

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA159; Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin

This guidance was issued in October 2008.

The guidance was considered for review in November 2011. In January 2012 it was decided to defer the consideration of the review until the end of 2013.

Background

At the GE meeting of 12 November 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.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list'.
Rationale for selecting this proposal	The new evidence for use of spinal cord stimulation in neuropathic pain supports the recommendation in TA159. The new evidence for use of spinal cord stimulation in pain of ischaemic origin is not sufficiently robust to impact on the current recommendations. It is therefore proposed that TA159 be placed on the static list until such time that further evidence is made available.

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.

Recommendation post consultation:	The guidance should be transferred to the 'static guidance list'.
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Physicians	Agree	The RCP agrees with this proposal. At present there is not enough new information to warrant review.	Comment noted. No action required.
Neuromodulation Society	Agree	<p>The Neuromodulation Society of the UK and Ireland (NSUKI) is broadly in agreement with the proposed transfer of the guidance to the static list.</p> <p>We agree that the evidence generated since the original guidance was issued in 2008 is unlikely to change the guidance radically at this stage.</p> <p>We however would like to point out some potential amendments required to your document:</p> <ol style="list-style-type: none"> 1. You note that 1 new company has obtained a CE mark since the original guidance (Spinal Modulation) as a matter of fact 3 new companies have now obtained a CE mark (Nevro, Spinal Modulation and StimWave Technologies 	Comments noted. Future NICE documentation will reflect the new CE mark holders and the published studies.

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		<p>(http://112.196.7.252/stimwave/html/)</p> <p>2. The study Analgesic Efficacy of High Frequency Spinal Cord Stimulation: a Placebo-controlled Study has already published (ref below)</p> <p>Perruchoud C, Eldabe S, Batterham AM, Madzinga G, Brookes M, Durrer A, Rosato M,</p> <p>Bovet N, West S, Bovy M, Rutschmann B, Gulve A, Garner F, Buchser E.</p> <p>Analgesic efficacy of high-frequency spinal cord stimulation: a randomized double-blind placebo-controlled study. <i>Neuromodulation</i>. 2013 Jul-Aug;16(4):363-9;</p> <p>Finally the figures quoted from your national audit showing the impact of the TA159 guidance contradicts our own findings of little impact of the guidance up to 2011/12; in our assessment shortly to be published in the BMJ online we record different findings using the OPCS codes specific to the implant procedure A48.3 and A48.7 these return a static figure of around 1000 new implants per year. I note that unlike your assessment we exclude codes for revision and reprogramming and attempt to separate trials from final stage implants so as to avoid duplication. We also have excluded Sacral Nerve Stimulation through indication review. I</p>	<p>Comment noted. Future review proposals will take into consideration the codes suggested and will refer your comments to NICE's Implementation and Audit team in order to consider how to improve the level of uptake for TA 159.</p>

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		believe if the above are taken into account you would arrive at a different conclusion regarding the impact of the guidance	
Association of British Neurologists	Agree	<p>This is a continuing positive recommendation for Neuropathic pain. The TA159 will continue without further review unless new evidence is available.</p> <p>I don't think there is enough new information out there yet to warrant a further review. Perhaps in two years we will have the RCT data on the new frequency stims.</p>	Comments noted.
Boston Scientific	Agree	<p>Boston Scientific is in agreement with the decision to put TA159 on the static list</p> <p>However we would like to make the following comment: Annex 3 makes for a worrying read – number of procedures for SCS is very low in the UK, and despite a modest increase following the 2008 publication, there has been a reduction recently. We would like to suggest that – in conjunction with being placed on the static list – there is an implementation project focused on SCS carried out by NICE. We would also like to suggest that the reduction in implants is brought to the attention of NHS England Clinical Reference Group on Complex Pain.</p>	Comment noted. The Technology Appraisals team will refer these comments to NICE's Implementation and Audit team.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
British Cardiovascular Society	Agree	<p>TA 159 refers to the use of spinal cord stimulation (SCS) in the management of chronic pain of neuropathic or ischaemic origin. The technology appraisal is dated 2008, and is marked as due for review in Nov 2011. There does not appear to be an updated document available on the NICE website. There is a link to 'Spinal Cord Stimulation for refractory angina' however this marked as 'not in remit', and has not been update since 2010. I will only comment on data pertaining to the use of SCS in refractory angina.</p> <p>The evidence was also reviewed by the British Pain Society in 2009, and their recommendations are available for download (http://www.britishpainsociety.org/pub_professional.htm#spinalcord)</p> <p>A PubMed search from 2007-2013 reveals no further randomised controlled trial data in this area. There are plans for a RCT, the hypothesis and research plan have been published (Eldabe S).</p> <p>In the absence of new data in the field of SCS for refractory angina TA 159 should be placed on the static list. The data emerging from the RCT may be valuable in informing practice.</p>	Comments noted.

