

A08/S/f

2013/14 NHS STANDARD CONTRACT FOR COLORECTAL: CYTOREDUCTIVE SURGERY (ADULT)

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS

| Service Specification No. | A08/S/f |
|---------------------------|---|
| Service | Colorectal: Cytoreductive surgery (Adult) |
| Commissioner Lead | |
| Provider Lead | A \ ' |
| Period | 12 months |
| Date of Review | |

1. Population Needs

1.1 National/local context and evidence base

Background

Peritoneal metastases commonly result from the regional spread of gastrointestinal, gynaecological and other malignancies. Peritoneal carcinomatosis is an advanced form of cancer associated with short survival and poor quality of life, which may lead to bowel obstruction, ascites (fluid in the peritoneal cavity) and pain.

Patients with peritoneal metastases from colorectal cancer have traditionally been treated with palliative intent. Recent evidence has shown that the use of cytoreductive surgery (CS) and hyperthermic intraperitoneal chemotherapy (HIPEC) can result in improved survival. In England, only two centres have developed the surgical experise to undertake this surgical technique as it is also beneficial in the treatment of Pseudomyxoma Peritonei. As the incidence of colorectal cancer is significantly greater than that of Pseudomyxoma Peritonei there is a need to develop the expertise required to provide this treatment more widely.

Cytoreduction surgery involves removing all of the visible (macroscopic) tumour. During the same operation, the peritoneal cavity is flushed with heated chemotherapy fluid with the aim of eliminating any microscopic traces of disease left behind.

The incidence of colorectal cancer in England is 65 per 100,000. Peritoneal metastatic disease occurs in 10% of patients with colorectal cancer. Some of these patients will not be suitable for this treatment because of high co-morbidity and/or the presence of metastatic disease elsewhere.

In February 2010 the National Institute for Health and Clinical Excellence (NICE) issued guidance for the treatment of peritoneal carcinomatosis interventional procedure guidance (IPG) 331. Since that guidance, a key publication (Elias et al 2011) has reported a multicentre registry of cases with evidence of improved outcomes.

Evidence Base

Cancer service guidance (CSGCC): Improving outcomes in colorectal cancer (manual update). NICE (2004).

IPG331 Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis: guidance (NICE: 2010) London

Achieving Long-term Survival with Cytoreductive Surgery and Perioperative Chemotherapy to Peritoneal Surfaces for Metastatic Colon Cancer (American Society for Clinical Oncology: 2011) Sugarbaker, P

2. Scope

2.1 Aims and objectives of service

The aim of this service is to optimise outcomes and improve life expectancy for patients with peritoneal metastatic disease secondary to colorectal cancer through surgical de-bulking of the malignant tumour concomitant with a flushing of the tumour site with a chemotherapy agent.

The service will achieve this aim by:

- Providing a timely assessment of referred candidate patients with a view to ascertaining suitability for treatment using this surgical technique.
- Developing a management plan for patients and either accepting them for surgery or providing an onward referral.
- Undertaking surgery on suitable patients in a timely way.
- Appropriate liaison with relevant Cancer Networks and multi-disciplinary teams (MDTs).
- Undertaking detailed audit relating to the delivery of this service.

2.2 Service description/care pathway

This service pathway for this service is as follows:

- Referral from Colorectal Cancer MDT.
- MDT assessment of suitability of cytoreductive surgery and HIPEC for patients with peritoneal metastases.
- Elective Admission for Surgery.
- Surgical Procedure.
- Recovery.
- In-patient discharge.
- Follow-up.
- Discharge to local MDT.

Peritoneal metastases commonly result from the regional spread of gastrointestinal, gynaecological and other malignancies. Peritoneal carcinomatosis is an advanced form of cancer associated with short survival and poor quality of life, which may lead to bowel obstruction, ascites and pain. The procedure detailed in this specification was developed by Paul Sugarbaker at the Washington Cancer Institute. A laparotomy is performed under general anaesthesia and all gross tumour is removed along with the involved organs, peritoneum and tissue. The surgery includes:

- removal of the right hemicolon, spleen, gall bladder, parts of the stomach, greater and lesser omentum.
- stripping of the peritoneum from the pelvis and diaphragm.
- stripping of tumour from the surface of the liver.
- removal of the uterus and ovaries in women.
- · removal of the rectum in some cases.

