

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>1. Service name</b>	Specialist Cancer Services (adults) Sub-heading: Hepato-Pancreatic Biliary (HPB) – Primary liver, secondary liver, perihilar biliary tract and gallbladder cancers.
<b>2. Service specification number</b>	2260
<b>3. Date published</b>	September 2024
<b>4. Accountable Commissioner</b>	NHS England – Cancer National Programme of Care (NPOC) <a href="#">NHS commissioning » Cancer (england.nhs.uk)</a> <a href="mailto:england.npoc-cancer@nhs.net">england.npoc-cancer@nhs.net</a>

<b>5.</b>	<b>Population and/or geography to be served</b>
<b>5.1</b>	<b>Population Covered</b>
	<p>This specification (the ‘Specification’) covers the provision of care for adults who have a suspected or confirmed diagnosis of Hepato-Pancreatic Biliary (HPB) cancer and who require assessment, management and specialist interventions delivered by the Specialist Hepato-Pancreatic Biliary (HPB) Cancer Service (the ‘Service’).</p> <p>HPB cancers include malignant diseases of the liver, bile duct and pancreas. This specification relates specifically to the curative and palliative treatment of primary liver, secondary liver, perihilar biliary tract and gallbladder cancers. The curative and palliative treatment of pancreatic and periampullary cancers is detailed in another NHS England service specification and these cancers are therefore excluded from this Specification.</p> <p>National standards relating to the delivery of Systemic Anti-Cancer Therapy (SACT), radiotherapy and PET-CT for HPB cancers are set out within standalone service specifications (section 7.6) and do not form part of this Specification.</p>
<b>5.2</b>	<b>Minimum population size</b>
	<p>The Service must be configured so that there is sufficient volume to ensure workforce sustainability and maintain professional expertise. Patients should be drawn from catchment areas with populations of at least two million and should have an annual team case throughput of 150 liver surgical procedures (75 of which should be major - 3 or more segments) for neoplastic disease or suspected neoplastic disease (<a href="#">National Peer Review Programme HPB Cancer Measures</a>, NHS. 2013).</p>
<b>6.</b>	<b>Service aims and outcomes</b>
<b>6.1</b>	<b>Service aims</b>
	<p>The aim of the Service is to:</p> <ul style="list-style-type: none"> <li>Deliver high quality clinical care and holistic support to Service Users in a culturally appropriate way.</li> </ul>

- Improve the clinical outcomes, quality of life and experiences of people affected by primary liver, secondary liver, perihilar biliary tract and gallbladder cancers.
- Ensure that there is equity of access for all elements of the Service and comparable clinical outcomes for all Service Users.
- Support and advise all professional groups within the system to offer care closer to home whenever it is clinically appropriate to do so; and
- Participate in clinical trials and research relating to primary liver, secondary liver, perihilar biliary tract and gallbladder cancers.

## 6.2 Outcomes

### NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	Y
Domain 2	Enhancing quality of life for people with long-term conditions	Y
Domain 3	Helping people to recover from episodes of ill-health or following injury	Y
Domain 4	Ensuring people have a positive experience of care	Y
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	Y

### Service defined outcomes/outputs

The quality of specialised services is monitored through Specialised Services Quality Dashboards (SSQDs), which normally comprise a range of quality outcomes (including clinical outcomes) and quality metrics which are supported by regular data collections. SSQDs are available on NHS England's website at: <https://www.england.nhs.uk/specialised-commissioning-document-library/>

Included in the range of outcomes metrics that support understanding of the quality of this service are:

Outcome Reference Number	Domain	Rationale	Name of Outcomes/Description
TBC	1, 2, 3	This indicates outcomes from the service through an understanding of mortality rates after surgical intervention	1 year mortality rates for patients undergoing curative liver resections
TBC	1, 3, 5	This indicates outcomes from the service through an understanding of mortality rates after surgical intervention	90-day mortality for patients following liver resection

The service will complete/upload data for all listed quality outcomes and metrics to the national Specialised Services Quality Dashboard (SSQD). The full definition of the quality outcomes and metrics and their descriptions including the

	<p>numerators and denominators can be accessed at <a href="https://www.england.nhs.uk/commissioning/spec-services/npcrcg/specdashboards/">https://www.england.nhs.uk/commissioning/spec-services/npcrcg/specdashboards/</a></p>
<b>7.</b>	<b>Service description</b>
<b>7.1</b>	<b>Service model</b>
	<p>The Provider is responsible for the delivery of the Service, which under the Hepato-Pancreatic Biliary (HPB) cancers service model means the provision of Level 3 services:</p> <ul style="list-style-type: none"> <li>• <b>Level 1:</b> The diagnostic process: rapid assessment and initial diagnostics for suspected primary liver, secondary liver, perihilar biliary tract and gallbladder cancers and referral to the specialist HPB cancer service as per locally agreed Network criteria and guidelines;</li> <li>• <b>Level 2:</b> Local designated cancer service, comprising a multidisciplinary team (MDT) / standalone diagnostic team based in a cancer unit. Responsible for: local care and palliative interventions, in accordance with</li> </ul>

locally agreed Network policy, for patients for whom specialist treatment is not appropriate; and

