

Policies for the Commissioning of Healthcare**Policy for Low Intensity Pulsed Ultrasound Therapy**

	Introduction
	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
1	Policy
1.1	The CCG considers that low intensity pulsed ultrasound therapy does not accord with the Principles of Appropriateness, Effectiveness and Cost-effectiveness and therefore the CCG will not routinely commission this intervention.
2	Scope and definitions
2.1	This policy is based on the CCGs Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	Fractures usually heal within a few weeks after treatment by closed or open reduction, and immobilisation using a cast or internal fixation. Sometimes healing may be delayed or not happen at all (non-union). Treatment of non-union may need complex and prolonged management with implications for the patient's quality of life and functional capacity ¹ . The aim of low-intensity pulsed ultrasound (LIPUS) is to promote healing by delivering micro-mechanical stress to the fracture site to stimulate bone healing. This procedure is used to treat fractures that are slower to heal than expected, and non-union fractures ¹ . The intervention involves short daily treatments using an ultrasound probe placed on the skin over the fracture. A device for patient home use is marketed as the EXOGEN ultrasound bone healing system. The patient uses it daily for months until the fracture is healed.
2.3	The scope of this policy includes the commissioning any system using low intensity pulsed ultrasound therapy, including Exogen devices, to promote bone healing.
2.4	The CCG recognises that a patient may have certain features, such as <ul style="list-style-type: none">• having slow to heal fractures or fractures which have failed to unite.• wishing to have an alternative to existing services provided for the treatment of fractures that are slower to heal than expected, and non-union fractures

	<ul style="list-style-type: none"> • being advised that they are clinically suitable for low intensity pulsed ultrasound and • be distressed by having slow to heal fractures or fractures which have failed to unite. <p>Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.</p>
2.5	The CCG has used NICE Interventional Procedure Guidance (IPG) 623 Low intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures, published in July 2018 ¹ as a source of reference.
3	Appropriate Healthcare
3.1	The purpose of low intensity pulsed ultrasound therapy is normally to promote healing of fractures which are slower than expected in healing (delayed union) and fractures that have failed to unite (non-union).
3.2	<p>The Principle of Appropriateness includes a consideration of whether use of a therapy is the best means of achieving the intended purpose, i.e. to improve the healing rate or time taken to heal of non-union fractures.</p> <p>This policy relies on the criterion of appropriateness in that the CCG considers that it has not been established that low intensity pulsed ultrasound therapy is the best means of achieving that outcome.</p>
4	Effective Healthcare
4.1	<p>This policy relies on the criterion of effectiveness in that the CCG considers the effectiveness of low intensity pulsed ultrasound therapy has not been demonstrated.</p> <p>NICE IPG 623 Low intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures, published in July 2018, states that “The current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research”¹.</p>
5	Cost Effectiveness
5.1	<p>This policy relies on the criterion of appropriateness in that the CCG considers the cost-effectiveness of Exogen (Low intensity pulsed ultrasound) has not been demonstrated.</p> <p>NICE IPG 623 Low intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures, published in July 2018, states that “The current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research”.¹</p> <p>The CCG considers that a therapy cannot be cost-effective if it is not effective.</p>

	Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects when considering an application to provide funding.
6	Ethics
6.1	<p>The CCG does not call into question the ethics of low intensity pulsed ultrasound therapy and therefore this policy does not rely on the Principle of Ethics.</p> <p>Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient when considering an application to provide funding.</p>
7	Affordability
7.1	<p>The CCG does not call into question the affordability of low intensity pulsed ultrasound therapy and therefore this policy does not rely on the Principle of Affordability.</p> <p>Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient when considering an application to provide funding.</p>
8	Exceptions
8.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
9	Force
9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	<p>In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then:</p> <ul style="list-style-type: none"> • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.
10	References

	1. Interventional Procedure Guidance IPG 623 Low intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures. Published July 2018. https://www.nice.org.uk/guidance/ipg623/chapter/2-The-condition-current-treatments-and-procedure
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Date of adoption

Date for review

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