National Institute for Health and Care Excellence

IP2024 Targeted Muscle Reinnervation for managing limb amputation pain

IPAC date: 3rd April 2025

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1.	Consultee 1 BAPRAS Trauma SIAG (British Association of Plastic, reconstructive and Aesthetic Surgery Trauma)	1	Response of the Trauma Special Interest Advisory Group of the British Association of Plastic Reconstructive & Aesthetic Surgeons to: NICE Interventional Procedures Consultation Document – Targeted Muscle Reinnervation for Managing Limb Amputation Pain February 20th 2025 Authors: [redacted] and [redacted] on behalf of the Members of the Trauma SIAG. Patients may require amputation of a limb for a variety of reasons including trauma, cancer, vascular disease and infection. A proportion of these patients will develop phantom limb pain, residual limb pain, or both. These conditions cause substantial suffering, can be difficult to treat, and in many cases persist despite treatment. Targeted muscle reinnervation (TMR) is a surgical procedure which may be offered to patients as treatment for these types of pain following amputation (secondary TMR), or to patients	Thank you for your comment. The committee discussed this comment but decided not to change the main recommendations because they concluded there are still uncertainties about the procedure that warrant further data collection.

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			undergoing amputation to reduce the risk of residual and phantom limb pain developing (primary TMR). We welcome the examination of this procedure by the NICE Interventional procedures Advisory Committee but, as a key stakeholder association, members of which are actively involved in amputation surgery, the surgical care of patients with complex amputations, peripheral nerve surgery, and the surgical management of pain, we are disappointed that the views of this association are not more actively reflected in the draft guidance published in January 2025. The following responses to this draft guidance were formulated during a series of discussions during February 2025, culminating in an online meeting of the Trauma Special Interest Advisory Group on February 20th. With regard to TMR for treatment of intractable pain that develops after limb amputation: 1. TMR for treatment of intractable pain that develops after limb amputation (secondary TMR) already has wide, international, adoption into surgical practice and can be considered a standard of care treatment alongside an armamentarium of longer-established techniques. This is supported by evidence of efficacy and safety, which the committee have reviewed. We recognize the paucity of level I and II evidence but nonetheless believe the collective weight of evidence is sufficient that suitably trained, educated and experienced surgeons should be free to offer this to appropriately selected patients within a standard audit and governance framework without special arrangements.	

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			With regard to TMR to prevent intractable pain from developing after limb amputation (primary TMR): 1. Primary TMR is already offered to selected patients in a number of hospitals across the United Kingdom. The evidence supporting this is less extensive than for secondary TMR, but does demonstrate reduction in the risk of phantom and residual limb pain (in comparison to amputation without TMR) with very little evidence of harm. 2. Chronic pain (both phantom and residual limb) have profound negative effects on quality of life for effected patients. The associated societal and direct healthcare costs are considerable, and treatment often prolonged and frequently ineffective. The benefits of a preventative approach should therefore receive asymmetric weighting in the absence of clear evidence of TMR-related harm. 3. The published literature likely overestimates the time-cost of primary TMR. In contrast to published studies where amputations with and without TMR are likely performed by the same surgeon, or surgeons of comparable experience, the majority of routine amputations are currently performed by surgeons of varied experience level, while amputations with TMR are uniformly performed by a small number of highly trained and experienced surgeons. 4. Further research to optimize patient selection would be beneficial, and there is wide support for a UK-based, multi-centre trial to address this and other questions. Currently there is consensus amongst members currently	