- **Level 3:** Specialist HPB cancer service, comprising the specialist multidisciplinary team (sMDT) based in a cancer centre. Responsible for: (i) review of diagnostic tests and planning further diagnostic tests; (ii) specialist treatment and procedures for primary liver, secondary liver, perihilar biliary tract and gallbladder cancers; (iii) management of recurrence of primary liver, secondary liver, perihilar biliary tract and gallbladder cancers.

The service model requires the Service to work closely with Level 1 and 2 services within the local cancer system to ensure a seamless care pathway for Service Users.

**The Provider must be a member of a Cancer Alliance and ensure that the Service:**

- Has a fully constituted sMDT in place to ensure all appropriate treatment options are considered for individual patients.
- Operates in accordance with MDT arrangements, referral criteria and pathways, clinical protocols (including acute oncology), network policies (including local surgical policies) and treatment pathways (including palliative care and end of life care) that have been agreed by the relevant Cancer Alliance. This must include clarity about the roles and responsibilities of all providers and partners across the primary liver, secondary liver, perihilar biliary tract and gallbladder cancers pathway.
- The network arrangements and associated documentation set out above must:
  - Enable prompt referral of Service Users with suspected or confirmed primary liver, secondary liver, perihilar biliary tract and gallbladder cancers to the sMDT from Level 1 and Level 2 providers.
  - Include a formal agreement where SACT and radiotherapy treatments are given by other providers. This must require that all treatment decisions are made by the sMDT and establish a mechanism for those providers to report Service User outcomes back to the sMDT.
  - Ensure that where Liver Transplant is not available onsite, there are clear referral pathways to dedicated transplant centres for Service Users who require this treatment.
  - Ensure that the Service has clear referral pathways to and from the neuroendocrine sMDT for specialist review and management of Service Users with suspected or confirmed metastatic neuroendocrine tumours.
  - Confirm whether or not the Service operates in partnership with other services to provide operational resilience, for example, where mutual aid arrangements are in place.
  - Ensure that the Service has access to pathology services to support the management of primary liver, secondary liver, perihilar biliary

	<p>tract and gallbladder cancers, in line with national guidance and policies.</p> <ul style="list-style-type: none"> <li>○ Ensure that the Service has access to diagnostic and therapeutic endoscopic ultrasound services to support the diagnosis and management of primary liver, perihilar biliary tract and gallbladder cancers in line with national guidance and policies.</li> <li>○ Ensure that the Service has access to interventional radiology services to support the diagnosis and management of primary liver, secondary liver, perihilar biliary tract and gallbladder cancers in line with national guidance and policies, including 24 hours a day/7days a week emergency cover.</li> <li>○ Ensure that the Service has effective communication and referral processes with associated hospital and community palliative care and end of life care services (where this is not provided by the specialist centre).</li> </ul> <ul style="list-style-type: none"> <li>● Implements new technologies that are recommended by the National Institute for Health and Care Excellence (NICE) and gives due regard to national clinical guidelines and guidance (See Section 7.9).</li> <li>● Gives due regard to other national guidance, including: relevant rapid cancer diagnostic and assessment pathways, optimal timed pathways (<a href="#">NHS England » Faster diagnosis</a>), personalised care and improving quality of life outcomes (<a href="#">NHS England » Personalised care and improving quality of life outcomes</a>) and elective recovery programmes, such as <a href="#">Outpatient Recovery and Transformation</a>.</li> <li>● Can be accessed by both primary care and secondary care referral.</li> <li>● Is open 24 hours a day, 7 days per week with an on-call rota and senior clinical expertise available to deliver routine and emergency care.</li> <li>● Undertakes continuous monitoring of risk and governance to ensure that clinical treatment is safe and effective.</li> <li>● Has arrangements in place to support groups within the population that are at increased risk of developing HPB cancers to access and benefit from the Service equitably. Such support arrangements may require the Service to work collaboratively with system partners and inequalities leads.</li> <li>● Provides personalised information and appropriate support to enable Service Users to make informed choices about their treatment and to live well following completion of treatment. This must also include information about travel and other welfare schemes that may be available.</li> <li>● Provides each Service User with an agreed recommended treatment pathway. This must either prescribe definitive treatment or outline necessary investigations leading to a final treatment plan.</li> <li>● Undertakes multidisciplinary assessments for each Service User, including holistic needs assessments (clinical, nutritional, physical, and psychological assessment using a validated tool), dementia assessments and clinical frailty scores, at multiple points along the care pathway. These must inform written Personalised Care and Support Plans for each Service User. Where appropriate, this should include referral to clinical support services, education, and information, plus referral to other support services.</li> </ul>
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- Has appropriate multi-modal prehabilitation and rehabilitation arrangements and enhanced recovery protocols in place with services that provide Specialist Dietitians, Physiotherapy, Occupational Therapy and Psychology.
- Provides Service Users with access to a 'key worker' - this is normally the Clinical Nurse Specialist (CNS) with expertise in HPB cancers. Service Users must meet their key worker as early as possible within their pathway of care.
- Delivers high-quality holistic and personalised care, including all aspects of rehabilitation and living with and beyond cancer, delivered or co-ordinated through the sMDT approach.
- Offers the option of Service User initiated follow-up and risk stratified follow-up subsequent to treatment.
- Provides long-term surveillance after definitive treatment, ensuring timely access for Service User experiencing late effects or complications following treatment for primary liver, secondary liver, perihilar biliary tract and gallbladder cancers.
- Provides supportive palliative care and end of life care which is delivered in line with National Institute for Health and Care Excellence (NICE) guidance and the relevant quality markers.