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NHS England	Agree	<p>I am responding on behalf of NHS England and specifically specialised commissioning. I can confirm that I have discussed the proposal below with the following clinical reference groups Specialised Pain, Complex Spinal Surgery, Neurosurgery. Their membership can be found at the following web address;</p> <p>http://www.england.nhs.uk/resources/spec-comm-resources/npc-crg/group-d/</p> <p>They are all in agreement that no new evidence has come to light that would lead to a change in the existing recommendations so they support the proposal to not review TAG159 at this current time.</p> <p>Two specific comments which I have said I would feedback to you is that;</p> <ul style="list-style-type: none">a) In the Matrix of Stakeholders” that the Neuromodulation Society should be included and for in any future stakeholder matrix relating to reviews of neuromodulation devices.b) Members felt the proposal was a very comprehensive document and presented the position clearly.	<p>Comments noted.</p> <p>Comment noted. The Neuromodulation Society has now been included in the matrix for this review proposal and it has provided comment to the proposal.</p> <p>Comment noted.</p>

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Royal College of Nursing	Agree	<p>The RCN notes NICE's report that no new evidence has come to light that would lead to a change in the existing recommendations.</p> <p>The RCN is equally not aware, at this stage, of any new evidence that would change the recommendations on the use of this technology. We would, therefore, support the proposal to transfer this guidance to the static list.</p> <p>We note that topics on the static list may be transferred back to the active list for further appraisal if new evidence becomes available that is likely to have a material effect on the last guidance issued.</p>	Comment noted.
Medtronic	Agree	<p>We support the proposal to transfer TAG 159 to the static list based on the rationale that no further landmark trials are anticipated that will impact upon the current guidance. The evidence base on the clinical and cost-effectiveness of standard spinal cord stimulation (SCS) techniques for neuropathic pain is robust and comprehensive therefore transferring this TAG to the static list is an appropriate course of action.</p> <p>It is important to note, however, that the uptake of SCS in terms of the number of new patients being treated with this procedure is still below</p>	<p>Comment noted.</p> <p>Comment noted. The Technology Appraisals team will refer these comments</p>

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		<p>the level of uptake recommended in the TAG 159 publication. Although the GE report (Appendix 3) documents that the TAG-recommended levels were attained in 2008-09, this Hospital Episodes Statistics (HES) data analysis includes all SCS-related procedures including trials, lead revisions and battery replacements, and does not reflect the number of new patients being treated with SCS. Closer examination of the HES data indicates that there were only around 550 new SCS implants conducted in 2011-12 for a neuropathic pain indication, equating to approximately 11 implants per million of the population in England, which is just over half of the NICE TAG 159 recommended uptake for new patients (Vyawahare et al., 2013, manuscript accepted for BMJ Open). We hope that by transferring the TAG 159 to the static list will help to reinforce the well-accepted clinical and cost-effectiveness of SCS as a standard treatment for neuropathic pain, thereby assisting greater uptake of this therapy in line with the TAG recommendations.</p>	<p>to NICE's Implementation and Audit team.</p>
Nevro	No comment	We have no comment to make on the proposal to move TA159 to the static list.	Comment noted.