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			performing primary TMR that it be offered to patients at elevated risk of developing phantom or residual limb pain (chiefly those with established pain pathology such as following failed limb reconstructive surgery), and those for whom the global cost of developing intractable pain would be greatest (chiefly young, high physical demand patients expected to mobilise well with prosthetic rehabilitation) but the potential was noted that some patients who would not go on to develop troublesome pain may receive TMR, and would therefore have been overtreated. On the basis of these factors, and the collective experience of this group in amputation surgery and the surgical management of pain, our strong recommendation is that the Interventional Procedures Advisory Committee consider revising this guidance to recommend that TMR to prevent intractable pain from developing after limb amputation remain available in the NHS while more evidence is generated, and that it be used with special arrangements for clinical governance, consent, and audit or research. We believe that this position more accurately reflects current national and international practice, supports the delivery by suitably qualified and experienced specialist surgeons of individualized medicine and shared decision making with patients facing amputation, and critically, will support broader-based generation of additional evidence than would restriction of this procedure to clinical trial.	
2.	Consultee 2 NHS Professional	1.4	I feel strongly that TMR should be offered by services undertaking primary amputations, and be recognised by NICE as a surgical option when undertaking amputation. The procedure involves very minimal extra surgical duration, or	Thank you for your comment. The committee discussed this comment but decided not to change

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			risk, when undertaken primarily. The potential cost and quality of life benefits are very high. The neurobiological logic of TMR is extremely solid. The cost, pre-surgical delays, and risk of secondary TMR for established pain are high, and it is likely that for those with central pathway mediated pain the outcome of post-hoc intervention in the periphery could never patch prevention.	the main recommendations because they concluded there are still uncertainties about the procedure that warrant further data collection.
3.	Consultee 3 NHS Professional	1.4	This recommendation seems overly restrictive, and I would strongly encourage this be reconsidered for the following reasons: 1. Phantom and residual limb pain following amputation not only can be, but frequently are, extremely debilitating resulting in very considerable suffering, social cost and chronic medical costs. 2. TMR for prevention of intractable pain from developing (primary TMR) is a surgical strategy which offers reduction in the risk of patients developing these pain conditions, and the associated suffering and cost. 3. Published evidence, which has been reviewed by the committee, supports the efficacy of primary TMR. The committee note that there is a lack of high quality evidence; while I agree that a large RCT is as yet absent from the literature quality studies of other designs should not be discounted out of hand. I would particularly highlight the 2021 cohort study by Chang and colleagues which demonstrates very substantial reductions in both phantom and residual limb pain, and is a well conducted study from a reputable team at a major US hospital. They also demonstrate significant reduction in opioid	Thank you for your comment. The committee considered published peer-reviewed evidence from study designs other than RCTs, including the study by Chang (2021). The committee discussed this comment but decided not to change the main recommendations because they concluded there are still uncertainties about the procedure that warrant further data collection.

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			requirement, and while the reduction in neuroleptic use was not significant I would suggest on this basis of my experience that with longer followup this would continue to fall. It is also noteworthy that this cohort was in highly comorbid patients, a group in which complications from any increase in duration or complexity of surgery might reasonably be expected to be greatest. The positive safety profile in this study is extremely encouraging for the safety of this procedure in less comorbid patients. 3. Primary TMR is already quite widely offered by specialists in this country and internationally. This is supported both by the available evidence, the low cost and risk of the procedure, and the very considerable morbidity and cost associated with phantom and residual limb pain should they develop. Practice in my institution (which is consistent with that of colleagues elsewhere with whom I have consulted) is to offer primary TMR on a case by case basis to patients undergoing amputation who are expected to be high demand prosthetic users (for whom the societal and quality of life loss from pain and restricted ambulation would be greatest) or who are at increased risk of complex pain as a result of their injuries, condition or other factors. 4. While there has been some debate that primary TMR may result in over treatment of some amputees if widely offered, the counter argument is I believe the stronger, that given the morbidity of, and the difficulty and cost of managing intractable post-amputation pain, a strategy or prevention rather than treatment is logically (and indeed morally) preferable.	