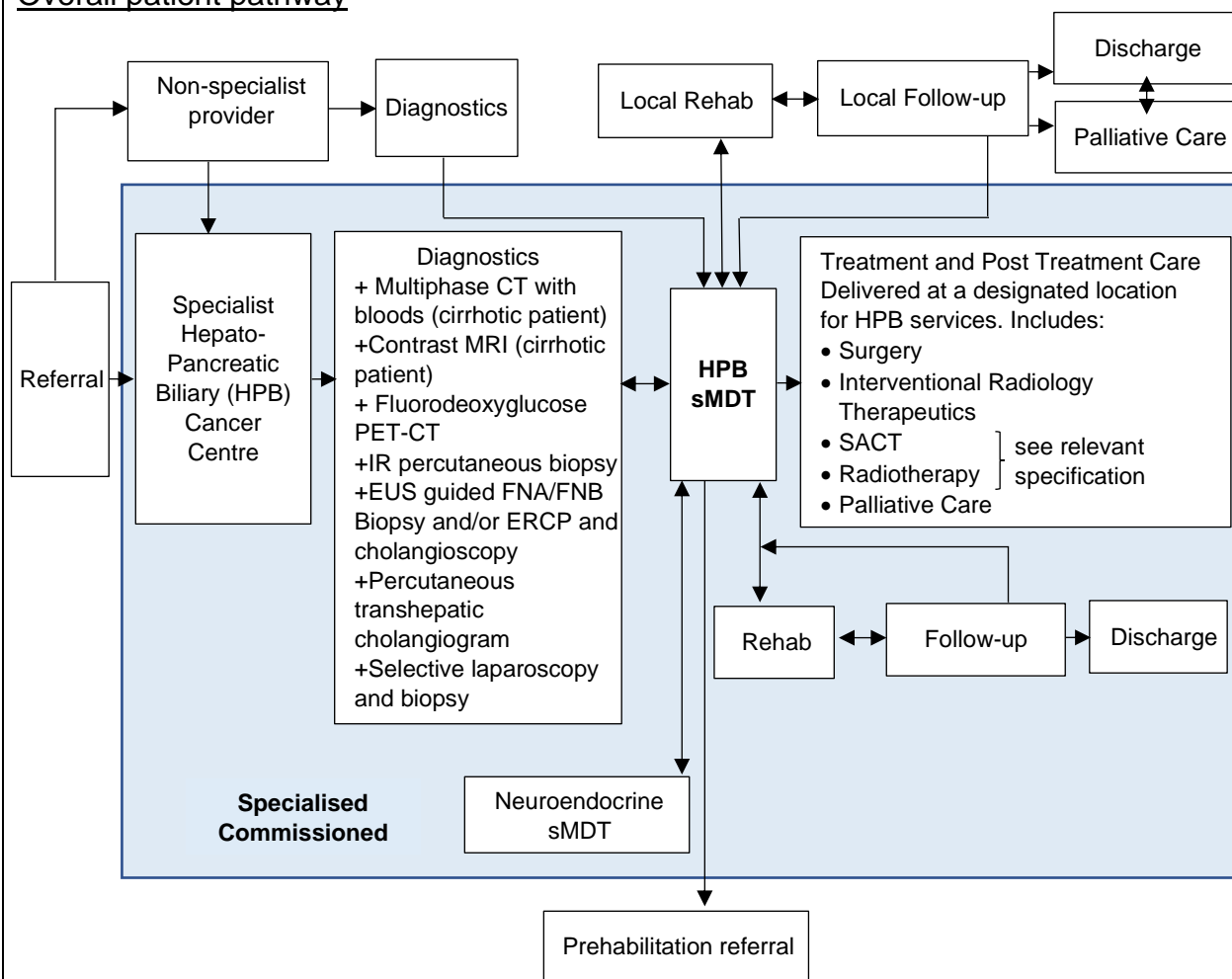
**The Provider must ensure that the sMDT:**

