

## Extracorporeal Shockwave Therapy (ESWT) and Radial Pulse Therapy (RPT)

### August 2016

**This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:**

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

*Collectively referred to as the Worcestershire CCGs*

#### **COMMISSIONING SUMMARY**

Worcestershire Clinical Commissioning Policy Collaboration has undertaken a review of the evidence and circumstances associated with use of Extracorporeal Shockwave Therapy (ESWT) and Radial Pulse Therapy (RPT) and concluded that for Worcestershire CCGs responsible patients:

- Services associated with use of either ESWT or RPT are NOT ROUTINELY COMMISSIONED for any indication including plantar fasciitis and Achilles tendinopathy.

Further clarity is required in relation to the optimum duration of use and long term benefit and the impact of either treatment on concomitant and future use of other interventions including progression to surgery.

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<b>Lead Executive/Director:</b>	Chris Emerson, Director of Contracting
<b>Name of originator/author:</b>	Fiona Bates, Medicines Commissioner and Public Health Liaison
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**Circulated to the following individuals/groups for comments:**

<b>Name</b>	<b>Date</b>
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	8 <sup>th</sup> March 2016

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## 1. Definitions

- 1.1 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e. similar patients). A patient with **exceptional clinical circumstances** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.
- 1.2 A **Similar Patient** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patients indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.
- 1.3 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.
- 1.4 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

## 2. Scope of policy

- 2.1 This policy is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address:  
<http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/>
- 2.2 This policy applies to all patients for whom the Worcestershire CCGs have responsibility including:
- People provided with primary medical services by GP practices which are members of any one of the CCGs and
  - People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.
- 2.3 The policy relates to electrocorporeal shockwave therapy treatment and radial pulse therapy used in the management of a variety of pain related conditions including but not limited to plantar fasciitis and Achilles tendinopathy.
- 2.4 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "exceptional clinical circumstances", please refer to the Definitions section of this document.

### **3. Background**

- 3.1. The NHS Constitution, which details the principles and values that guide the NHS, has been applied in the agreement of this policy.
- 3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.
- 3.3. Extracorporeal Shockwave Therapy (ESWT) is a relatively new development that has been trialled in the treatment of chronic heel pain, including but not limited to, pain caused by plantar fasciitis and Achilles tendinopathy.
- 3.4. In ESWT, acoustic pressure waves are delivered to the focus of pain on the heel, with a view to achieving a reduction in pain. Multiple treatments may be given. The mechanism of action is not yet known, although there are various hypotheses.
- 3.5. There are various machines manufactured currently that deliver ESWT, which generate shockwaves using electromagnetic, electrohydraulic, or piezoelectric power.
- 3.6. Radial Pulse Therapy (RPT) is a similar treatment, but can be distinguished from focused ESWT as it differs both in the way it generates and delivers shock waves (using a ballistic source, and delivering pressure pulses more superficially). However, not all clinicians make this distinction.
- 3.7. ESWT is proposed as a possible non-invasive alternative to surgery where conservative measures such as analgesia, heel supports and physiotherapy have been unsuccessful in significantly improving pain. Avoidance of surgery could prevent associated complications and morbidity for patients, and potentially reduce costs for CCGs, if the effect is maintained.

### **4. Relevant National Guidance and Facts**

- 4.1 ESWT was evaluated by NICE in 2009 for both plantar fasciitis (IPG 311) and Achilles tendinopathy (IPG 312). At the time, ESWT had been shown to be safe to use in both conditions, but there had not been convincing evidence for its efficacy in treating either cause of heel pain. NICE Guidance therefore stated that ESWT 'should only be used with special arrangements for clinical governance, consent and audit or research.'
- 4.2 However, further trials and systematic reviews have since been published, which should be taken into account as NICE guidance is no longer representative of the body of data currently available.
- 4.3 The British Orthopaedic Foot & Ankle Society does not make mention of ESWT or RPT for the management of either plantar fasciitis or Achilles tendinopathy.

4.4 NICE have issued draft interventional procedure guidance for use of ESWT for Achilles tendinopathy due for final publication in September 2016. The draft recommendations are:

- a. The evidence on extracorporeal shockwave therapy (ESWT) for Achilles tendinopathy raises no major safety concerns. Current evidence on efficacy of the procedure is inconsistent and limited in quality and quantity. Therefore, ESWT for Achilles tendinopathy should only be used with special arrangements for clinical governance, consent and audit or research.
- b. Clinicians wishing to do ESWT for Achilles tendinopathy should take the following actions.
  - Inform the clinical governance leads in their NHS trusts.
  - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
  - Audit and review clinical outcomes of all patients having ESWT for Achilles tendinopathy.
- c. NICE encourages further research into ESWT for Achilles tendinopathy. Studies should clearly describe patient selection, treatment protocols, use of local anaesthesia and the type and duration of energy applied (see section 3). Studies should include validated outcome measures and have a minimum of 1 year of follow-up. NICE may update the guidance on publication of further evidence.