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			This is not to say that I would advocate for all amputations to include primary TMR but that it should remain available as an option on a case by case basis consistent with current practice as outlined above. I would also note that my experience suggests published data on the additional operative time for amputation with vs without TMR likely overestimates the difference, as at a population level not all amputations are performed by specialist surgeons with volume experience, but currently, all amputations with TMR will be. Finally, with regard to experience in my institution, primary TMR has been offered to selected patients over the past 2 years as outlined above. It has not been possible to formalise the dataset within the timescale of this consultation, but there have been no significant complications, the vast majority of patients are pain free, and patient feedback has been uniformly positive.	
4.	Consultee 5 Consultant in Rehabilitation Medicine (Professional Expert)	1.4	The recommendation that primary TMR can only be offered at primary time of amputation in research studies is unnecessarily restrictive. There is good evidence that TMR reduces pain scores and reduces the amount of analgesia required. I accept that not all patients will go on to develop residual and phantom limb pain. I also accept that patients undergoing TMR at the time of amputation appear to have higher complications immediately post surgery in the available literature, this is to be expected with additional procedures as part of the primary surgery. I think it is unnecessarily restrictive and punitive for complex patients with background and / or existing pain or those who have a complex history with opiates such as recovering IVDUs that	Thank you for your comment. The committee discussed this comment but decided not to change the main recommendations because they concluded there are still uncertainties about the procedure that warrant further data collection.

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			primary TMR cannot be considered for them within appropriate governance structures and informed consent according to NICE principles. I would hope that NICE could relax the language to say that primary TMR should not routinely be offered outwith research studies but that within appropriate governance structures as outlined for secondary TMR that select patients may benefit from primary TMR. Thanks for your consideration.	
5.	Consultee 4 NHS Professional	1.5	1.5 – there is a large body of evidence that TMR is effective as a treatment, for my group of patients where the neuroma recurs after standard treatments such as pulsed RF, RF ablation or excision, TMR or RPNI offers an option to both reduce the recurrence risk and pain levels. This is a technique of what to do with the nerve end that has been cut and is not a new procedure, limiting it to plastic surgeons with appropriate training would be appropriate but if limited to research only we will be condemning hundreds of amputees to recurrent pain and operations with significant continued morbidity and increasing costs to the NHS in terms of pain management, amputee rehabilitation and recurrent surgical costs. If you make it only research at a time when the NHS is literally bursting at the seams then it just wont happen, there is a disconnect here between this paper and the realities of being able to effectively carry out research in the state the NHS is in. If NICE wishes to keep patients in pain, burden services then formal research is the way to go, there is ample papers out there to demonstrate that this is an effective treatment in amputees.	Thank you for your comment. Section 1.5 of the draft guidance only refers to the procedure being done at the same time as the amputation to prevent pain from developing. Section 1.1 states that the procedure can be used in the NHS while more evidence is generated to treat problematic pain that has developed after limb amputation. The headings have been changed to make this clearer. The committee discussed this comment but decided not to change the main recommendations because they concluded there are still uncertainties about the procedure that warrant further data collection.
6.	Consultee 8	1.4	TMR must NOT be indicated as a prophylactic intervention at time of the initial amp amputation to prevent the development	Thank you for your comment.

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	British Society of Physical and Rehabilitation Medicine		of painful neuromas. This is because only a small percentage of amputees experience painful neuromas. Performing prophylactic TMR surgery risks many patients having unnecessary complicated surgical intervention which involves a longer scar and extended surgery time.	Consultee thinks that TMR should not be done as a primary procedure to prevent pain from developing after amputation.
7.	Consultee 8 British Society of Physical and Rehabilitation Medicine	Not specified	We strongly feel there is no clear role yet for prophylactic / primary TMR.	Thank you for your comment. Consultee feels there is no clear role yet for prophylactic TMR.
8.	Consultee 4 NHS Professional	1.6	1.6 – I refer to comments of 1.5, there are over 100 papers on this subject, this is new in the grand scheme of things but not in clinical practice over the last 10 + years. Agreed that further research is needed but it should not come at a cost of a treatment option that only takes an extra 30 – 45 min on from a neuroma excision. Berger LE, Shin S, Haffner ZK, Huffman SS, Spoer DL, Sayyed AA, Franzoni G, Bekeny JC, Attinger CE, Kleiber GM. The application of targeted muscle reinnervation in lower extremity amputations: A systematic review. Microsurgery. 2023 Oct;43(7):736-747. doi: 10.1002/micr.31030. Epub 2023 Mar 2. PMID: 36864779.	Thank you for your comment. Berger (2023) is included in table 5 of the overview.
9.	Consultee 4 NHS Professional	1.4	1.4 – is this referring to TMR at the time of the primary amputation surgery or is it referring to treatment after amputation surgery? This is not clear. There are papers already supporting TMR in primary amputations but the issue will be that only plastics surgeons can do TMR and they tend not to be the ones doing primary amputations -that would be predominantly vascular surgeons and secondarily orthopaedic surgeons.	Thank you for your comment. Section 1.4 refers to TMR at the time of the primary surgery, to prevent pain from developing. The headings have been amended to clarify what each of the recommendations refer to.
10	Consultee 3 NHS Professional	1.1	This is an entirely reasonable recommendation supporting continuation of what is already quite wide spread clinical	Thank you for your comment.