- Has a single named lead clinician who is a core team member, and nominated persons responsible for:
  - Ensuring that recruitment into clinical trials and other well-designed studies is integrated into the function of the multidisciplinary team.
  - Ensuring that audits and service developments are undertaken.
  - User engagement and information for Service Users and carers.
- Takes overall responsibility for the assessment, treatment planning and management, including taking all treatment decisions, of all referrals to the Service.
- Holds weekly meetings to discuss all new and recurrent cases of primary liver, secondary liver, perihilar biliary tract and gallbladder cancers, for example after treatment or progression of the cancer. In making treatment decisions, the sMDT must have all clinical disciplines present (i.e., surgical and oncology), even where oncology treatments may be delivered by different providers.
- Provides an option for members to participate in the sMDT virtually.
- Provides expert management of all elements of the diagnostic pathway for primary liver, secondary liver, perihilar biliary tract and gallbladder cancers, utilising the most up to date validated diagnostic tools and knowledge.
- Considers referral to genetics services / family history services, as appropriate.
- Considers referral to fertility services, as appropriate.
- Reviews the pathological and radiological basis for the diagnosis of primary liver, secondary liver, perihilar biliary tract and gallbladder cancers, including those from Level 1 and 2 services where these are referred to the sMDT.

- Ensures that for all diagnostic tissue sampling, care is taken where possible to preserve tissue for molecular profiling to investigate for potentially actionable mutations.
- Ensures that tissue and serum samples are provided for indicated molecular profiling, genomic and biomarker analysis when recommended.
- Provides expert management of those with confirmed primary liver, secondary liver, perihilar biliary tract and gallbladder cancers, through the use of the most up-to-date validated diagnostic tools, commissioned clinical protocols and surgical interventions.
- Makes recommendations for care at each stage in the Service User's pathway, including: treatment (surgery, radiotherapy, SACT, interventional radiology therapeutics), palliative interventions, follow-up, rehabilitation and living with and beyond cancer.

