NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Achilles Tendinopathy, Refractory Tennis Elbow and Plantar Fasciitis: treatment with extracorporeal shockwave therapy, autologous blood or platelet rich plasma injections

Category 1 Intervention - Not routinely commissioned

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Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) 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.
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Document control:		
Date:	**Version Number:**	**Section and Description of Change**
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1. Introduction

1.1 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

1.2 This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined in Appendix 1.

1.3 At the time of publication, the evidence presented per procedure/treatment was the most current available.

2. Purpose

2.1 This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

3. Policy statement

3.1 Autologous blood, platelet rich plasma injections or extracorporeal shockwave therapy are not routinely commissioned for *Achilles tendinopathy*.

3.2 Autologous blood, platelet rich plasma injections or extracorporeal shockwave therapy are not routinely commissioned for *refractory tennis elbow*.

3.3 Autologous blood, platelet rich plasma injections or extracorporeal shockwave therapy are not routinely commissioned for *plantar fasciitis*

4. Exclusions

4.1 None

5. Rationale

5.1 For *plantar fasciitis*, there is significant uncertainty regarding the evidence of efficacy for autologous blood, shockwave therapy and platelet rich plasma. For this reason, these interventions are not routinely commissioned for this indication.

5.2 For *Achilles tendinopathy,* there are similar uncertainties regarding evidence of efficacy for autologous blood, shockwave therapy and platelet rich plasma. For this reason, these interventions are not routinely commissioned for this indication.

5.3 For *tennis elbow*, the limited data which are available suggest these interventions provide little or no clinical benefit.

6. Underpinning evidence

6.1 This policy relates to 3 types of "tendinopathy" *viz* plantar fasciitis, Achilles tendinopathy and refractory tennis elbow. The specified interventions are injectable agents (autologous blood & platelet rich plasma) and extracorporeal shockwave therapy. This rapid review will consider all 3 of these interventions at each of the 3 anatomical sites.

6.2 **Plantar fasciitis** or heel pain is one of the most common foot conditions treated by healthcare providers.[1] It is characterised by a painful "inflammatory" process involving the plantar fascia (the tight band of connective tissue which supports the arch of the foot)[2] which results in pain on the underside of the heel. It may be caused by overuse, injury or by mechanical abnormalities and may be associated with micro-tears or fibrosis.[3] It is more noticeable after the "first step" and during weight-bearing tasks particularly after periods of rest.[4] Affected patients may have impaired health-related quality-of-life which could include social isolation, poor perception of health status and reduced functional capabilities. The pain is stabbing in nature and as stated above, may occur during the very first steps in the morning. However, once the foot is on the go and walking, the pain usually subsides although it is likely to return after long periods of standing or getting up from a seated position.[5]

6.3 Pathologically, the condition isn't the result of excessive inflammation, and the changes are more degenerative in nature (although partially reversible) presumably due to repetitive micro trauma.[2] Strictly speaking, the term "fasciitis" refers to inflammation whereas "fasciosis" describes noninflammatory degradation or degeneration. Thus, plantar fasciitis is perhaps a misnomer although this is the term which is generally used in the literature.[6] Usually, the condition is self-limiting.[3]

6.4 Plantar fasciitis is said to affect between 4% – 7% of the community [4] and is more likely to occur in middle-aged or older people and in women slightly more than men.[2] The lifetime prevalence is up to 10% of the population.[1] Other common risk factors include a restricted ankle dorsiflexion range of motion, most of the workday spent on the feet and a BMI greater than 30 kg/m².[7]

6.5 ***Autologous blood*** is claimed to promote healing through the action of growth factors which are contained within it.[3] A 2021 systematic review compared autologous blood versus steroid injections in plantar fasciitis. The systematic review and meta-analysis found no significant difference between autologous blood and corticosteroids.[8] In a separate trial, 90 patients were randomised to receive either autologous blood injection or an identical "dry needling" technique. The RCT showed no significant improvements between the 2 treatments in terms of pain reduction or function.[9] The National Institute for Health and Care Excellence in its interventional procedure guidance on autologous blood injections for plantar fasciitis highlights the uncertainty about the efficacy of this treatment and recommend special arrangements for clinical governance and audit.[3]