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			practice both in the UK and internationally, while further evidence is generated.	Consultee agrees with main recommendation in section 1.1 of the draft guidance.
11	Consultee 4 NHS Professional	1.3	Page 4 – it is important to consider that it is not just for intractable pain, the issue with neuroma development and recurrence is that the pain occurs often when there is pressure applied to the neuroma, this can be by direct pressure such as digital pressure but more commonly occurs when wearing the limb including using different suspension systems such as liner suspension systems, neuromas that are adhered to muscle can be triggered by the muscle contraction and those that are squashed between the socket on the outside and the bone on the inside lead to pain when using the prosthesis. Thus neuroma treatment is not just about intractable pain by the definition here, it is pain that is stimulated by limb use and leads to significant morbidity and increase in disability and reduction in participation and independence as limb use becomes more problematic. TMR offers a potential solution if simple excision leads to recurrence of neuroma.	Thank you for your comment. 'Intractable pain' was used to distinguish this from short-term postoperative pain that can be effectively managed by other options. The term has been replaced with 'problematic' pain.
12	Consultee 4 NHS Professional	2.2	2.2 – current treatments are not all included here • Prosthetic socket off loading techniques • Non- limb use leading to crutch walking or wheelchair use • non-steroidal anti-inflammatory drugs such as ibuprofen (does not work for a neuroma) • antiepileptics such as pregabalin or gabapentin • antidepressants that are used to treat nerve pain such as amitriptyline, nortriptyline or Duloxetine • opioids such as codeine or morphine • Ketamine can be used for severe phantom limb pain, neuroma pressure can exacerbate phantom limb pain setting off severe episodes.	Thank you for your comment. Section 2.2 is intended to give some examples of commonly used treatments for the indication rather than a comprehensive list of all treatments available. A sentence has been added to section 2.2 to note that there may be other treatment options such as spinal cord or peripheral nerve stimulation.

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			• Hypnosis can reduce the severeity • Mirror box therapy • corticosteroid or local anaesthetic injections. • Pulsed radiofrequency treatment • Ablative radio-frequency treatment • Peripheral nerve stimulation • Spinal cord stimulation the treatment options depend on the nature of the pain and possible treatment options. The decision on pain management stratergies are individual clinician at the top moving down the list to increasingly mixed MDTs involving pt and rehab + pain management +/or plastics/vasc/ortho	
13	Consultee 4 NHS Professional	2.5	2.5 – again not just about intractable pain – I cannot stress this enough that the patient usually have gone through or been considered for all of the above followed by neuroma excisions before TMR	Thank you for your comment. 'Intractable pain' was used to distinguish this from short-term postoperative pain that can be effectively managed by other options. The term 'intractable' has been replaced with 'problematic'.
14	Consultee 2 NHS Professional	Unmet need	should add "Current medical therapies are frequently insufficient, or patients find dose side effects outweigh benefit." Also more accurate to read "Conventional surgical treatments for neuroma include excision and burying the nerve endings in muscle or other deep tissues, but neuroma will reform and pain symptoms commonly reoccur."	Thank you for your comment. The first and last sentences of the unmet need have been amended.
15	Consultee 4 NHS Professional	3.1	3.1 – only 10 sources - this is not very many, a quick pubmed search 'TMR amputations' leads to 157 results with many more than 10 relevant, why was only 10 considered,	Thank you for your comment. Interventional procedures guidance is based on a rapid review of the