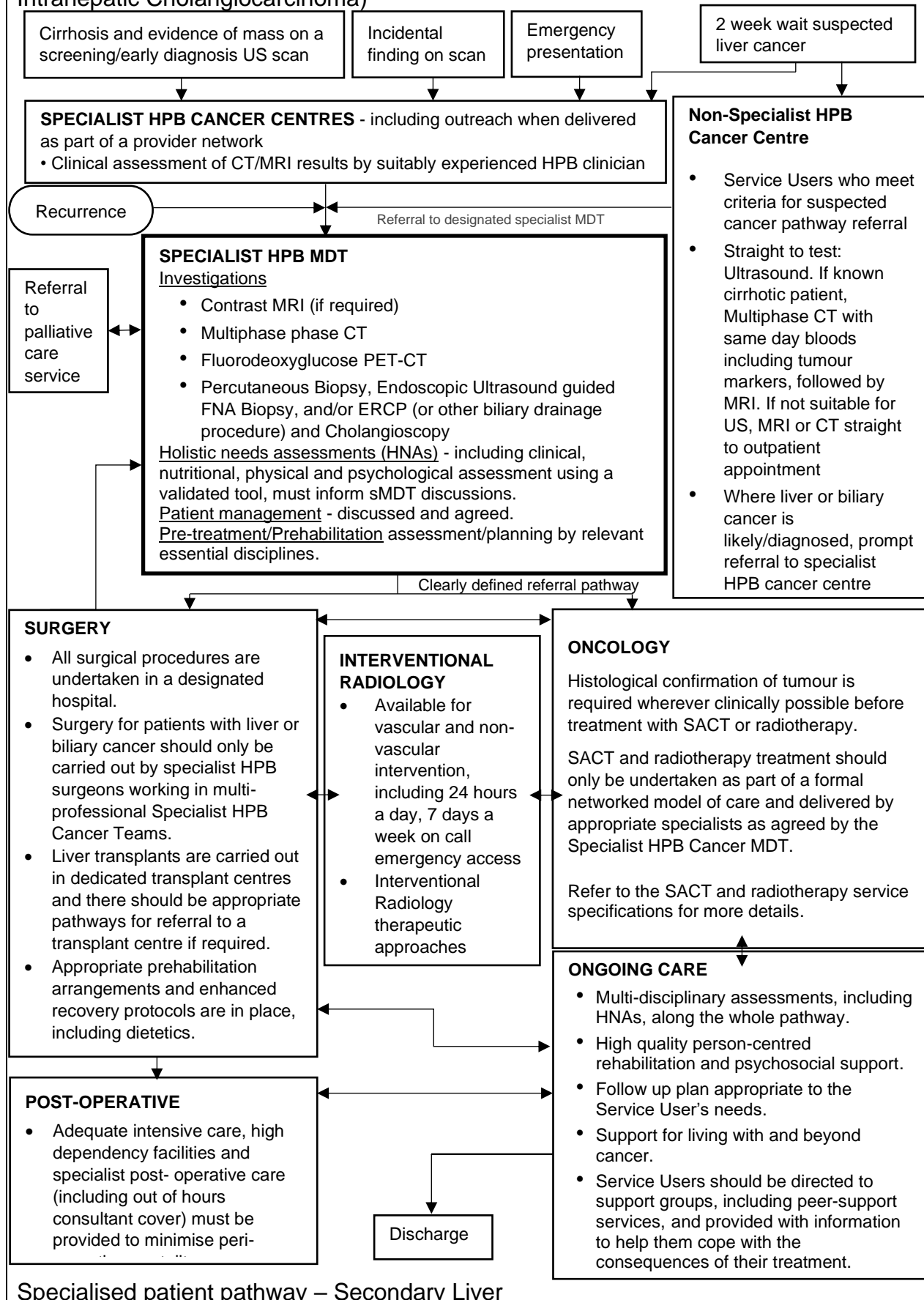
## 7.2 Pathways

### Overall patient pathway



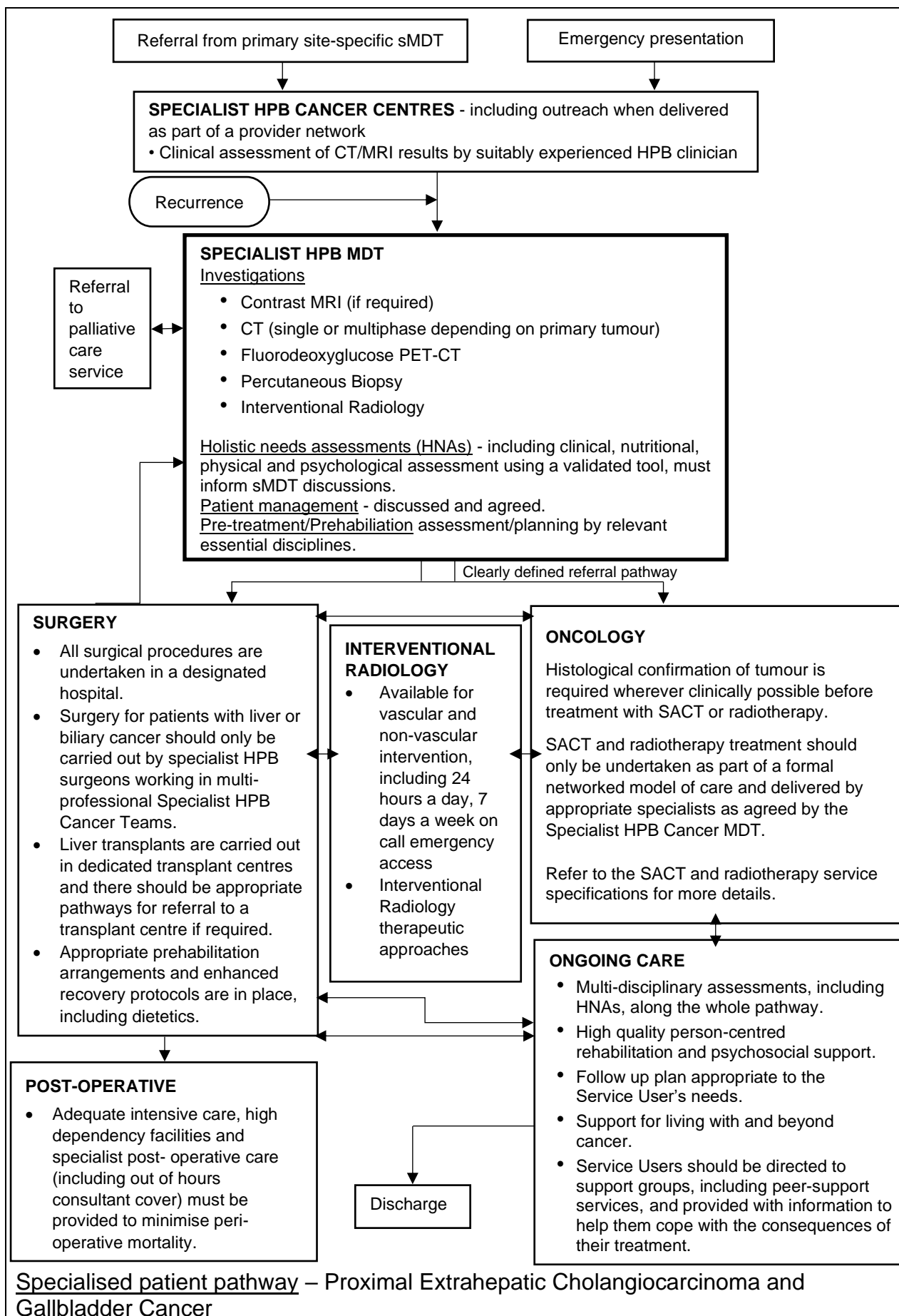
*Note: Some elements of the patient pathway (e.g., diagnostics and rehabilitation) are undertaken outside of the specialist HPB cancer centre. In these circumstances, those elements do not form a part of the specialised service. Activities delivered in the specialist HPB cancer centre form part of the specialised patient pathway as illustrated above.*

