

A08/S/e

**2013/14 NHS STANDARD CONTRACT
FOR COLORECTAL: TRANSANAL ENDOSCOPIC MICROSURGERY (TEMS)
(ADULT)**

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

Service Specification No.	A08/S/e
Service	Colorectal: Transanal Endoscopic Microsurgery (TEMs) (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Transanal endoscopic surgery is a form of minimally invasive surgery, where the surgeon accesses the site, usually somewhere in the rectum, through the anus. There are a number of benefits to this approach, including shorter post-surgical recovery and less discomfort for patients.

Trans-anal endoscopic surgery for benign and malignant rectal tumours is a relatively recent development which is technology driven started by the development of the TEMS kit. This technology allows removal of tumours of the rectum which cannot be removed through a flexible endoscope and those that are “out of reach” of standard per anal surgical techniques which are confined to very low tumours.

With the development of laparoscopic techniques and skills to treat colorectal cancer, similar technology and skills have been applied to excising rectal tumours. The currently available technologies include:

- TEMS (Transanal Endoscopic Microsurgery)
- TEO (Transanal Endoscopic Operations)
- Endoscopic Submucosal dissection
- Glove-port rectal surgery
- SILS (single incision laparoscopic surgery) port rectal operations.

These techniques enable complete removal of the tumour with good vision and a more radical excision (full thickness) of the rectal wall and some mesorectum than can be achieved at standard endoscopy. Lesions up to the recto-sigmoid junction can be treated using these techniques.

The need for these procedures is increasing with the trend towards earlier diagnosis due to screening.

The National Institute for Health and Clinical Excellence (NICE) has not, as yet, offered any specific guidance on TEMS (last update 2010) but has recommended the formation of an Early Rectal Cancer multi-disciplinary team (MDT) (Clinical Guideline (CG)131, recommendation 1.2.3.4).

'An early rectal cancer MDT should decide which treatment to offer to patients with stage I rectal cancer, taking into account previous treatments, such as radiotherapy'

NICE has published an example of an Early Rectal Cancer MDT to show how it can be run.

2. Scope

2.1 Aims and objectives of service

Aim

The aim of the Transanal Endoscopic Surgery Service is to provide adults with diagnosed or suspected early rectal cancer with a seamless, quality assured surgical service that will both optimise outcomes in relation to survival and morbidity and provide the best possible patient experience.

Objectives

The service will deliver this aim by:

- Providing high quality treatment and care services which are linked in to the Cancer Networks and screening services, covering a defined catchment population.
- Achieving cancer wait time targets.
- Assessing each referral to the service by the MDT.
- Identifying patients suitable for trans anal endoscopic surgery.
- Undertaking surgery on suitable candidate patients.
- Referring unsuitable patients on/back to an appropriate service.
- Following-up patients post-operatively until they can safely be discharged back to local services.
- Undertaking detailed audit and monitoring of outcomes for patients treated by the service, and comparing these data to those of other providers of this service.

2.2 Service description/care pathway

The trans-anal endoscopic surgery specialised service comprises the following elements:

- Assessment of patients referred with diagnosed or suspected early rectal cancer that is unsuitable for resection using flexible endoscopic techniques
- Onward referral or referral back to originator for patients deemed unsuitable for trans anal endoscopic surgery
- Surgical intervention using trans-anal endoscopic surgery techniques
- Immediate post-surgical follow-up
- Discharge back to local services.

The service will be delivered as follows:

- The service will be delivered via an 'Early Rectal Cancer (ERC) MDT' will, as a minimum comprise the MDT specified below.
- Patients with suspected or proven rectal cancers suitable for trans anal procedures will be discussed at the MDT.
- The ERC MDT shall
 - Meet regularly and be quorate.
 - Review all clinical and pathological data.
 - Assign a surgeon and key worker to the patient who will see the patient and discuss the role of local excision with that patient.
 - Discuss entry into national trials
 - If suitable, perform the excisional surgery (full thickness rectal wall excision with adequate margins) by appropriate techniques.
 - Deliver a properly oriented specimen to histopathology.
 - Ensure that the final histology is discussed at the MDT.
 - Appropriate plans are made for further follow-up.
 - A detailed and prescriptive follow-up pathway including dates for surveillance endoscopies and MRI scans is communicated to the referring MDT so that these can be performed closer to the patient's home.
 - If local excision is thought to be inappropriate, refer the patient back to the referring MDT for radical surgery
 - The nurse specialist (key worker) from the ERC and primary MDTs should ensure accurate and timely communication about the patient's progress through the pathway.