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			this is not representative of the research that has already been published.	evidence and detailed data extraction was done for 10 key studies. These included a recent systematic review, which included 10 studies (Tham 2023). A further 26 studies are briefly described in table 5 of the overview. The initial search returned more than 700 studies, so observational studies with fewer than 20 people were excluded.
16	Consultee 4 NHS Professional	Overview: evidence summary	only 10 sources - this is not very many, a quick pubmed search 'TMR amputations' leads to 157 results with many more than 10 relevant, why was only 10 considered, this is not representative of the research that has already been published.	Thank you for your comment. Interventional procedures guidance is based on a rapid review of the evidence and detailed data extraction was done for 10 key studies. These included a recent systematic review, which included 10 studies (Tham 2023). A further 26 studies are briefly described in table 5 of the overview. The initial search returned more than 700 studies, so observational studies with fewer than 20 people were excluded. A further 3 studies were added to the key evidence when the update search was done.
17	Consultee 2 NHS Professional	Overview: indication and	'Medicines that may be used to help relieve persisting limb pain after amputation include non-steroidal anti-inflammatory drugs such as ibuprofen, antiepileptics such as pregabalin or gabapentin, antidepressants that are used to treat nerve pain	Thank you for your comment.

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		current treatment	such as amitriptyline or nortriptyline, opioids such as codeine or morphine, corticosteroid or local anaesthetic injections.' would be more specific to read: "Medicines that may be used to help relieve persisting limb pain after amputation include non-steroidal anti-inflammatory drugs such as ibuprofen or corticosteroid injections that counteract inflammatory pain, agents that stabilise inappropriate nerve activity such as antiepileptics including as pregabalin or gabapentin and local anaesthetic injections, or antidepressants that are used to treat nerve pain such as amitriptyline or nortriptyline, agents that modulate the central response to pain awareness including opioids such as codeine or morphine."	The wording in the overview has been amended as suggested by the consultee: 'Medicines that may be used to help relieve persisting limb pain after amputation include: • non-steroidal anti-inflammatory drugs such as ibuprofen or corticosteroid injections, which counteract inflammatory pain • agents that stabilise inappropriate nerve activity such as antiepileptics including pregabalin or gabapentin and local anaesthetic injections • antidepressants that are used to treat nerve pain such as amitriptyline or nortriptyline • agents that modulate the central response to pain awareness including opioids such as codeine or morphine.'
18	Consultee 2 NHS Professional	Overview: indication and current treatment	This contain incorrect text. 1. Neurolysis by definition is NOT the removal of nerve tissue (that is neurectomy), it is the release of nerve tissue from constriction, ischaemia or traction by scarred surrounding tissues.	Thank you for your comment. 'Neurolysis' has been deleted from the description and the text amended as suggested.

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			2. "repair and reconstruction of the damaged nerve to make the nerve fibres regenerate into the distal nerve end with the possibility to regain function." is not accurate, as it implies restoration into the anatomical distal nerve. More accurate would be to say "reconstruction of the damaged nerve to allow its axons to regenerate through neural tissue to a sensory target organ, with the possibility to regain sensory input to the CNS."	
19	Consultee 6 Consultant Plastic, Hand and Reconstructive Surgeon (Professional expert)	Overview: indication and current treatment	In nerve surgery excision of the nerve would be described as neuroma excision and neurolysis is freeing the nerve from surrounding tissue.	Thank you for your comment. 'Neurolysis' has been deleted from the description.
20	Consultee 2 NHS Professional	Overview: What the procedure involves	not necessarily true, it can be done under forms of regional anaesthesia which are less morbid and enhance outcome	Thank you for your comment. The wording has been amended to: 'the procedure is done under general **or regional** anaesthesia'.
21	Consultee 6 Consultant Plastic, Hand and Reconstructive Surgeon (Professional expert)	Overview: What the procedure involves	It can be performed under spinal or regional anaesthetic	Thank you for your comment. The wording has been amended to: 'the procedure is done under general **or regional** anaesthesia'.
22	Consultee 2 NHS Professional	Overview: What the procedure involves	Better to read "It has been hypothesised that the nerve endings stop causing pain once they have found an alternative sensory organ within the muscle, because their physiology is restored. It is important to note that even nerves that supply muscles contain more sensory nerve fibres than motor fibres, and muscles contain many sensory organs that do not trigger pain awareness."	Thank you for your comment. The wording has been amended to: 'It is thought that the nerve endings stop causing pain once they have found an alternative **sensory organ within the** muscle, because their physiology is restored.'

