews on an annual basis. Patient outcomes and experience will be reported in alignment with quality indicators in 3.1.

- Performance monitoring will include monthly reporting of activity delivered against the agreed contract activity baseline.
- WHSSC may require a breakdown of activity by indication (including primary cancer/secondary cancer, exploration (open & close) and repeat resection).

4.2 Key Performance Indicators

The providers will be expected to monitor against the full list of Quality Indicators in 3.1.

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

In particular, the provider will be expected to monitor against the following target outcomes:

- Single Cancer Pathway waiting time target
- Liver surgery component waiting time for patients on the SCP
- Resection rates (for primary and metastatic disease)
- Hospital stay (median length of stay in days)
- Equitable access (by LHB population) to specialist hepatobiliary cancer surgery

In addition, the hepatobiliary cancer surgery service should have systems in place to routinely collect patient reported experience and outcomes.

These KPIs are in addition to performance and quality reporting requirements specified in WHSSC contracts with providers of hepatobiliary cancer surgery.

4.3 Date of Review

This document is scheduled for review before 2024 where we will check if any new evidence is available.

If an update is carried out the policy will remain extant until the revised policy is published.

5. 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 will be subjected to an Equality Impact Assessment following stakeholder consultation.

6. Putting Things Right

6.1 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.

6.2 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, 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

Annex i Patient Pathway

A flow chart of the patient pathway will be added to this document following stakeholder consultation.

Annex ii Codes

Code Category	Code	Description
OPCS	J02.2	Left hepatectomy
OPCS	J02.7	Extended left hepatectomy
OPCS	J02.1	Right hepatectomy
OPCS	J02.6	Extended right hepatectomy
OPCS	J02.4	Wedge resection
OPCS	J02.3	Resection of segment of liver

Annex iii Abbreviations and Glossary

Abbreviations

AWMSG All Wales Medicines Strategy Group

IPFR Individual Patient Funding Request

SMC Scottish Medicines Consortium

WHSSC Welsh Health Specialised Services

Glossary

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.

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.