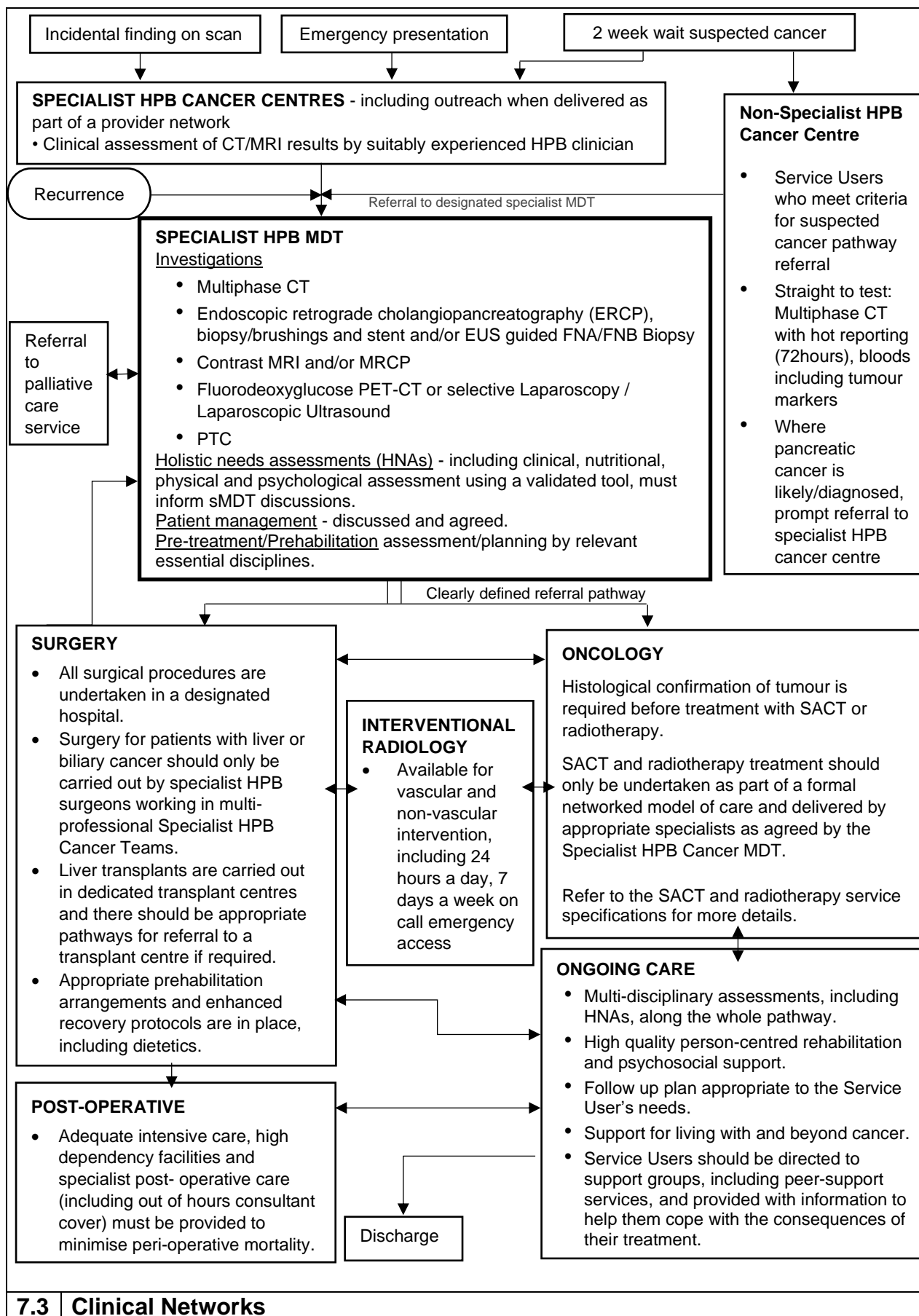
## Specialised patient pathway – Primary Liver (Hepatocellular Carcinoma and Intrahepatic Cholangiocarcinoma)