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23	Consultee 6 Consultant Plastic, Hand and Reconstructive Surgeon (Professional expert)	Overview: What the procedure involves	"not functional" is confusing as can be read as in reference to the motor branch rather than the muscle., and the motor branches must be functional for the TMR to work. I would prefer- Motor branches to redundant muscles after amputation are identified and divided.	Thank you for your comment. The wording has been amended.
24	Consultee 7 British Society of Physical and Rehabilitation Medicine	Title	The title of the proposal “Targeted Muscle Reinnervation” - overlook other similar procedures which may be more appropriate for certain patients namely: - Regenerative Peripheral Nerve Interface (RPNI) - intramuscular nerve re-implantation.	Thank you for your comment. The guidance only refers to targeted muscle reinnervation and is not intended to include other procedures.
25	Consultee 7 British Society of Physical and Rehabilitation Medicine	Not specified	We welcome the selected outcome measures chosen in this consultation.	Thank you for your comment.
26	Consultee 7 British Society of Physical and Rehabilitation Medicine	Not specified	The proposed guidelines should emphasise the role of Rehabilitation Medicine (RM) Consultant input in patient selection and referral process. The proposed surgical procedure in carefully selected cases should be planned with the rehabilitation multidisciplinary team to plan future functional prosthetic rehabilitation and optimise the surgical and patient outcomes.	Thank you for your comment. A recommendation has been added that patient selection should be done by a multidisciplinary team that could include a rehabilitation medicine consultant.
27	Consultee 7 British Society of Physical and Rehabilitation Medicine	Not specified	Further training for NHS Medical as well as therapy teams (including Prosthetist) need to be outlined clearly. These are mostly very effective procedure if the patients are selected wisely.	Thank you for your comment. A recommendation has been added that patient selection should be done by a multidisciplinary team that could include a rehabilitation medicine consultant.
28	Consultee 8	Not specified	Overall, the decision making process about whether a patient will benefit from any nerve procedure in an established amputee should be led by a consultant in Rehabilitation	Thank you for your comment.

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	British Society of Physical and Rehabilitation Medicine		Medicine specialising in amputee care working closely with surgeons in a specialist care centre.	A recommendation has been added that patient selection should be done by a multidisciplinary team that could include a rehabilitation medicine consultant.
29	Consultee 7 British Society of Physical and Rehabilitation Medicine	Not specified	As it needs a lot of funding, initially there should be limited number of cases per year performed in the NHS, as scope and training for rehabilitation are limited currently.	Thank you for your comment.
30	Consultee 8 British Society of Physical and Rehabilitation Medicine	Not specified	There is significant peri-operative co-morbidity and wound healing issues in vascular patients who comprise the majority of cases seen in the NHS. So clearly any additional operating time and tissue handling will increase these risks and impact on recovery and rehabilitation. The vascular society should certainly be consulted.	Thank you for your comment. Consultee notes that most cases in the NHS would involve people with vascular disease.
31	Consultee 8 British Society of Physical and Rehabilitation Medicine	Not specified	Other non-invasive interventions should be explored first before considering any surgery for limb amputation pain.	Thank you for your comment.

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