

Exceptional Circumstances Prescribing Procedure

**Approved by Orkney NHS Board Orkney Clinical
Governance Committee: Draft 1**

Review Date: December 2011

Responsible Officer: Medical director

NHS Orkney

Area Drug & Therapeutic Committee

Draft Procedure for Exceptional Circumstances Prescribing

NHS Scotland national policy on the introduction of new drugs is for Boards to take advice from the Scottish Medicines Consortium (SMC) through the adoption of local formularies. NHS Guidance in 2007 stated that NHS Boards should have processes in place to consider non-NHS formulary treatment requests, and one of (and arguably the fairest) means for this was for Boards to have Exceptional Cases Panels in place. This procedure is written for NHS Orkney to deal with the potential for patients or clinicians to ask for funding for medicines that have not been recommended by the SMC, or for use outside of SMC recommendation, or for use before SMC has published its decision. It will also be used as the local process for considering the provision of orphan drugs within the national risk sharing scheme (a very small number of which are not SMC approved).

Orkney NHS Board will usually fund new medicines only within SMC guidelines. If a patient or clinician seeks funding for a new medicine outwith SMC guidance the supporting clinician should apply in writing to the Medical Director. The application should include:

- Details of the drug including indication, regime and cost
- Details of the named patient for whom the application is being made including specific details of the relevant condition.

The application should specify how the patient's circumstances are exceptional in variation to the SMC recommendation to justify the new drug and evidence of reasonable expectations of success, such as published trial evidence in terms of for instance being part of a specific population sub-group, or having specific target characteristics with different efficacy or effectiveness to justify a decision to fund.

A submission from a clinician must include evidence of peer support and written consent from the patient for the application.

The Medical Director will seek advice on the application from the Orkney Exceptional Cases Panel for this purpose, who may seek additional relevant clinical advice in support of its consideration.

Any Application will be responded to within one calendar month. If necessary an extraordinary meeting of the panel will be convened to consider an application. The panel will consist of members drawn from the AD and TC and as a minimum will include the medical director or authorised deputy who will be a doctor the pharmacy director or authorised deputy, who will be a pharmacist. A lay member must also be present. The meeting can be conducted by telephone or email.

Responses to applications will be made available anonymised as public information in line with Freedom of Information requirements and published on a quarterly basis on the Boards web site (subject to patient confidentiality precautions). Decisions will also be reported to the Board via the Director of Pharmacy's Annual Report.

An appeal against any decision can be made in writing to the Board's Chief Executive who will seek advice from the Board's Clinical Governance Committee and appropriate external clinicians in responding to the appeal.

1. Rapid Impact Checklist Orkney NHS Board

Procedure for Exceptional Case Prescribing

<p>Which groups of the population do you think will be affected by this proposal?</p> <ul style="list-style-type: none"> • minority ethnic people (incl. gypsy/travellers, refugees & asylum seekers) • women and men • people in religious/faith groups • disabled people • older people, children and young people • lesbian, gay, bisexual and transgender people 	<ul style="list-style-type: none"> • people of low income • people with mental health problems • homeless people • people involved in criminal justice system • staff 	<p>Other groups:</p> <p>Potentially all, but none disproportionately.</p>
<p>N.B. The word proposal is used below as shorthand for any policy, procedure, strategy or proposal that might be assessed.</p>	<p>What positive and negative impacts do you think there may be?</p>	
<p>What impact will the proposal have on lifestyles? For example, will the changes affect:</p> <ul style="list-style-type: none"> • Diet and nutrition? • Exercise and physical activity? • Substance use: tobacco, alcohol or drugs? • Risk taking behaviour? • Education and learning, or skills? 	<p>Which groups will be affected by these impacts?</p> <p>Not directly. The procedure should ensure fair and equitable distribution of resources, with decisions made in a transparent and consistent way. It may have direct impact on the lifestyle of an individual in terms of quality of life if a potentially health improving medicine is not approved as an exceptional case, alternatively it may ensure that resources aimed at the larger number of the population receiving services are used to best effect, so indirectly having a positive impact on a greater number of individuals.</p>	
<p>Will the proposal have any impact on the social environment? Things that might be affected include</p> <ul style="list-style-type: none"> • Social status • Employment (paid or unpaid) • Social/family support • Stress • Income 	<p>Individual decisions made within the procedure may have an impact on the social environment of the individual in terms of how their health impacts on their social environment, again the procedure should ensure that these decisions are made fairly and transparently.</p>	
<p>Will the proposal have any impact on</p> <ul style="list-style-type: none"> • Discrimination? • Equality of opportunity? • Relations between groups? 	<p>The procedure should ensure that decisions are made based on need and evidence rather than on emotional weight, which should reduce discrimination against people whose voice is less well heard. It should protect against the disproportionate use of resources to individual demand as opposed to need.</p>	
<p>Will the proposal have an impact on the physical environment? For example, will there be impacts on:</p> <ul style="list-style-type: none"> • Living / working conditions? • Pollution or climate change? • Accidental injuries or public safety? • Transmission of infectious disease? 	<p>No</p>	
<p>Will the proposal affect access to and experience of services? For example,</p> <ul style="list-style-type: none"> • Health care • Transport • Social services • Housing services • Education 	<p>Yes, the proposal may affect access to services in terms of funding, but is designed to bring fairness and transparency to this one aspect of decision making on resource allocation.</p>	

Rapid Impact Checklist: Summary Sheet

Positive Impacts (Note the groups affected)	Negative Impacts (Note the groups affected)
<p>Should ensure fairness and transparency in decision making.</p> <p>Should avoid the disproportionate use of resources to meet individual demand as opposed to need, or the need of one individual compared to wider community needs, and should encourage a more evidence – informed approach to decision making on the exceptional use of medicines.</p>	<p>There may be individuals who are denied treatment that is not cost-effective or where the evidence shows that the cost is disproportionate to the benefit of a specific treatment.</p>
Additional Information and Evidence Required	
<p>Recommendations</p> <p>There are no specific recommendations.</p>	
<p style="text-align: center;">From the outcome of the RIC, have negative impacts been identified for race or other equality groups? Has a full EQIA process been recommended? If not, why not?</p> <p>No specific impacts on equality groups has been identified, and therefore a full EQIA process is not recommended.</p>	

Manager's Signature:

Date: 2008