No response received from:

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none">• Boston Scientific• St. Jude Medical (UK) <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none">• Action on Pain• Afiya Trust• Arachnoiditis Neuropathic Pain Information and Support• Arthritic Association• Arthritis Care• Arthritis and Musculoskeletal Alliance (ARMA)• Back Care• BASIC• Black Health Agency• Blood Pressure UK• Brain and Spine Foundation• Cardiac Risk in the Young• Coalition of Ankylosing Spondylitis Patients• Diabetes UK• Disability Rights UK• Equalities National Council• Fibro Action• Fibromyalgia Association UK• Herpes Viruses Association & Shingles Support Society• Leonard Cheshire Disability• Muslim Council of Britain• Muslim Health Network• National Ankylosing Spondylitis Society• National Osteoporosis Society	<p><u>General</u></p> <ul style="list-style-type: none">• Allied Health Professionals Federation• Association of British Healthcare Industries• Board of Community Health Councils in Wales• Care Quality Commission• Commissioning Support Appraisals Service• Department of Health, Social Services and Public Safety for Northern Ireland• EUCOMED• Healthcare Improvement Scotland• Medicines and Healthcare Products Regulatory Agency• National Association of Primary Care• National Pharmacy Association• NHS Alliance• NHS Commercial Medicines Unit• NHS Confederation• Scottish Medicines Consortium• Wales Neurological Alliance <p><u>Comparator manufacturer(s)</u></p> <ul style="list-style-type: none">• Boston Scientific• Medtronic• St. Jude Medical (UK) <p><u>Relevant research groups</u></p> <ul style="list-style-type: none">• Antithrombotic Trialists' (ATT) Collaboration• Arthritis Research UK• Bone Research Society• British Society for Cardiovascular Research
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- National Rheumatoid Arthritis Society
- Network of Sikh Organisations
- Neurological Alliance
- Neuropathy Trust
- Pain Concern
- Pain Relief Foundation
- Pain UK
- Pelvic Pain Support Network
- Somerville Foundation
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Spinal Injuries Association
- STEPS Charity Worldwide

Professional groups

- Association of Anaesthetists
- Association of Surgeons of Great Britain and Ireland
- Brain and Spine Foundation
- British Association for Nursing in Cardiovascular Care
- British Atherosclerosis Society
- British Cardiac Intervention Society
- British Geriatrics Society
- British Health Professionals in Rheumatology
- British Heart Foundation
- British Hip Society
- British Institute of Musculoskeletal Medicine
- British Institute of Radiology
- British Nuclear Cardiology Society
- British Orthopaedic Association
- British Pain Society

- Cardiac and Cardiology Research Dept, Barts
- Cochrane Heart Group
- Chronic Pain Policy Coalition
- Cochrane Musculoskeletal Group
- Cochrane Peripheral Vascular Diseases Group
- European Council for Cardiovascular Research
- Health Research Authority
- MRC Clinical Trials Unit
- National Heart Research Fund
- National Institute for Health Research
- Research Institute for the Care of Older People
- Society for Back Pain Research
- Wellcome Trust

Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline groups

- National Clinical Guideline Centre

Associated Public Health groups

- Public Health England
- Public Health Wales NHS Trust

- British Psychological Society
- British Scoliosis Society
- British Society for Rheumatology
- British Society of Cardiovascular Imaging
- British Society of Rehabilitation Medicine
- British Society of Skeletal Radiologists
- Chartered Society of Physiotherapy
- College of Occupational Therapists
- Physiotherapy Pain Association
- Primary Care Cardiovascular Society
- Primary Care Rheumatology Society
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal College of Surgeons
- Royal Society of Medicine
- Society for Cardiological Science and Technology
- Society of Cardiothoracic Surgeons
- UK Health Forum
- United Kingdom Clinical Pharmacy Association
- Vascular Society

Others

- Department of Health
- NHS East and North Hertfordshire CCG
- NHS Southern Derbyshire CCG
- Welsh Government

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