#### 4.5 **Plantar Fasciitis:**

- Pain caused by wear and tear of plantar fascia (tissue in the sole of the foot) due to overuse, injury, or biomechanical predisposition
- 10% lifetime prevalence
- More common in athletes, high BMI, and 40-60 year-olds
- Causes 80% of all heel pain
- No association with gender
- 80% of people will have complete resolution of symptoms within one year  
90% of cases will resolve with non-surgical management
- Usual Management:  
First-line: analgesia, arch support, heel cushion, rest, plantar fascia stretches  
Second-line: corticosteroid injection  
Third-line: surgical release of plantar fascia (plantar fasciotomy)

#### 4.5 **Achilles Tendinopathy:**

- Heel pain resulting from damage to the Achilles tendon, caused by injury, overuse, or biomechanical predisposition.
- It can be categorised according to the part of the Achilles tendon that is affected – i.e. 'midportion' AT affects the middle of the tendon, whereas 'insertional' AT occurs where the tendon inserts into the heel.
- 6% cumulative lifetime incidence in people who are not physically active; as much as 50% in elite athletes.
- Most common in men, especially athletes between 30-40 years of age.
- Usual Management:  
First-line: analgesia, rest, stretching exercises, strength training, physiotherapy, heel support. Not suitable for corticosteroid injection  
Second-line: surgical removal of adhesions/nodules or tendon decompression (up to 25% of refractory Achilles tendinopathy patients progress to surgery)

## 5. Evidence Review

5.1 Two robust and most recent systematic reviews were available and analysed. Two further systematic reviews undertaken by the York Centre for Reviews and Dissemination were published prior to this and were also analysed. Two of the

reviews incorporated ESWT (and RPT) for plantar fasciitis and 3 of the reviews incorporated ESWT for Achilles tendinopathy.

- The review by Speed (2013) includes patients with either plantar fasciitis or Achilles tendinopathy, primarily incorporating randomised controlled trials and assessed as high quality.
- The review by Mani-Babu (2014) was specific to Achilles tendinopathy and included a mix of randomised controlled trials and prospective studies, assessed as 50% high quality.
- Al-Abbad (2013) review focussed on Achilles tendinopathy with overall evidence assessed as satisfactory and concerns regarding the reliability of conclusions reached.
- Chang (2012) review focussed on plantar fasciitis but appears to be well-conducted and reported comparing different methods/intensity of shockwave delivery.
- Concerns across all reviews related to the inconsistent definition of ESWT in terms of high dose, low dose and RPT which is sometimes classified as low dose, the number of impulses, and the number of treatment sessions and intervals between; variable patient characteristics in terms of symptoms and use of co-interventions; variable outcome measures.

## 5.2 Plantar Fasciitis

- There is high quality evidence available to support the efficacy of high dose ESWT and RPT.
- There is limited evidence to suggest that ESWT
  - is comparable to physiotherapy and achieves quicker outcomes.
  - has a better long term outcome compared with corticosteroid injection.
  - is comparable to surgery, without the risks of an invasive procedure
- The available evidence involves short-term intervention of up to 3 sessions over a 3 month period, with follow-up of between 3-6 months.

## 5.3 Achilles Tendinopathy

- There is some degree of evidence supporting high dose ESWT in insertional Achilles tendinopathy, whereas low dose evidence is contradictory.
- There is insufficient evidence for ESWT in midportion Achilles tendinopathy.
- The available evidence involves short-term intervention of up to 4 sessions over a 4 month period, with medium term follow-up of between 1-2 years

5.4 No other evidence was found to indicate whether ESWT for any indication affects the following:

- Progression to surgical intervention
- Reduced need for concomitant intervention/healthcare contacts

5.5 There is insufficient evidence with which to support the use of either ESWT or RPT in clinical practice for either plantar fasciitis or Achilles tendinopathy. There is no clarity regarding the optimum duration of treatment and long-term benefit and the impact on the need for both concomitant and future use of other interventions.

It is evident from both trial data assessed and local audits of use that treatment is often undertaken early when there is a high chance of resolution without intervention and that other lifestyle changes may impact on symptom resolution in advance of intervention.

There is no evidence from either trial data or local audit data that ESWT/RPT delays the progression to surgical intervention.