6.6 ***Extracorporeal shockwave therapy*** is a non-invasive treatment in which a device passes acoustic shock waves through the skin to the affected area. It may be applied once or in several sessions and sometimes local anaesthesia is required because the high energy can be painful. The mechanism of action is unknown.[10 ,11]

6.7 Evidence of efficacy for shockwave therapy is unclear and at times contradictory. A meta-analysis (2019) which compared shockwave versus ultrasound found no significant difference between the 2 groups.[12] An earlier systematic review (2017) of various conservative treatments (which included shockwave therapy) for plantar heel pain found very small improvements in symptoms and this was based on mostly low or moderate quality evidence. The authors were unable to give definitive conclusions for clinical practice.[13] Also, a small trial (n = 102) which compared autologous blood with shockwave therapy found no

significant difference between the groups despite statistical improvement in pain scores yet no improvement in patient functioning at follow-up.[14]

6.8 In contrast, a meta-analysis on the efficacy of shockwave therapy in chronic plantar fasciitis showed patients had better pain control and fewer complications than patients on other methods.[15] Similarly, a best practice guideline concluded that those patients who didn't improve on taping, stretching or individualised education should be offered shockwave therapy followed by custom orthoses.[4] In further contrast, a 2nd meta-analysis concluded that current evidence regarding the most effective treatment for plantar heel pain is equivocal. The authors highlighted the need for large, methodologically robust, multicentre RCTs.[16]

6.9 ***Platelet rich plasma*** is obtained by centrifugation of the patients' blood to produce a concentrated suspension of platelets in plasma. A 2019 systematic review examined a variety of treatments (which included platelet rich plasma) for plantar fasciitis and concluded to date, there was no definitive treatment guideline which could be derived from the data.[17] However, a more recent systematic review compared platelet rich plasma with corticosteroid injections and concluded that the platelet injection was more effective in relieving pain than corticosteroids.[18] Follow-up was up to 12 months.

6.10 **Achilles tendinopathy:** Achilles tendon injuries are often causes of posterior heel pain. These injuries are most prevalent in long distance runners and in a variety of other sports such as football or tennis. Reported prevalence's range from <1% in football players to 11% in runners. Affected patients tend to be in their 20s.[19] The problem occurs when the activity of the athlete exerts so much mechanical loading that the tendon's capacity is exceeded.[20]

6.11 The evidence of efficacy for ***autologous blood*** in Achilles tendinopathy is limited. A small study compared the effect of adding autologous blood injections to an exercise programme. The authors found that the addition of 2 injections, one month apart, provided no additional benefit in the treatment of midportion Achilles tendinopathy.[21,22]

6.12 Several authors have commented that there is no general consensus on the effectiveness of ***shockwave therapy*** for Achilles tendinopathy whilst also stating the intervention has a positive effect. [19,23] A meta-analysis found that shockwave reduced pain and improved functional outcomes, but further research was needed to determine the optimal energy level.[24] One author speculated that the apparent variation in efficacy may in part be due to no standardised application parameters (e.g., energy level).[20]

6.13 Data on ***platelet rich plasma*** for Achilles tendinopathy are also limited. A 2020 systematic review found a positive advantage in using platelet rich plasma according to the cited retrospective studies. However, within the same review, the higher level (quality) evidence studies reported no significant difference compared to comparators. The authors concluded that although the results were promising, there is a requirement for much larger scale, high quality studies.[25]

6.14 Finally, a wide-ranging systematic review considered all forms of conservative treatments for Achilles tendinopathy. This concluded that no therapy is universally accepted except for exercise training which is considered to be the gold standard.[26] In addition, 2 other reviews examined the efficacy of both autologous blood and platelet rich plasma. Of these, one concluded that the evidence hasn't been "synthesised" (i.e., produced) [27] and the other concluded that neither product was superior to placebo.[28]

6.15 Perhaps the most authoritative evidence is a 2015 Cochrane review of injections for Achilles tendinopathy.[29] The "injections" included corticosteroids, autologous blood and platelet rich plasma. The review concluded that the currently available evidence is insufficient to support the routine use of injection therapy for painful Achilles tendons in adults. Future studies were needed to provide definitive evidence for this potentially important treatment.

