

Decision Summary

Meeting Date	Friday 6 November 2009		
Application #	09010V		
Title of TCP	Direct Peroral Cholangioscopy (Spyglass)		
<input checked="" type="checkbox"/> New TCP	<input type="checkbox"/> Substitute/replacement for existing	<input type="checkbox"/> Extended use of existing	<input type="checkbox"/> Other
<p>Spyglass direct cholangioscopy is a new technology that uses a miniature probe passed through the channel of an endoscope and into the bile duct. This procedure allows the operator to see inside the bile ducts and to more accurately diagnose and treat conditions that obstruct the bile duct such as stones (that cause abdominal pain, fever and blood infection) or strictures (narrowing) that can be benign or malignant (pancreatic and bile duct cancer/cholangiocarcinoma).</p> <p>This application was approved by the TCPC in 2007 subject to receipt of external funding. The application for VPACT funding was unsuccessful that year, however the Department of Health has invited Southern Health to resubmit based on more recent evidence. The TCPC has ratified the earlier decision to approve the application for submission to VPACT.</p>			
CONFLICT OF INTEREST DECLARATION			
Applicant	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflicts of interest to declare.	
Committee	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflicts of interest to declare.	
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		
General Conditions			
<p>a. The Head of Department/Unit is required to notify the Secretariat of TCPC in the event of:</p> <ul style="list-style-type: none"> ▪ Any change in protocol and the reason for that change together with an indication of ethical implications ▪ Adverse effects of the TCP and steps to deal with them ▪ Any unforeseen events <p>b. Adverse Events</p> <ul style="list-style-type: none"> ▪ If an adverse event occurs the Head of Department/Unit must immediately notify the TGA in addition to the TCPC. <p>c. Compliance with Quality Assurance (<i>must be completed prior to commencement of the TCP at Southern Health</i>)</p> <ul style="list-style-type: none"> ▪ Applicants are required to complete either the Quality Assurance supplement letter or a new Quality Assurance application (whichever is applicable) and forward to Southern Health HREC <p>d. Data Collection</p> <ul style="list-style-type: none"> ▪ Data to be collected in all patients receiving the new TCP and reports provided to TCPC. The TCPC will provide details of data required by DHS. <p>e. Reporting</p> <ul style="list-style-type: none"> ▪ Patient outcome reporting required at three monthly intervals; January – March, April – June, July – September, October – December; for a two year period. ▪ Progress reports required only at six monthly intervals; January – June and July – December; for a two year period.. ▪ Reports to be forwarded to TCPC Secretariat. TCPC to forward reports to DHS. <p>f. Review</p> <ul style="list-style-type: none"> ▪ At the conclusion of the two year period the original application will be reviewed by the TCPC to determine if it should be considered standard practice. 			
Special Conditions			
<p>g. Operational Restrictions</p> <ul style="list-style-type: none"> ▪ Approval of this TCP is subject to successful application for full funding. If only partial funding is received, applicants are required to notify the TCPC and the application will be reviewed prior to implementation. <p>h. Patient Information</p> <ul style="list-style-type: none"> ▪ Patient information must be submitted to the TCPC for review prior to commencement of the TCP 			