## 5.6 A further piece of work reviewed both the need for and the evidence for use of ESWT in diabetic patients:

- Achilles tendinopathy is reported as more prevalent in diabetic patients but this could not be substantiated in the literature. There is conflicting evidence regarding an association between differences in Achilles tendon structure in the diabetic population.
- Plantar fasciitis has no association in the literature with diabetes.
- There are no published trials specifically investigating efficacy of shockwave therapy for Achilles tendinopathy or plantar fasciitis in the diabetic population.
- Speed et al specifically excludes patients with “co-existing disease”.
- There is no sub-group analysis of the diabetic population in any of the published systematic reviews.
- An earlier meta-analysis of 19 randomised controlled trials for the use of ESWT in plantar fasciitis involved 9 studies which excluded patients with diabetes.
- Just one cohort study of 225 patients identified 5 diabetic patients in whom treatment with ESWT for plantar fasciitis was significantly less likely to be successful.

## 6. Patient Eligibility

### 6.1 Plantar Fasciitis and Achilles Tendinopathy

Services involving use of Extracorporeal Shockwave Therapy and Radial Pulse Therapy are not supported for use within the NHS for the Worcestershire CCGs' responsible population.

### 6.2 Other Indications

No other indications for use of ESWT or RPT will be funded for use within the NHS for the Worcestershire CCGs' responsible population.

Any identified new indications for use require submission of a completed new technologies request form for consideration by the Clinical Commissioning Policy Collaboration.

## 7. Supporting Documents

- Worcestershire CCPC: Brief Evidence Review of Shockwave Therapy for Heel Pain. October 2015
- Worcestershire CCPC: Report “Should Shockwave Therapy be Available To Patients with Diabetes Mellitus for Plantar Fasciitis and Achilles Tendinopathy?”. May 2016
- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- NHS England: Ethical Framework for Priority Setting Resource Allocation
- NHS England: Individual Funding Requests
- NHS Constitution, updated 27<sup>th</sup> July 2015

## 8. Equality Impact Assessment

Organisation	Worcestershire CCGs'		
Department	Commissioning	Name of lead person	Fiona Bates
Piece of work being assessed	Electrocorporeal Shockwave Therapy (ESWT) and Radial Pulse Therapy (RPT) Commissioning Policy		
Aims of this piece of work	To define the circumstances whether and when ESWT and RPT services will be funded in Worcestershire		
Date of EIA	07/03/2016	Other partners/stakeholders involved	CCPC
Who will be affected by this piece of work?	Patients with heel pain arising from either plantar fasciitis or Achilles tendinopathy.		

Single Equality Scheme Strand	Baseline data and research on the population that this piece of work will affect. What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. <b>Include consultation with service users wherever possible</b>	Is there likely to be a differential impact? Yes, no, unknown
<b>Gender</b>	Achilles tendinopathy is more common in men, who may be affected more by the limitations of this policy; there is no gender difference reported for plantar fasciitis.	Yes
<b>Race</b>	Achilles tendinopathy and plantar fasciitis are both more common in athletes and there may be varying prevalences of athletes by both race and sport.	Yes but extent and nature unknown
<b>Disability</b>	The increased prevalence of heel pain in athletes will disadvantage the more abled person; 6% cumulative lifetime incidence in people who are not physically active; as much as 50% in elite athletes.	Yes
<b>Religion/ belief</b>	No evidence of a link between religion and heel pain	No
<b>Sexual orientation</b>	No evidence of a general link between sexual orientation and heel pain	No
<b>Age</b>	Plantar fasciitis is more common in athletes (who are likely to be younger) and 40-60 year olds. Achilles tendinopathy is more common in athletes and 30-40 year olds.	Yes
<b>Social deprivation</b>	There are associations between social class and levels of physical activity. The Health Survey for England 2008 identified that males in the lowest income quintile had the lowest percentage that met the recommended amount of physical activity. For women, the top quintile demonstrates the highest level of physical activity. When work related activity is removed this disparity with men is increased.	Yes
<b>Carers</b>	No evidence of a link between carers and heel pain	No
<b>Human rights</b>	No impact	No

### Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Gender	Higher prevalence Achilles tendinopathy in males	No action – cannot influence prevalence.	NA		
Race	Varying prevalences of different sports by race	No action - cannot influence prevalence	NA		
Disability	Able bodied people who undertake exercise more likely to be disadvantaged by policy	Unable to influence the extent to which exercise is undertaken	NA		
Age	There are different age groups in whom heel pain is more prevalent.	As these indications are largely associated with “wear and tear”, it is not possible to influence.	NA		
Social Deprivation	Level of income can influence the level of physical activity and therefore the likely incidence of heel pain.	Unable to influence	NA		