

Specialised Services Policy: CP02 Hyperthermic Intraperitoneal Chemotherapy (HIPEC) and Cytoreductive Surgery for treatment of Pseudomyxoma Peritonei

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Approved by:	Management Group	
Issue Date:	September 2015	
Review Date:	March 2025	
Document No:	CP02	

CP02 Version: 2.1

Hyperthermic Intraperitoneal Chemotherapy (HIPEC) and Cytoreductive Surgery for treatment of Pseudomyxoma Peritonei

Document History

Revision History			
Version No.	Revision date	Summary of Changes	Updated to version no.:
1.0	27.07.15	Updating Commissioning organization details. Updating histological classification	1.1
1.1	04.09.15	Policy approved by Management Group subject to addition of wording regarding approval process	2.0
2.0	16.01.24	Review date extended – agreed at policy group	2.1
Date of next	revision	September 2018	

Consultation		
Name	Date of Issue	Version Number

Approvals		
Name	Date of Issue	Version No.
Management Group	27/08/2015	2.0
Policy Group	16/01/2024	2.1

Distribution – this document has been distributed to			
Name	Ву	Date of Issue	Version No.

This written control document replaces all previous approved and draft versions

Policy Statement

Background	Cytoreductive Surgery involves removal of the maximum amount of the visible tumour through a number of surgical resections. The exact scope and extent of the surgery is dependent on the spread of the visible tumour assessed on an individual patient basis. Hyperthermic Intraperitoneal Chemotherapy (HIPEC) involves flushing the abdominal cavity with a heated chemotherapy
Access Criteria	agent following surgical excision. Funding for treatment with Cytoreductive surgery and HIPEC for adult patients with confirmed Pseudomyxoma Peritonei is supported by the Welsh Health Specialised Services Committee. Prior to making a referral to specialist services for PMP, an application for funding must be
	made to WHSSC in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR). The application will be screened in accordance with the All Wales Policy.
Responsibilities	Referrers should: • inform the patient that this treatment is only routinely funded for proven Pseudomyxoma Peritonei
	Clinicians considering treatment where the patient does not have Pseudomyxoma should: • inform the patient that this treatment is not routinely funded and consider alternative treatment options

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1.1 Introduction

The purpose of this Commissioning Policy (the Policy) is to clearly set out the circumstances under which patients will be able to access the services specified.

The Policy clarifies the referral process, indicates which organisations are able to provide a service for Welsh patients and defines the criteria that patients must meet in order to be referred.

In addition the Policy provides background information to support the proposed level of access; this includes the epidemiology and anticipated outcomes.

The purpose of this document is to:

- set out the circumstances under which patients will be able to access the service;
- clarify the referral process; and
- define the criteria that patients must meet in order to access treatment.

1.2 Relationship with other Policies and Service Specifications

This document should be read in conjunction with:

- All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR)
- Policy Position 090: Cytoreductive Surgery with Hyperthermic Intraperitoneal Chemotherapy for Peritoneal Carcinomatosis

1.3 Prioritisation

In the preparation of this policy Welsh Health Specialised Services has involved local clinicians in the development of a care pathway with the aim of ensuring that referrals to specialist services are appropriate.

This service has been identified as an area for ongoing investment.

1.4 Review

Welsh Health Specialised Services' Commissioning Policy Group will review this policy every three years or following the publication of relevant guidance, for example, from NICE.

2. SCOPE

2.1 Definition

Pseudomyxoma peritonei is a clinical syndrome where there is intraperitoneal spread of mucinous producing tumour. It affects approximately 50 people per year in the UK. If this calculation is applied to Wales, this would mean approximately 3 cases per year.

These are most commonly appendiceal mucinous neoplasms.

Pseudomyxoma peritonei can be classified to WHO criteria (2010) as either low or high grade.

Low grade: Mucin pools with low cellularity (<10%), bland cytology and non-stratified simple cuboidal epithelium.

High grade: Mucin pools with high cellularity, moderate/severe ctyologic atypia and cribiform/signet ring morphology with desmoplastic stroma.

