

Decision Summary

Meeting Date	27 March 2009		
Application #	09003N		
Title of TCP	Transanal Endoscopic Microsurgery (TEM)		
<input checked="" type="checkbox"/> New TCP	<input checked="" type="checkbox"/> Substitute/replacement for existing	<input type="checkbox"/> Extended use of existing	<input type="checkbox"/> Other
Transanal endoscopic microsurgery is a minimally invasive surgical technique, which is performed endoluminally and is optically enhanced (usually through stereoscopic vision). It is primarily used for the removal of certain lower and upper rectal tumours. This procedure was recommended by the Medical Services Advisory Committee (MSAC) ¹ and funding for the equipment is available from the Victorian Department of Human Services.			
CONFLICT OF INTEREST DECLARATION			
Applicant	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflict of interest	
Committee	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflict of interest from any TCPC members or invitees present	
SAFETY			
<input checked="" type="checkbox"/> Safer than current practice	<input checked="" type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	
The MSAC review notes that in the studies available there was no difference in the rate of complications between TEM and direct local excision for adenomas and carcinomas. In one non-randomised study there were significantly fewer complications with TEM than radical resection for a subgroup of patients with low risk carcinomas. No perioperative deaths were reported.			
EFFECTIVENESS			
High quality evidence?	The MSAC review notes the following: Adenomas: On the basis of one RCT, TEM appears to result in less local recurrence (6%) than direct local excision (22%). Relative risk 0.28 (95%CI 0.12, 0.66). The 6% rate of local recurrence for TEM in this trial is consistent with the rates found in TEM case series (5% median). (MSAC, 2003). Carcinomas: No difference in survival or local recurrence rate between TEM and anterior resection was detected in an RCT and a non-randomised comparative study.		
Consistent, clinically important benefit?	TEM appears to be more beneficial for adenomas but as effective as current practice for carcinomas		
Applicable to Southern Health?	Yes		
COST			
Funding received from DHS for capital outlay (\$40,000). The cost-effectiveness assessment in the MSAC review reports that the base case cost for treating an adenoma or carcinoma with TEM is considerably lower than local excision, anterior resection and abdominoperineal resection.			
CLINICAL FEASIBILITY			
Resource implications	This procedure can be performed within current resources. Expected decrease in number of bed days required. Expected increase in theatre time during learning curve.		
Credentialing and competency assurance undertaken	Colorectal Surgical Society of Australia and New Zealand developing guidelines for credentialing and scope of practice. Surgeon training scheduled for May 2009.		
Prof Bruce Waxman to undertake training and be credentialed initially. Surgical Program Director to develop credentialing guidelines for in-house training in future			
ISSUES RELATED TO ACCESS & EQUITY AND LEGAL & ETHICAL IMPLICATIONS			
Patient information to be developed. Eligibility criteria and referral algorithm to be developed. Internal education/dissemination program to be undertaken to inform colleagues of the approval of this new procedure and ensure that all eligible patients are referred to the credentialed surgeon. TEM expected to be introduced in September 2009.			

¹ Medical Services Advisory Committee (MSAC), 2003. *Transanal Endoscopic Microsurgery: Assessment Report*, MSAC Reference 15. Department of Human Services, Commonwealth of Australia.

Final decision by the Southern Health Technology/Clinical Practice Committee	
<input type="checkbox"/>	Recommended: Approved with no further need for assessment.
<input checked="" type="checkbox"/>	Restricted Recommendation – Audit: Approval subject to implementation under audit conditions. Conditions are specific to the technology.
<input type="checkbox"/>	Restricted Recommendation – Clinical Trial: Endorsed, however approval subject to implementation in clinical trial with Southern Health Human Research and Ethics Committee approval.
<input checked="" type="checkbox"/>	Restricted Approval – Operational Restrictions: Endorsed, however financial or operational restrictions apply.
<input type="checkbox"/>	Not Recommended
<p>Conditions</p> <ul style="list-style-type: none"> ▪ Data collection tool (spreadsheet/database) to be forwarded to TCPC ▪ Data to be collected on all patients and reports provided to TCPC at six monthly intervals for two years ▪ Adverse events to be reported immediately to TGA and TCPC <p>Special Conditions</p> <p>Prior to commencement of procedure:</p> <ul style="list-style-type: none"> ▪ Patient information to be submitted to TCPC for review by Consumer Representative ▪ Credentialing and scope of practice guidelines to be provided to TCPC and Credentialing Committee ▪ Eligibility criteria and referral algorithm to be submitted to TCPC and education/dissemination program undertaken 	

SH Policy	Quality and Risk Management	ACHS	Leadership and Management
Reviewer	Director, Centre for Clinical Effectiveness	Last review date	January 2008
Authoriser	Chair, Technology/Clinical Practice Committee	Next review date	August 2010

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