

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA185; Trabectedin for the treatment of advanced metastatic soft tissue sarcoma**

This guidance was issued February 2010 with a review date of February 2013.

**Background**

At the GE meeting of 15 January 2013 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<b>Proposal put to consultees:</b>	The guidance should be transferred to the 'static guidance list'.
<b>Rationale for selecting this proposal</b>	As no changes to the marketing authorisation or costs are known, and no changes to the evidence base have emerged or are expected, it is proposed that TA185 be transferred to the 'static guidance list'.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

<b>Recommendation post consultation:</b>	The guidance should be transferred to the 'static guidance list'.
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
Sarcoma UK	Agree	<p>We support the proposal to move TAG No 185 to the static list. We recognise that it may again be considered for review whenever new evidence is published or new technologies are registered which may affect the clinical use of trabectedin.</p> <p>We are not aware of research evidence which might significantly alter the rationale on which this Guidance is based.</p> <p>We are aware of current studies using trabectedin in both second and first-line treatment which may produce evidence of significance. These studies are recruiting or awaiting analysis and there are no predicted dates of which we are aware for publication of results. We are also aware of studies of new agents (completed, underway and planned) which may affect the treatment options for patients with advanced sarcoma. These studies are all noted in your Appendix B.</p>	Comments noted.
Bath & North East Somerset, and Wiltshire PCT Cluster	Agree	<p>We have reviewed the evidence, and requested input from our provider acute trusts. Having done this, we are pleased to confirm that we have no new evidence to contribute, and we are satisfied with the approach taken by the NICE.</p>	Comments noted.

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
National Cancer Research Institute Royal College of Physicians Royal College of Radiologists Association of Cancer Physicians	Agree	The NCRI/RCP/RCR/ACP/JCCO agree with the NICE proposal that the guidance should be transferred to the 'static guidance list'. Our experts agree that no new relevant evidence has been published	Comment noted.
Royal College of Nursing	No comment	Feedback received from nurses working in this area of health suggest that there is no additional evidence to submit on behalf of the RCN to inform the development of this guidance, other than what can be found in systematic reviews.	Comment noted.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
PharmaMar	Agree	<p>PharmaMar agrees with the proposed list of stakeholders.</p> <p>PharmaMar agrees with the contents of the review to the Technology Appraisal Guidance 185 except for the information included in Section 8 “implementation”. We would like to indicate that the sales figures for trabectedin described in this section are not accurate. Monthly sales of trabectedin for the period September 2010 to January 2012 ranged from £83,374 (December 2011) and £302,985 (September 2010). Monthly sales for the same period averaged £184,985.</p> <p>These sales incorporate the patient access scheme for trabectedin in soft tissue sarcoma and are fully audited. It should be noted that sales are only soft tissue sarcoma prescriptions.</p>	<p>Comments noted. The figures in section 8 were taken from Hospital Pharmacy Audit Index data on the Net Ingredient Cost (NIC) and volume of trabectedin prescribed and dispensed in hospitals in England between January 2008 and March 2012 (see Appendix 3 of the decision paper for further details). It is also noted that the figures do not refer to the volume of trabectedin prescribed for soft tissue sarcoma only but cover all indications for which trabectedin is licensed.</p>

**No response received from:**

<p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> <li>• Afiya Trust</li> <li>• Black Health Agency</li> <li>• Cancer 52</li> <li>• Cancer Black Care</li> <li>• Cancer Equality</li> <li>• Equalities National Council</li> </ul>	<p><u>General</u></p> <ul style="list-style-type: none"> <li>• Allied Health Professionals Federation</li> <li>• Board of Community Health Councils in Wales</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for</li> </ul>
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<ul style="list-style-type: none"> <li>• Helen Rollason Heal Cancer Charity</li> <li>• Independent Age</li> <li>• Macmillan Cancer Support</li> <li>• Maggie’s Centres</li> <li>• Marie Curie Cancer Care</li> <li>• Muslim Council of Britain</li> <li>• Muslim Health Network</li> <li>• National Council for Palliative Care</li> <li>• Rarer Cancers Foundation</li> <li>• South Asian Health Foundation</li> <li>• Specialised Healthcare Alliance</li> <li>• Sue Ryder</li> <li>• Tenovus</li> </ul> <p><u>Professional groups</u></p> <ul style="list-style-type: none"> <li>• British Association for Services to the Elderly</li> <li>• British Geriatrics Society</li> <li>• British Institute of Radiology</li> <li>• British Orthopaedic Association</li> <li>• British Orthopaedic Oncology Society</li> <li>• British Psychosocial Oncology Society (BPOS)</li> <li>• British Sarcoma Group</li> <li>• Cancer Network Pharmacists Forum</li> <li>• Cancer Research UK</li> <li>• Royal College of General Practitioners</li> <li>• Royal College of Pathologists</li> <li>• Royal Pharmaceutical Society</li> <li>• Royal Society of Medicine</li> <li>• Society and College of Radiographers (SCoR)</li> <li>• United Kingdom Clinical Pharmacy Association</li> </ul>	<p>Northern Ireland</p> <ul style="list-style-type: none"> <li>• Healthcare Improvement Scotland</li> <li>• Medicines and Healthcare Products Regulatory Agency</li> <li>• National Association of Primary Care</li> <li>• National Pharmacy Association</li> <li>• NHS Alliance</li> <li>• NHS Commercial Medicines Unit</li> <li>• NHS Confederation</li> <li>• Public Health Wales NHS Trust</li> <li>• Scottish Medicines Consortium</li> </ul> <p><u>Comparator manufacturers</u></p> <ul style="list-style-type: none"> <li>• None</li> </ul> <ul style="list-style-type: none"> <li>• <u>Relevant research groups</u></li> <li>• Institute of Cancer Research</li> <li>• MRC Clinical Trials Unit</li> <li>• National Cancer Research Network</li> <li>• National Institute for Health Research</li> <li>• Research Institute for the Care of Older People</li> </ul> <p><u>Assessment Group</u></p> <ul style="list-style-type: none"> <li>• Assessment Group tbc</li> <li>• National Institute for Health Research Health Technology Assessment Programme</li> </ul> <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> <li>• National Collaborating Centre for Cancer</li> </ul> <p><u>Associated Public Health Groups</u></p>
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<ul style="list-style-type: none"> <li>• United Kingdom Oncology Nursing Society</li> </ul> <p><u>Others</u></p> <ul style="list-style-type: none"> <li>• Department of Health</li> <li>• Southampton, Hampshire, Isle of Wight &amp; Portsmouth PCT Cluster</li> <li>• Welsh Government</li> </ul>	<ul style="list-style-type: none"> <li>• None</li> </ul>
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**GE paper sign-off:** Elisabeth George, Associate Director – Technology Appraisals Programme

**Contributors to this paper:**

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