Low grade morphology is associated with a significantly longer survival than high grade (overall 5 year survival 63% versus 23% Carr et al 2012).

This however does not apply to tumours limited to the appendiceal mucosa which have no potential for aggressive disease when completely resected (Nicole et al 2012).

Clinical evidence indicates that Cytoreduction and Hyperthermic Intra Peritoneal Chemotherapy (HIPEC) effective in the treatment of patients with a low grade peritoneal mucinous tumour giving rise to Pseudomyxoma Peritonei, in which tumour cells appear low grade, are relatively scant and do not invade organs or lymph nodes and where the tumour will usually emanate from the appendix, but occasionally from the bowel or the gynaecological tract.

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For this group of patients evidence indicates an 86% survival at 5 years, compared to 50% for patients with a more malignant pathology.

Cytoreduction and HIPEC will involve radical abdominal surgery including:

- Removal of the part or total colectomy, spleen, gallbladder, greater and lesser omentum;
- Stripping of the peritoneum from the pelvis and diaphragm;
- Stripping the tumour from the surface of the liver;
- Removal of uterus and ovaries in women;
- Removal of the rectum in some cases:
- Insertion of Heated Intraperitoneal chemotherapy in to the abdominal cavity before the wound is closed.

WHSSC are responsible for funding Cytoreduction and HIPEC for Welsh patients at the 2 Nationally Designated Centres based at The Christie NHS Foundation Hospital Trust, Manchester and Hampshire Hospitals NHS Foundation Trust, Basingstoke.

Other treatments surgical and non-surgical (debulking and systemic chemotherapy) treatments for mucinous deposits resulting from abdominal tumours are the commissioning responsibility of Local Health Boards.

3. ACCESS CRITERIA

3.1 Policy position

Funding for treatment with Cytoreductive surgery and HIPEC for adult patients with confirmed Pseudomyxoma Peritonei is supported by the Welsh Health Specialised Services Committee.

3.2 Clinical Assessment

Accurate diagnosis for PMP is essential in order to ensure that patients receive the appropriate treatment. Patients will often present with symptoms such as abdominal pain, nausea, fatigue or infertility. They will often undergo a laporotomy to investigate presenting symptoms. At this point a biopsy should be taken to

confirm diagnosis. If the primary site is unclear, further diagnostic investigations should be undertaken.

It is likely that initial investigations will take place locally. However it is recommended that all cases are supported by:

- Staging laparoscopy
- Specialist histological review;
- Recent CT scan to confirm level and presence of any local and distant metastasis; and
- Reviewed by appropriate local Multidisciplinary Team.

Referrals to specialist services for PMP will be supported for patients who have undergone the investigations described above, where histology proves diagnosis of Pseudomyxoma Peritonei; there is no evidence of direct invasion of abdominal organs or metastatic disease, and patient has been assessed as generally fit and well.

Prior to making a referral to specialist services for PMP, an application for funding must be made to WHSSC in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR). The application will be screened in accordance with the All Wales Policy.

It is possible that for a very small number of patients the diagnosis will not be clear despite following the pathway described above. These cases will need to be considered on an individual case by case basis by WHSSC.

3.3 Exceptions

Funding for peritoneal carcinomatosis is not supported.

If the referring clinician believes that there are exceptional grounds for treatment, an Individual Patient Funding Request (IPFR) can be made to WHSSC under the <u>All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR)</u>.

3.4 Responsibilities

Referrers should:

• Inform the patient that this treatment is not routinely funded and consider alternative treatment options.

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Clinicians considering treatment should:

• Inform the patient that this treatment is not routinely funded and consider alternative treatment options.

4. PUTTING THINGS RIGHT: 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:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel.
- If the patient or their representative is not happy with the
 decision of the All Wales IPFR Panel the patient and/or
 their representative has a right to ask for this decision to
 be reviewed. The grounds for the review, which are
 detailed in the All Wales Policy: Making Decisions on
 Individual Patient Funding Requests (IPFR), must be
 clearly stated. The review should be undertaken, by the
 patient's Local Health Board;
- When 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. 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.