6.16 **Lateral epicondylitis (tennis elbow):** This is a degenerative rather than an inflammatory tendinopathy which causes chronic recalcitrant pain in elbow joints.[30] Most patients either resolve spontaneously or respond to standard conservative management such as rest, analgesics, NSAIDs, orthoses and exercise.

6.17 A very recent (2022) systematic review compared ***platelet rich plasma*** to surgery.[31] The review found that platelet rich plasma and surgical treatment produced equivalent pain scores and functional outcomes in patients with lateral elbow tendinosis. The authors concluded that this treatment may be a reasonable alternative for patients who are either apprehensive about or unsuitable for surgery. However, maximum follow-up was 52 weeks and the proportion of patients receiving platelet rich plasma injection who then proceeded to surgery was not stated.

6.18 In contrast and in direct contradiction, another systematic review on injections for tennis elbow suggested that placebo injections are very effective, and no other injections (including platelet rich plasma and autologous blood) convincingly improve the condition better than placebo.[32] A 2nd Cochrane review studied the impact of autologous blood and platelet rich plasma injections for lateral elbow pain.[33] The review found that the available data do not support the use of either of these products. The authors concluded that the injections probably provide little or no clinically important benefit for pain or function. There is a small risk of infection and with no evidence of benefit, the costs and risks are not justified.

6.19 In summary, for *plantar fasciitis*, NICE have stated that efficacy data for autologous blood injection are uncertain. For extracorporeal shockwave therapy although there is some positive evidence, there is still significant uncertainty and some authors have highlighted the need for large-scale, high quality RCTs. For platelet rich plasma, the evidence is contradictory.

6.20 For *Achilles tendinopathy*, there is similar uncertainty regarding the place of shockwave therapy with many authors agreeing there is no general consensus on its effectiveness with a limited amount of positive data. There is strong evidence (a Cochrane review) that currently available evidence on autologous blood or platelet rich plasma is insufficient to support the routine use.

6.21 For *tennis elbow*, a 2nd Cochrane review concluded that autologous blood or platelet rich plasma injections probably provide little or no clinically important benefit for pain or function. There were no identified studies on shockwave therapy for this indication.

6.22 The overall conclusion for all indications is there is a lack of high-quality data to establish the effectiveness of these interventions. Until such data are apparent, it is reasonable that the current “not routinely commissioned” policy should be continued. Neighbouring CCGs either have no policy or are “not routinely commissioned” (which is the case for Mersey).

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7. Force

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

8. Coding

8.1 Office of Population Censuses and Surveys (OPCS) - none

8.2 International classification of diseases (ICD-10) - none

9. Monitoring And Review

9.1 This policy may be subject to continued monitoring using a mix of the following approaches:

- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

9.2 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

10. Quality and Equality Analysis

10.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

Appendix 1 - Core Objectives and Principles

Objectives

The main objective for having healthcare commissioning policies is to ensure that:

- Patients receive appropriate health treatments
- Treatments with no or a very limited evidence base are not used; and
- Treatments with minimal health gain are restricted.

Principles

This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

- Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
- Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
- Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
- Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
- Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
- Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
- Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
- NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

Cosmetic Surgery

Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

A summary of Cosmetic Surgery is provided by NHS Choices. Weblink:
http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and
http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

Diagnostic Procedures

Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

Clinical Trials

The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

Clinical Exceptionality

If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy.