A08/S(HSS)/b

2013/14 NHS STANDARD CONTRACT FOR PSEUDOMYXOMA PERITONEI SERVICE (ADULT)

PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION

Service Specification No.	A08/S(HSS)/b
Service	Pseudomyxoma peritonei service (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

The purpose of this specification is to provide a framework for the commissioning of a national Pseudomyxoma Peritonei (PMP) service. The governing principle underlying this specification is that there should be a single national service provided across two sites. The two sites currently designated are Basingstoke Hospital, Hampshire Hospitals NHS Foundation Trust and The Christie NHS Foundation Trust.

This specification is for the evaluation and treatment of patients with pseudomyxoma peritonei of appendiceal origin. Commissioning will be for units to provide complete surgical cytoreduction and intraperitoneal chemotherapy initially described by Dr Paul Sugarbaker (Director of Surgical Oncology, Washington Cancer Centre), and subsequently developed through international collaboration.

This specification will be used by NHS England to monitor the performance and quality of the providers of cytoreduction and intraperitoneal chemotherapy for pseudomyxoma peritonei.

The specification has been developed to take account of agreements, developments and changes related to:

- standards and accreditation for a pseudomyxoma peritonei centre
- indications for complete cytoreduction and intraperitoneal chemotherapy based on evidence based reviews of clinical practice
- clinical outcomes: detailed outcome results will be evaluated
- discussions with provider centres on benchmarking of prices and content of complete cytoreduction and intraperitoneal chemotherapy packages of care

The service aims to provide advice, assessment and treatment for all patients diagnosed with pseudomyxoma peritonei. A key aspect is to provide information and support to healthcare workers across the designated region on the appropriate investigation, treatment and management of pseudomyxoma. Patients are offered outpatient assessment at the request of their treating physicians once appropriate details, imaging and pathology has been supplied and assessed.

It is recognised by NHS England that there are other instances of pseudomyxoma e.g. ovarian pseudomyxoma, and other conditions which require the Sugarbaker technique. These are not covered by this specification.

The nurse specialists, clinical fellows and team members provide telephone access to new patients, relatives and all patients already in the system. A central administration area is organised and run by a senior administrative officer to provide rapid communication networks for this service as there are often very urgent referrals and requests for immediate information by clinicians, patients and relatives.

Evidence Base

The incidence of PMP is approximately 2-3 per million per year as indicated by the combined workload of the two designated centres at Hampshire Hospitals NHS Foundation Trust and The Christie NHS Foundation Trust also supported by a recent pathological epidemiological report from Holland. A number of patients, approximately 10-20 per annum, with other pathologies such as pseudomyxoma peritonei type syndrome of ovarian or mucinous colorectal adenocarcinoma of gastrointestinal (GI) origin will be referred and in many instances the diagnosis will be uncertain and unresolved until the operation has been performed. Due to the rarity of the condition there are no randomised controlled trials on optimal treatment but accumulating reports of large case series support complete cytoreduction and heated intraperitoneal chemotherapy (HIPEC) as the standard of care (Moran et al 2008, NICE guidance) + Rout et al 2010

There is now an International Society (Peritoneal Surface Malignancy Oncology Group International) with biennial meetings. A consensus statement on the management of PMP emanated from the Milan 2006 meeting (Moran, BJ, Baratti D, Yan TD et al Consensus statement on the locoregional treatment of appendiceal mucinous neoplasms with peritoneal dissemination Journal of Surgical Oncology 2008;98:277-282).

2. Scope

2.1 Aims and objectives of service

This service covers all patients having complete cytoreduction and intraperitoneal chemotherapy and patients who have major palliative surgery or laparotomy only for histologically confirmed PMP of appendiceal origin. Patient selection for treatment is

by:

- clinical assessment
- tumour markers (Carcinoembryonic antigen (CEA), Cancer Antigen (CA)125, CA19.9)
- an up to date **computed tomography** (CT) scan and
- pre-operative investigations as necessary to ensure fitness for major surgery

It is anticipated that approximately two-thirds of the patients referred will undergo surgical intervention and approximately two-thirds of these will undergo complete cytoreduction with intraperitoneal chemotherapy. It is anticipated that there will be 130-140 cases per annum of pseudomxyoma peritonei of appendix origin.

The centres will provide regular information to NHS England on the length of stay and post-operative events. Delays in planned or agreed transfers will be audited. Morbidity and mortality will be documented and reported regularly.

2.2 Service description/care pathway

- surgical procedures will be performed after the decision to proceed is agreed between the patient and the pseudomyxoma peritonei treatment centre clinical team
- some cases are unsuitable for complete cytoreduction, due to disease aggressiveness or medical morbidity, or unwilling to have such a major intervention and are managed by major palliative cytoreduction, generally involving an extended right hemicolectomy, greater omentectomy and splenectomy on occasions (Sugarbaker, NICE, Moran), or chemotherapy leading to disease stabilisation and/or regression. (Farquaharson)
- the vast majority of cases will be treated electively as planned procedures at mutually agreed dates by the patient and surgical teams
- patients will be booked for treatment according to clinical stability and requirement for intervention. A change in their clinical condition may require urgent intervention. Audit and report of these exceptions will occur
- good quality information will be made available to patients and relatives. The patient will be sent a copy of all correspondence at their request. Patients will be provided with information leaflets
- the provider will work with NHS England to ensure sufficient considerations are given to communications
- the patients contact with the unit will be facilitated by arrangement for overnight stay as necessary for assessment and by provision of services to allow patients to travel to and from the centre in a day if possible
- a specialist nursing service will be available which provides counselling and support for the patient, carers and relatives. Specialist nurses will also engage in

education, audit, research and development

- the environment of the pseudomyxoma centre should afford privacy and an appropriate atmosphere for families and patients who experience long delays. Accommodation should be available for relatives of patients who have to travel long distances. The pseudomyxoma centre should have a policy on death and bereavement which is culturally sensitive and considers the needs of staff as well as patients
- discharge should be planned and agreed with all parties concerned though responsibility for effective discharge lies with the consultant
- a clearly defined after-care programme should be developed with the patient and the referring provider unit and general practice. Communication with general practitioners and staff in primary care and the referring clinician should be timely, efficient and continuous. The general practitioner should be informed at all stages of the patient's treatment and should be informed on how to access advice

Staffing and Facilities

- pseudomyxoma peritonei centres should have a named lead clinician of the service. There should be a minimum of two consultant surgeons
- pseudomyxoma peritonei centres should be staffed on a twenty-four hour basis. There should be appropriately trained specialised nursing staff. There should be sufficient administrative and management support to facilitate contact with referring doctors and patients, and staffed by personnel experienced in dealing with complex referrals
- There should be a full range of support staff including:
  - social workers
  - paramedic support
  - chemotherapy
  - pharmacy
  - radiology and
  - dedicated anaesthetic support with two consultant anaesthetists or the equivalent
- a pseudomyxoma peritonei centre should have access to a full range of general surgical and general medical back-up services on a 24 hour basis including to an intensive therapy unit, specialist respiratory, renal, gastro-enterological and microbiological expertise
- strategies for prevention, control and treatment of infections and other complications should be defined and updated
- the centre should have facilities for the isolation of patients and reverse barrier nursing of patients
- the pseudomyxoma peritonei centre should have designated operating theatre facilities and critical care facilities. A dedicated critical care bed is required such that no cancellations of these major procedures occur due to lack of intensive care facilities. It is impractical to reschedule a major cytoreduction with intraperitoneal chemotherapy if a critical care bed is not available. Experience has shown that the bed and facilities should be made available separate to the normal requirements of the treatment centre

- the pseudomyxoma centre should have a designated ward area where the patients are accommodated. This could be part of a larger general surgical facility. The high complexity and major morbidity associated with treatment warrants a high patient to qualified nurse rate. There should be a minimum ratio of 4 to 1
- the pseudomyxoma peritonei centre should be able to perform on site all procedures connected to the treatment of pseudomyxoma peritonei. If not available on site the centre should confirm to NHS England that alternative appropriate arrangements have been made with, and confirmed with, another centre

The centre should have a comprehensive stoma care service.

Discharge planning

Patients are deemed ready for discharge when they are able to tolerate diet, mobilise and be self caring with hygiene requirements and stoma care if applicable.

Any patient with a stoma will be provided with contact details of the local stoma service and the service will be alerted that the patient is being discharged.

Patients with wound infections may be discharged to the care of the general practitioner and arrangements for wound care will be established with the district nursing service prior to discharge.

Patients requiring palliative care prior to discharge would be referred to the palliative care team or hospice in the patients' locality with prior communication between the teams to ensure the smooth, safe transfer of the patient. Details of the hospital stay should accompany the patient and a copy sent to the patients general practitioner.

Days/hours of operation

The service provides 24-hour treatment for inpatients

2.3 Population covered

Please see section 2.4

2.4 Any acceptance and exclusion criteria

Inclusion Criteria:

- pseudomyxoma peritonei of appendiceal origin, confirmed or presumed disease distribution amenable to complete or near complete (residual individual tumours being no bigger than 2.5mm diameter – complete cytoreduction (CC0) or CC1) surgical resection

- absence of systemic disease (i.e. node positivity, unresectable distant metastases)
- performance status sufficient to withstand a major surgical procedure
- availability of all previous relevant imaging, histology and medical notes

Exclusion criteria:

- unresectable disease (>CC2)
- significant co-morbidities
- malignant peritoneal mesothelioma

In addition to the above absolute criteria there is the relative exclusion criteria for complete cytoreduction and HIPEC include advanced age, major co-morbidity including renal, cardiac, respiratory, liver or other major organ disease. Multidisciplinary assessment by anaesthetic, surgical, medical and nursing teams may be required for some patients with major morbidity. Palliative cytoreduction may be appropriate to improve quality of life.

Response time & detail and prioritisation

Patients referred will be seen and assessed on completion of the referral criteria process. It is the responsibility of the referring clinical team to provide appropriate and timely information, x-rays and pathological specimens as required. The patient will then be given a date for appointment for review by a surgeon and nurse specialist. The time to outpatients will depend on patient wellbeing and clinical need (for example patients who have undergone major surgery require time for recovery). Providers will aim to see patients within 2 weeks of assessment and review of all completed information

Following review patients are categorised as:

- suitable for surgery – Placed on waiting list for surgery – This will be within 12 weeks or at a mutually agreed time
- put on a surveillance programme with sequential imaging, serology assessment and a review
- deemed unsuitable for treatment and referred back to the referring clinical team for on-going care
- other palliative interventions

Accessibility/acceptability

The provider will ensure that the service is available to all irrespective of age, culture, disability or gender sensitive issues. No person should be discriminated against by reason of any of the above.

The provider has a duty to co-operate with the commissioner in undertaking equality impact assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation.

The provider will provide information to patients on public transport access and

accommodation for patients and relatives as needed.

2.5 Interdependencies with other services

The nationally approved and funded centres will communicate at a clinical, managerial and strategic level and will aim to provide a comprehensive equitable service.

NHS England units will aim to meet formally on an annual basis at a mutually agreed place and time.

NHS England units will aim to involve patient groups in service assessment and development.

Special arrangements will need to be in place to ensure appropriate access to critical care, both for initial intervention and management of subsequent major complications

NHS ENGLAND centres will provide information, access and treatment to the cancer networks and will liaise with colorectal and gynae cancer multi-disciplinary teams (MDTs) who initially diagnose and access the majority of PMP patients. There are no relevant screening programmes for PMP.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

- providers will ensure that clinical teams will have inbuilt time and resources for continuous professional development, educational and service developments
- the facilities and environment required to be safe and appropriately staffed to deliver and care for these complex cases
- incidents recorded and investigated
- annual report of morbidity and mortality
- annual report of complaints and outcomes of recommendations
- see also NHS England service standards for pseudomyxoma peritonei

4. Key Service Outcomes

Service assessment

The following will be monitored carefully:

- post-operative bleeding
  - bleeding requiring surgical exploration for resolution or blood transfusion requiring more than 5 units of blood within a 24 hour period
  - bleeding requiring intervention but not requiring surgical treatment such as bleeding from a peptic ulcer requiring endoscopy and treatment
- re-operation for any cause, in particular for sepsis secondary to a fistula or intra-abdominal abscess or other indication
- infection – any positive culture of body tissue or fluid requiring treatment with antibiotics (excluding prophylactic antibiotics) or other antimicrobial medication excluding post splenectomy prophylaxis
- thromboembolism – deficit in any non-cerebrovascular organ system (pulmonary, renal, hepatic, splenic or limb) demonstrated to be due to acute vascular occlusion through standard diagnostic assessment or at autopsy
- neurological events that persist for at least 24 hours due to documented disturbance of the cerebral circulation
- renal dysfunction requiring replacement therapy in the form of filtration or dialysis after post-operative day 1
- cardiovascular dysfunction – abnormal function of the cardiovascular system e.g. new arrhythmia, new myocardial infarction, systemic hypertension that occurs greater than 24 hours post-operatively
- respiratory dysfunction – continued ventilatory support from more than 5 days post-operatively or subsequent re-intubation for respiratory distress
- miscellaneous events requiring intervention:
  - rate of discharge to home
  - readmission following surgery to any hospital or to provider centre
  - pre and post surgical mortality
  - percentage overall survival including 30 days, 1 year, 3 years and 5 years

Audit and research

A register of all patients having cytoreduction and intraperitoneal chemotherapy will be maintained.

Provider units will share the clinical results with referring clinicians including them in education and audit reviews usually by presentation at national and international meetings and publication in peer reviewed journals.

Quality and Performance Standards

Quality performance indicator examples	***Threshold***	***Method of measurement***	***Consequence of breach***	***Report due***
Infection Control – MRSA		Pre admission and weekly while an inpatient	Commence treatment prior to admission	
Infection Control – C Diff		Stool specimen as indicated by symptoms		
Numbers waiting				
Length of wait				
Mortality	Less than 5% per annum	Continuous audit		
Unplanned admissions	Less than 10%			
Improving service users & carers xxperience		Biennial patient survey		
Outcomes	5 year survival for complete >50%	Continuous audit		
	Re-interventions	Continuous audit		

5. Location of Provider Premises

- Basingstoke Hospital, Hampshire Hospitals NHS Foundation Trust
- The Christie NHS Foundation Trust Manchester

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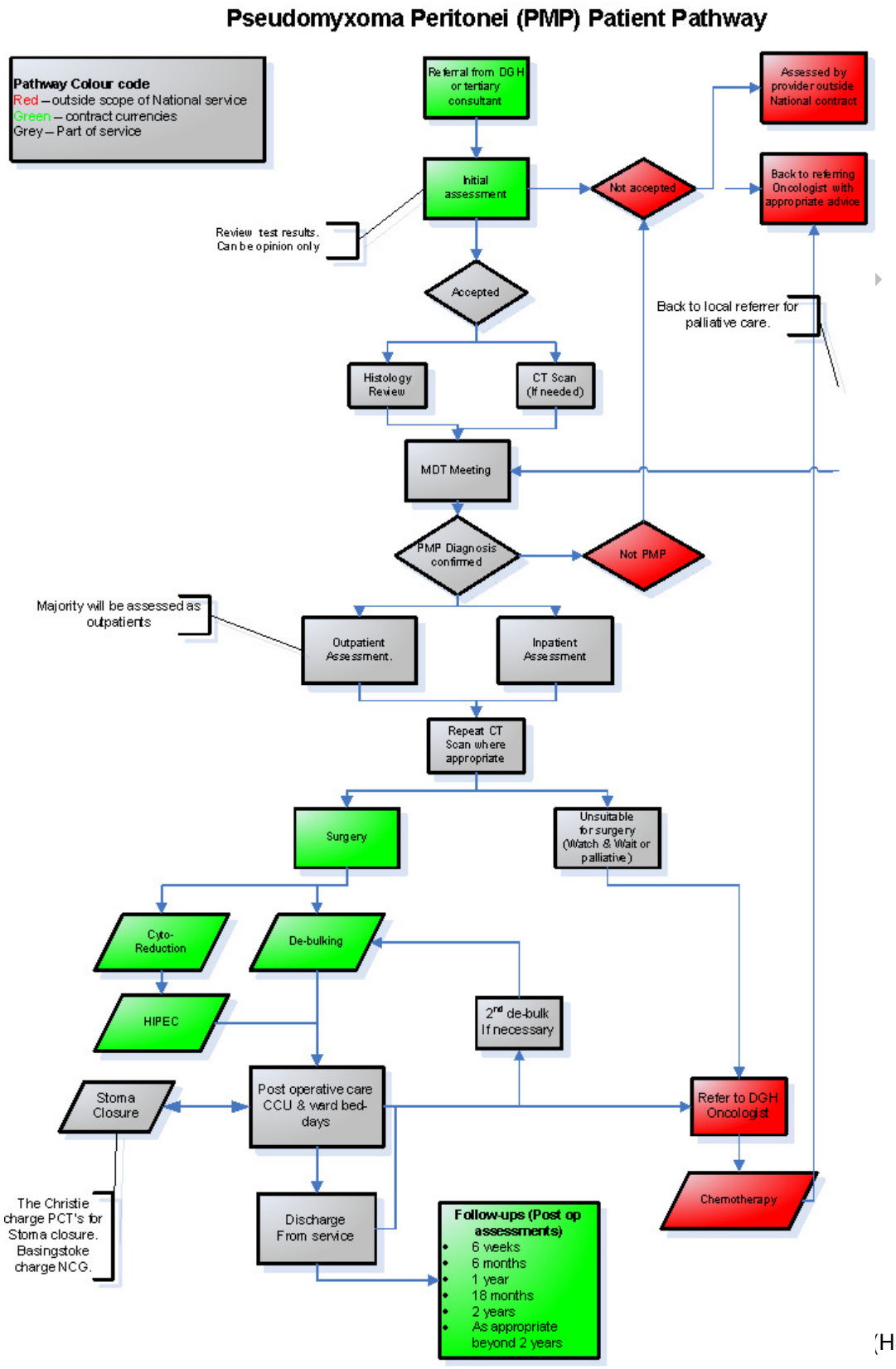
Appendix 1 - Overview Care Pathway



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