The aim of the surgery is to remove all macroscopic tumour. Then the abdomen is perfused with fluid containing a chemotherapy agent, heated to between 40 and 48°C. The fluid is perfused for 60 to 120 minutes and then drained from the abdomen, before the laparotomy is closed. A further course of systemic or intraperitoneal chemotherapy may be administered after the surgery.

Intraoperative intraperitoneal administration of chemotherapy allows the drug to be distributed uniformly to all surfaces of the abdomen and pelvis. Potential advantages of heating the perfusion fluid are that it increases drug penetration and the cytotoxic effect of drugs such as mitomycin C and cisplatin.

Minimum Staffing Required:

- Core MDT
 - Two surgeons trained in cytoreductive surgery
 - Lead Radiologist
 - Lead Pathologist
 - Clinical/ Medical Oncologist
 - Clinical Nurse specialist (including Macmillan Link Nurse)
 - Clinical Pharmacist
- Theatre Support Staff
 - Two Anaesthetists

- Two HIPEC perfusionists
- Stoma Therapy Service
- Nutrition Support Team (with total parenteral nutrition (TPN) capability)
- Data Manager particular focus on Audit and Outcomes

Minimum Infrastructure Requirements:

- Suitable outpatient facilities.
- Inpatient facilities
- Access to Operating Theatre (with dedicated elective theatre allocation)

Entry/Exit Point to Specialised Service:

The Specialised Service commences at the point where a referral is received by a suitably qualified referrer (as outlined below in Section 2.4).

Patients will remain under the care of the specialised service until:

- They are assessed as being unsuitable for cytoreductive surgery and are discharged back to the referrer or are referred on to another service.
- They complete the pathway and following surgery are determined ready and it is safe for discharge back to local services. This will ordinarily be at the first outpatient attendance following discharge from the inpatient surgical spell. Occasionally "tidy up" surgery or closure of a stoma may be necessary. This will be performed by the specialised unit if clinically indicated. If not the patient will be returned to the referring unit.
- They become ineligible for NHS funded care or they die whilst undergoing treatment.
- They elect to discontinue receiving care provided by this service.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England1 (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 127393

Specifically, this service is for adults (aged 18 and over) with diagnosed metastatic cancer of the peritoneal cavity secondary to a gastrointestinal cancer.

NHS England/ A08/S/f

¹ Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England

2.4 Any acceptance and exclusion criteria

This service will accept referrals from Colorectal Cancer MDTs. Referrals will be made to the specialised service as a whole and not to individual named consultant surgeons.

Acceptance Criteria: Patients who have been identified through the local colorectal MDT to fulfil criteria provided by the specialist service provider. Patients will have had a diagnosis of primary colon or rectal cancer with evidence of metastases involving the peritoneal surfaces of the abdomen and pelvis.

Exclusion Criteria: Patients with cancer of the appendix – this service is commissioned nationally through another mechanism.

2.5 Interdependencies with other services

Co-located services

Services which must be provided from the same healthcare setting (i.e. the same hospital site) as the specified service are as follows:

- Full general medical services
- Intensive care
- Nutrition Support Team
- Stoma Therapy Team

Interdependent services

Services which the specified service will require access to routinely, for care provided during the period of the pathway described in this specification, but for which there is no absolute requirement for these services to be physically colocated on the same healthcare delivery site are:

Specialised Fertility Services – Cryopreservation of Sperm/Embryo

Related services

The service forms part of a pathway of care provided in a number of settings by different providers. The service will need to maintain excellent communication with other agencies and services providing care to the patient including their General Practitioner and secondary care Cancer Centre who will be responsible for the longer-term follow-up of patients treated by this service.

3. Applicable Service Standards

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

International standards relating to Completeness of Cytoreduction (CC) score according to Sugarbaker International grading system for surgical complications

4. Key Service Outcomes

A database is required to document performance indicators to include:

- Completeness of cytoreduction
- Peritoneal Cancer Index
- Procedure time
- · Length of Stay in Critical Care Unit
- · Length of Stay per episode
- Blood transfusion volume
- · Return to theatre
- Post op complications Grade 1-4 (Int ref)
- 30 day mortality
- 1,3 and 5 year survival
- Permanent stoma rate