

### Decision Summary

<b>Name</b>	Natalizumab (Tysabri®)		
<b>Application</b>	08006	<b>TCPC meeting date</b>	Friday 14 March 2008
<b>Description</b>	<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>New drug for Multiple Sclerosis. To be used in patients with relapsing remitting MS (RRMS), patients with most severe symptoms who are not responding to standard treatment and who have had one or more relapse in the previous year.</p> <p>Use of this drug within Southern Health has been approved by the Therapeutics Committee. It has been referred to TCPC to consider cost and capacity of infusion services.</p>			
<b>Conflict of Interest Declaration completed</b>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	No conflict declared
<b>SAFETY</b>			
<input type="checkbox"/> Safer than current practice	<input type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	<input checked="" type="checkbox"/> Unclear
<p>Most side effects of natalizumab relate to infusion reactions, side effects of current treatments are flu-like symptoms and injection site reactions. Risk of progressive multifocal leucoencephalopathy with natalizumab (cited as 1:1000). Patients to be monitored clinically for signs of PML. No information is known about safety beyond 2 years</p>			
<b>EFFECTIVENESS</b>			
Quality of evidence	No head to head trials comparing natalizumab with current treatments. Two RCTs using natalizumab for RRMS are cited, but both studies excluded patients who had been on the treatments currently in use at SH. Therefore no evidence available in the population proposed (ie patients not responding to standard treatment)		
Consistency and clinical importance of benefits	Benefits of natalizumab compared with placebo in patients who have not received any of the treatments currently in use at SH include decreased progression of disease, decreased relapse rate and decreased new or enlarging lesions. But no information is available regarding use of natalizumab in patients who have received, and/or are not responding to, current treatment		
Applicability to Southern Health	Patient group for the available evidence is likely to be the same as SH patients with RRMS. However available evidence does not cover the patient group proposed for this application.		
Comments	No evidence available in the population proposed in this application		
<b>COST</b>			
<p>The manufacturer has agreed to provide funding until natalizumab is available through PBS. Before treatment can commence, a letter is required from the company stating that it will cover costs of the drug until it is available through PBS. Patients must be informed that SH will not fund this drug.</p> <p>Costs to pharmacy for infusion preparation to be compiled</p>			
Comments: Southern Health will not accept any patients without funding.			
<b>CLINICAL FEASIBILITY</b>			
Resource implications	Adequate resources will be available to admit these patients to the new Infusion Centre		
Credentialing and competency assurance undertaken	Medical and nursing staff involved in prescribing and delivering this medication have undertaken the required training		
Comments: There is adequate operational capacity and capability to implement this new process			
<b>PATIENT INFORMATION AND CONSENT FORM</b>			
<p>The patient information sheet needs to be amended to include a statement that SH will not fund this drug in the event that the manufacturer no longer provides it free of charge</p> <p>The consent form needs to be amended so that the warning information and signatures are on the same sheet of paper. Currently warning on one page and signatures on the other. Pages can be separated. As the first page is just a graphic and the last page is blank, the box highlighting the warning and the consent form itself could be combined on one double-sided A4 sheet</p>			
<b>ISSUES RELATED TO ACCESS &amp; EQUITY AND LEGAL &amp; ETHICAL IMPLICATIONS</b>			
<p>Patient group, clinical indications and treatment regimen to be outlined in a protocol provided to Therapeutics Committee. Six monthly ongoing monitoring of patient outcomes to be undertaken. Plan for monitoring to be provided to Therapeutics Committee.</p> <p>All patients who meet indications should be treated. Treatment should not be restricted by quota (ie number of cases per year). Application for Authorised Prescriber status to go to SH Human Research Ethics Committee (HREC).</p>			

Final decision by the Southern Health Technology/Clinical Practice Committee	
<input type="checkbox"/>	<b>Recommended:</b> Approved with no further need for assessment.
<input type="checkbox"/>	<b>Restricted Recommendation – Audit:</b> Approval subject to implementation under audit conditions. Conditions are specific to the technology.
<input type="checkbox"/>	<b>Restricted Recommendation – Clinical Trial:</b> Endorsed, however approval subject to implementation in clinical trial with Southern Health Human Research and Ethics Committee approval.
<input checked="" type="checkbox"/>	<b>Restricted Approval – Operational Restrictions:</b> Endorsed, however financial or operational restrictions apply.
<input type="checkbox"/>	<b>Not Recommended</b>
Conditions to be fulfilled prior to final approval <ul style="list-style-type: none"> <li>▪ Patients cannot be treated at SH unless funding is provided               <ul style="list-style-type: none"> <li>– Written confirmation from manufacturer that they will continue to fund this drug is required</li> <li>– Patients must be informed in writing that SH will not fund this treatment</li> </ul> </li> <li>▪ Consent form needs to include the warning on the same piece of paper as the signatures</li> <li>▪ Written protocol for use of natalizumab to be provided to the Therapeutics Committee</li> <li>▪ Plan for ongoing monitoring of patient outcomes to be provided to Therapeutics Committee</li> <li>▪ Authority prescriber status to be approved by SH HREC</li> </ul> Final approval and ongoing monitoring to be undertaken by Therapeutics Committee. No further action by TCPC	

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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