Surgery will be undertaken either as a day-case or as an inpatient procedure, with an anticipated length of stay of one to two days.

Minimum Staffing Required:

Core MDT

- Two surgeons trained in trans anal endoscopic procedures.
- Lead Radiologist.
- Lead Pathologist.
- Clinical/ Medical Oncologist.
- Clinical Nurse specialist (including Macmillan Link Nurse).

- Colonoscopist.

Minimum Infrastructure Requirements:

- Suitable outpatient facilities.
- Inpatient facilities.
- Access to Operating Theatre (with dedicated elective theatre allocation).
- The appropriate specialised operating equipment.

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 trans anal endoscopic 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 safe for discharge back to local services. This will ordinarily be at the first outpatient attendance following discharge from the inpatient surgical spell.
- 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 19 and over) with diagnosed or suspected early rectal cancer who, in the opinion of the referring clinician, are unsuitable for local removal using a flexible endoscope technique.

2.4 Any acceptance and exclusion criteria

The population covered will ordinarily be above the age of 50 and usually have been detected on the Bowel Cancer Screening Programme. However, younger patients with a genetic predisposition to bowel cancer may also be referred. It is unlikely that very young

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

adults will need this service, but referral through the primary MDT should enable equitable access. Nurse specialists from both the primary (referring) MDT and from the ERC MDT will act as key workers and ensure fair access to the service.

Commissioning for trans-anal endoscopic surgery shall be restricted to:

- Patients who have an early rectal cancer.
- Patients with rectal tumours which are suspicious of cancer without definite histology.

The criteria for referral shall be

- The rectal cancer (or suspicious neoplasm) is less than 3cm in size. There may be reasons when, exceptionally, a malignant lesion of greater than 3 cm is treated by these techniques (e.g. patient co-morbidity). This decision must be made by the MDT and the outcome audited for each case.
- The lesion is T1/T2 N0 M0 on magnetic resonance imaging (MRI) and preferably on endo-rectal ultrasound.
- The patient has been seen by a colorectal surgeon and has been fully discussed at the referring MDT.
- The patient's views on local excision have been sought after discussion of risks/benefits of more radical procedures.
- The patient is fit for the procedure.
- All necessary details are on a referral proforma signed by the chair of the referring MDT or consultant colleague on his behalf.

All patients referred would have been investigated, staged, discussed and counselled at the primary MDT. Referrals should be on an agreed proforma with the minimum dataset. This should be signed off by the chair of the primary MDT.

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

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 co-located on the same healthcare delivery site are:

- positron emission tomography - computed tomography (PET-CT) scanning facilities and other complex imaging services
- Histopathology

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.

This service is MDT based and relies on many specialities working together both in the primary (referring) MDT and the ERC MDT. It involves travel and possible treatment away from home which may need input from social services.

3. Applicable Service Standards

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

Trans anal endoscopic surgery services, (when performed for cancer) are required to meet Cancer Waiting Time standards. These are:

- Maximum two week wait for suspected cancers
- 31 day maximum wait from diagnosis to first definitive treatment
- 31 day maximum wait for subsequent treatment
- 62 day maximum wait from urgent GP referral or screening referral or consultant upgrade to first definitive treatment.

This is a very new treatment and there are no national standards yet. Most of these treatments are provided as part of clinical trials. The Association of Coloproctologists of Great Britain and Ireland (2007) have suggested that only T1 tumours less than 3 cm be treated by endo anal excision.

This is the reason for the recommendation that the patient is discussed at the local colorectal MDT as well as the specialised early rectal cancer MDT before treatment. The participating ERC MDTs should contribute to the National Bowel Cancer Audit (NBOCAP) as well as maintaining a detailed database of outcomes including local and systemic recurrence and need for salvage radical resections and their outcomes.

The ERC MDT should have an annual audit meeting dedicated to discussing outcomes. Referring MDTs should be invited to attend these meetings. Operational meetings should be held regularly to ensure smooth patient journey through the pathway.

4. Key Service Outcomes

Key Short term outcomes:

- All patients discussed at both MDTs and have a complete dataset
- R0 (complete resection) of T1/2 rectal tumours
- Very low 30 and 90 day mortality
- Very low intra peritoneal perforation rate
- A robust surveillance program set up for follow up for resected tumours
- Majority of cancer resections done as part of national trials
- All communication is completed within 48hrs of an MDT discussion

Key Long term outcomes

- Acceptable recurrence rates
- Recurrences detected at an early stage without compromising overall cure rates

Interim for adoption from 01/10/13