## Specialised patient pathway – Secondary Liver







### 7.3 Clinical Networks

	<p>All Providers will be required to participate in a networked model of care to enable services to be delivered as part of a co-ordinated, combined whole system approach.</p>
<b>7.4</b>	<b>Essential Staff Groups</b>
	<p>There should be a single named lead clinician for the specialist service who should also be a core multidisciplinary team member. The Provider should ensure that the Service is able to operate a compliant sMDT with the following essential staff groups at least:</p> <ul style="list-style-type: none"> <li>• 2 HPB surgeons</li> <li>• 2 radiologists at least one of which should be an interventional radiologist so that interventional and diagnostic radiology are covered.</li> <li>• 2 HPB nurse specialists.</li> <li>• 2 endoscopy practitioners, between them, covering endoscopic ultrasound and ERCP.</li> <li>• a physician gastroenterologist.</li> <li>• an oncologist taking responsibility for systemic therapy.</li> <li>• a histopathologist.</li> <li>• a core member of the specialist palliative care team.</li> <li>• MDT co-ordinator/secretary.</li> <li>• Specialist Dietitian.</li> <li>• Hepatologist.</li> <li>• Nuclear medicine.</li> <li>• Pathologist.</li> <li>• Clinical oncologist for radiation oncology expertise.</li> </ul> <p>All members of the multidisciplinary team should be specialists in the management of primary liver, secondary liver, perihilar biliary tract and gallbladder cancers. The number of people required to fulfil each role will depend on the team's workload.</p> <p>At least one clinical core member of the team with direct clinical contact, should have completed the training necessary to enable them to practice at level 2 for the psychological support of cancer patients and carers, and should receive a minimum of 1 hour's clinical supervision by a level 3 or level 4 practitioner per month.</p> <p>An NHS-employed member of the core or extended team should be nominated as having specific responsibility for Service Users' issues and information for patients and carers.</p> <p>A member of the core team nominated as the person responsible for ensuring that recruitment into clinical trials and other well-designed studies is integrated into the function of the sMDT.</p>
<b>7.5</b>	<b>Essential equipment and/or facilities</b>
	<p>The Service must have access to:</p> <ul style="list-style-type: none"> <li>• Remote/networked access to diagnostics and results.</li> <li>• Radiological, pathological, endoscopic, and diagnostic facilities to effectively diagnose, classify and stage the condition prior to planning treatment.</li> </ul>

- Treatment rooms.
- Fully staffed operating theatre.
- Fully staffed Interventional Theatre (with Cone Beam CT).
- Fully operational HDU and ITU beds.
- Appropriate ward/bed capacity.
- Enhanced recovery unit.
- Prehabilitation and rehabilitation facilities (inpatient and outpatient).
- Specialist Dietetics.
- 24/7 specialist consultant cover.

**7.6 Interdependent Service Components – Links with other NHS services**

Interdependent service	Relevant Service Specification/ Standards	Proximity to service
PET-CT	B02/S/a Positron Emission Tomography - Computed Tomography (PET CT) Scanning (All Ages) <a href="#">Positron Emission Tomography – Computed Tomography (PET CT) Scanning (All Ages)</a>	Not applicable
SACT	B15/S/a Cancer: Chemotherapy (Adult) <a href="#">B (england.nhs.uk)</a>	Not applicable
Radiotherapy	170091S - Adult External Beam Radiotherapy Services Delivered as Part of a Radiotherapy Network <a href="#">External-Beam-Radiotherapy-Services-Delivered-as-Part-of-a-Radiotherapy-Network-Adults.pdf (england.nhs.uk)</a>	Not applicable
Teenage and Young Adult Cancer Services	<a href="#">Specialist cancer services for children and young people: teenage and young adults principal treatment centre services</a>  <a href="#">Teenage and young adult cancer clinical network specification</a>  <a href="#">Specialist cancer services for children and young people: teenage and young adults designated hospitals</a>	Not applicable
Adult Critical Care	220502S - Adult Critical Care <a href="#">220502S-adult-critical-care-service-specification.pdf (england.nhs.uk)</a>	Co-located
Upper Gastrointestinal	B11/S/a - Cancer: Oesophageal and Gastric (Adult) <a href="#">b11-cancer-oesop-gast.pdf (england.nhs.uk)</a>	Co-located / accessibility to surgical oncology

