

Decision Summary

Meeting Date	Wednesday 8 April 2009		
Application #	09004V		
Title of TCP	Free light chain high cut off protein dialysis membrane		
<input type="checkbox"/> New TCP	<input checked="" type="checkbox"/> Substitute/replacement for existing	<input type="checkbox"/> Extended use of existing	<input type="checkbox"/> Other
The free light chain high cut off protein dialysis membrane is aimed at treating acute renal failure in the setting of multiple myeloma. The high cut off protein permeable membrane HCO1100 has pore sizes three times greater than that of the normal dialysis membrane, permitting the removal of larger molecules from the blood.			
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	
SAFETY			
<input type="checkbox"/> Safer than current practice	<input type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	
Limited information is available regarding safety of this procedure therefore no definitive conclusions could be drawn to determine if this new procedure carries any significant side effects or adverse events. This device has TGA approval.			
EFFECTIVENESS			
High quality evidence?	No comparative studies are available		
Consistent, clinically important benefit?	This treatment has the potential to reduce the dependence of patients on dialysis.		
Applicable to Southern Health?	Yes		
There is no high quality evidence regarding the clinical effectiveness of this procedure. Several pieces of low level evidence were found including some case series' which showed the HCO 1100 membrane may be effective in removing free light chains during dialysis and a small historical cohort which showed an increase in the number of patients becoming dialysis independent. No direct, comparative studies have been completed. A RCT is currently underway in Europe.			
COST			
Expected cost per patient is \$45,000. No specific cost-effectiveness studies were provided with this application. Significant outlay per procedure is required. Southern Health has been invited to participate in a joint application for external (VPACT) funding led by St. Vincent's.			
CLINICAL FEASIBILITY			
Resource implications	Adequate resources are available to perform these procedures if application is successful in VPACT funding.		
Credentialing and competency assurance undertaken	No credentialing or competency training beyond that of existing dialysis therapies is required		
This is feasible within current operational capacity with no additional associated service utilisation required.			
ISSUES RELATED TO ACCESS & EQUITY AND LEGAL & ETHICAL IMPLICATIONS			
If application for VPACT funding is successful, all eligible patients will be treated within current systems and under VPACT funding arrangements. Eligibility is based on clinical assessment and patient choice to undergo the procedure. There should be no limiting of patient numbers per year. Patient information is to be developed and provided to patients prior to obtaining informed consent. Patient information should state that Southern Health is offering this treatment as an alternative to standard treatment and that long term effects are unknown. Data to be collected on all patients via a renal unit registry and reports provided to TCPC at six monthly intervals.			

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. 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>d. Reporting</p> <ul style="list-style-type: none"> ▪ Reporting required 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>e. 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>f. Evaluation</p> <ul style="list-style-type: none"> ▪ Given the limited evidence of safety and effectiveness, the committee requires that the application is amended to reflect the establishment of a data registry across the participating health services that will provide the relevant data. <p>g. Patient Information</p> <ul style="list-style-type: none"> ▪ Patient information should include wording around 'this procedure is a new emerging treatment that is being offered to you as an alternative to current standard treatment' ▪ Patient information should include wording around the establishment of a registry to collect data on patients undergoing this new procedure ▪ Patient information to be submitted to TCPC for review by Consumer Representative prior to commencement of the procedure <p>h. Operational restrictions</p> <ul style="list-style-type: none"> ▪ Approval is conditional upon availability of full funding from VPACT for introduction of the new procedure (equipment and consumables) 	

SH Policy	Quality and Risk Management	ACHS	Leadership and Management
Reviewer	Director, Centre for Clinical Effectiveness	Last review date	April 2009
Authoriser	Chair, Technology/Clinical Practice Committee	Next review date	April 2011

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Please see the Southern Health Policy and Protocol intranet site for current policies, protocols and guidelines.