SPECIALISED COMMISSIONING - CLINICAL EVIDENCE EVALUATION CRITERIA FOR CLINICAL COMMISSIONING POLICY PROPOSITION

URN: 1827
TITLE: Ablative surgery, moulage technique brachytherapy and surgical reconstruction (AMORE) for head and neck soft tissue sarcoma in children and young people
CRG:
NPOC: Cancer
Lead:
Date: 21 November 2018

This policy is being considered for:	For routine commissioning	X	Not for routine commissioning	
Is the population described in the policy similar to that in the evidence reviewed, including subgroups?	The policy was restricted to Rhabdomyosarcoma as this was the diagnosis in the study participants. The main studies were all based on a cohort of patients treated in England and Amsterdam. The cohort was recruited over 20 years.			
Is the intervention described in the policy similar to the intervention for which evidence is presented in the evidence review?	Panel noted that the interventions would be unlikely to have remained constant over the study period. In particular, radiotherapy techniques have changed very greatly over the 20 years of the study period and it is unclear whether potential advantages of brachytherapy in the AMORE treatment cohort would persist compared with modern radiotherapy techniques used in standard treatment.			
Are the comparators in the evidence reviewed plausible clinical alternatives within the NHS and are they suitable for informing policy development?	The comparator was standard treatment in an English centre. The comparator and possibly the intervention would be expected to change over the study period.			
Are the clinical benefits described in the evidence review likely to apply to the eligible population and/or subgroups in the policy?	This is not clear. The evidence is derived from a prospective, non-randomised study of cohorts of head and neck rhabdomyosarcoma patients who were treated either in Amsterdam, where AMORE was available as a treatment option (n=49), or in London where AMORE was not available (n=31). The potential benefits are limited to adverse events avoided as the failure free survival, overall survival and health related quality of life show no statistically significant differences between the groups.			
Are the clinical harms described in the evidence review likely to apply to the eligible and /or ineligible population and/or subgroups in the policy?	The harms are similar between the groups; although there are reported differences between the groups in terms of burden of adverse events. The number of survivors with a burden score of severe or high was similar between the treatment centres, but more Amsterdam cohort survivors had a burden score of low or none. Clinical Panel determined that given that the evidence is limited to cohort studies in the same treatment populations, and the likely changes in treatment over time, it was not possible to have any degree of certainty that AMORE offered a significant advantage over current treatment regimens.			

<table>
<tr><td>The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover:
• Balance between benefits and harms
• Quality and uncertainty in the evidence base
• Challenges in the clinical interpretation and applicability of policy in clinical practice
• Challenges in ensuring policy is applied appropriately
• Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review.</td><td colspan="3">Panel considered that AMORE is not one intervention but a method of delivering a set of interventions (including brachytherapy) in a particular way. The shortened duration of treatment may offer some advantages, although there may also be disadvantages if the treatment is more intensive. These potential benefits / disbenefits were not demonstrated in the studies. Panel also noted that Proton Beam Therapy (PBT) might need to be taken into account as a potential option in the pathway of care. Panel determined that the evidence base was insufficient to justify a routine clinical commissioning policy.

Clinical Panel determined that a ‘not for routine commissioning’ clinical commissioning policy should be produced. The strength of evidence was insufficient to support a for routine clinical commissioning policy position. Panel recognised that there may be some potential advantages in organising treatment in a manner similar to that delivered by the Amsterdam service. However, this was not demonstrated by the research available. Panel were informed that ‘AMORE’ is only delivered in Amsterdam and treatment may not be delivered in this way anywhere else in the world. This itself raised questions about why ‘AMORE’ had not been adopted elsewhere. An evaluative approach may be an option. Any future evaluation or service development approach should take account of options including PBT as part of the treatment pathway and look at other models of good practice in other centres of excellence in order to ensure that fully informed decisions are made on the treatment model to be evaluated.

Clinical Panel advised that the outcome from Clinical Panel is considered by the Programme of Care for consideration of next steps. Supporting further research / evaluation could be considered.</td></tr>
<tr><td rowspan="4">Overall conclusion</td><td rowspan="2">This is a proposition for routine commissioning and</td><td>Should proceed for routine commissioning</td><td></td></tr>
<tr><td>Should be reversed and proceed as not for routine commissioning</td><td>Yes</td></tr>
<tr><td rowspan="2">This is a proposition for not routine commissioning and</td><td>Should proceed for not routine commissioning</td><td></td></tr>
<tr><td>Should be reconsidered by the PWG</td><td></td></tr>
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Report approved by:
David Black
Deputy Medical Director
19 December 2018