	Hepato-Pancreatic Biliary (HPB) Pancreatic Cancer	[In development - ADD LINK WHEN AVAILABLE]	Co-located
	Hepato-Pancreatic Biliary (HPB) non-cancer	[In development - ADD LINK WHEN AVAILABLE]	Co-located
	Interventional Radiology (vascular and non-vascular)		Co-located
	Gastroenterology		Co-located
<b>7.7</b>	<b>Additional requirements</b>		
<b>7.8</b>	<b>Commissioned providers</b>		
	The list of commissioned providers for the services covered by this specification can be found here. [ADD LINK TO THE COMMISSIONED PROVIDER LIST ONCE AVAILABLE]		
<b>7.9</b>	<b>Links to other key documents</b>		
	<p>Please refer to the <a href="#">Prescribed Specialised Services Manual</a> for information on how the services covered by the Specification are commissioned and contracted for.</p> <p>Please refer to the Identification Rules tool for information on how the activity associated with the Service is identified and paid for.</p> <p>Please refer to the relevant Clinical Reference Group <a href="#">webpages</a> for NHS England Commissioning Policies which define access to a service for a particular group of Service Users. The specific clinical policies that relate to the services covered by the Specification include:</p> <ul style="list-style-type: none"> <li>• Stereotactic ablative radiotherapy (SABR) for hepatocellular carcinoma (adults)</li> <li>• Stereotactic ablative radiotherapy (SABR) for patients with metachronous extracranial oligometastatic cancer (all ages)</li> <li>• Selective internal radiation therapy for chemotherapy refractory intolerant metastatic colorectal cancer</li> <li>• The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for patients with Hepatocellular carcinoma or Cholangiocarcinoma</li> <li>• Chemosaturation for liver metastases from ocular melanomas</li> <li>• Selective internal radiation therapy (SIRT) for the treatment of chemotherapy refractory or intolerant, unresectable primary intrahepatic cholangiocarcinoma (all ages)</li> </ul> <p><b>Relevant NICE Guidance (exc. Technology Appraisals)</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Living-donor liver transplantation [IPG535]</a>: NICE (2015)</li> </ul>		

- [Selective internal radiation therapy for primary hepatocellular carcinoma \[IPG460\]](#): NICE (2013)
- [Colorectal cancer \[NG151\]](#): NICE (2020, updated 2021)
- [Colorectal cancer \[QS20\]](#): NICE (2012, updated 2022)
- [Irreversible electroporation for treating liver metastases \[IPG445\]](#): NICE 2013
- [Radiofrequency ablation for colorectal liver metastases \[IPG327\]](#): NICE (2009)
- [Ex-vivo hepatic resection and reimplantation for liver cancer \[IPG298\]](#): NICE (2009)
- [Microwave ablation of hepatocellular carcinoma \[IPG214\]](#): NICE (2007)
- [Radiofrequency-assisted liver resection \[IPG211\]](#): NICE (2007)
- [Laparoscopic liver resection \[IPG135\]](#): NICE (2005)
- [Microwave ablation for treating liver metastases \[IPG553\]](#): NICE (2016)
- [Selective internal radiation therapy for unresectable colorectal metastases in the liver \[IPG672\]](#): NICE (2020)
- [Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver \[IPG691\]](#): NICE (2021)
- [Irreversible electroporation for primary liver cancer \[IPG664\]](#): NICE (2019)
- [Photodynamic therapy for bile duct cancer \[IPG134\]](#): NICE (2005)
- [Radiofrequency ablation of hepatocellular carcinoma \[IPG2\]](#): NICE (2003)
- [The SpyGlass direct visualisation system for diagnostic and therapeutic procedures during endoscopy of the biliary system \[MIB21\]](#): NICE (2015)
- [Suspected Cancer: Recognition and Referral \[NG12\]](#): NICE (2015, updated 2021)
- [Suspected Cancer \[QS124\]](#): NICE (2016, updated 2017)
- [Improving Supportive and Palliative Care for People with Cancer \[CSG4\]](#): NICE (2004)
- [End of Life Care for Adults \[QS13\]](#): NICE (2011, updated 2021)

#### **National Clinical Guidance**

- [The Provision of Services for Upper Gastrointestinal Surgery](#): AUGIS (2016)

#### **Getting It Right First Time (GIRFT)**

- [Gastroenterology GIRFT National Specialty Report](#): NHS (2021)