Purchasing Guidance: Considered Judgement Form

This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations

Meeting Date:	**13 February 2017**
Topic:	**The effectiveness of injection of steroid into elbow (medial or lateral epicondyles) as a form of interventional pain management**

Purpose

This purchasing guidance (considered judgement) document accompanies a systematic review commissioned by ACC Research from the International Centre for Allied Health Evidence, University of South Australia.

The objective of this review is to critique and summarise the evidence regarding:

- Efficacy of steroid injections into the elbow (medial and lateral epicondyle) in relieving pain and/or in improving functional outcomes in patients with pain; and

- Safety of steroid injections into the elbow (medical and lateral epicondyle)

And determine whether the current purchasing recommendation formulated in 2005 and presented as part of the online Interventional Pain Management (IPM) guidance needs to change.

The current purchasing recommendation regarding steroid injections for Lateral Epicondylitis is:

- Injection of steroid injection with local anaesthetic could be considered in the treatment of adults with lateral epicondylitis in the short term (3 – 6 weeks).

For medial epicondylitis:

- Steroid and local anaesthetic injection may be considered in the treatment of adults with medial epicondylitis in the short-term

Background

Lateral Epicondylitis

Lateral Epicondylitis (also known as 'tennis elbow') is the most common condition affecting the elbow clinically. It mostly occurs after minor and often unrecognised trauma of the wrist extensors; however work-related movements involving repetitive and forceful elbow flexion and extension, repetitive wrist extension and pronation / supination, non-neutral position of hands and arms during work, and use of heavy tool are also attributed to this condition.

- The primary anatomical site of pain is the insertion of the common extensor tendon onto the lateral epicondyle of the humerus; however the under-surface of extensor carpi radialis longus can also be show pathological changes.

Medial Epicondylitis

Medial Epicondylitis (also known as 'golfers elbow') is associated with pathology of the common flexor tendon at the medical epicondyle. It is associated with repetitive movements and forceful activities and in younger patients has been associated secondary to overhead throwing activities.

Although there is some debate in the literature regarding terminology for this condition due to the underlying physiological mechanisms leading to the disorder (epicondylagia vs epicondylitis), as epicondylitis is the term used most commonly used in the literature, epicondylitis has been used in this review.

1. Effectiveness, Volume of Evidence, Applicability / Generalisability and Consistency / Clinical impact

Comment here on the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible, any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand population, and the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence. Comment on the clinical impact e.g. size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit.

Lateral epicondylitis

Systematic Reviews

Volume and quality of evidence:

The authors found a total of 19 systematic reviews, 15 of these were published after 2005, 1 was rejected due to low study quality. As this is an update of the original 2005 IPM review, only the SRs from 2005 are reported in this Considered Judgement Form. Across these reviews steroid injections were compared against saline injections; non-steroidal anti-inflammatories (NSAIDS); local anaesthetic injections; physiotherapeutic interventions; blood products including autologous blood or plasma related protein injections; prolotherapy and hyaluronic acid.

The systematic reviews were graded as:

- *High Quality* (n = 8): Barr et al, 2009; Krogh et al, 2013; Olaussen et al, 2013; Arirachakar et al, 2016; Claesson et al, 2016; Dong et al, 2016; Qian et al, 2016; and Tsikopoulos et al, 2016
- *Acceptable Quality* (n = 3): Nimgade et al, 2005; Sayegh & Strauch, 2015; Sirico et al, 2016
- *Low Quality* (n = 1): Rodriguuez, 2014;
- *Rejected* (n = 1): Elmajee et al, 2016.

Comparisons were made in the short-term (less than six weeks) and long term (six weeks or more).

Effectiveness (in terms of pain relief and/or improved function):

Findings are grouped according to short and long-term time periods:

***Short-term**: less than six weeks*

The systematic reviews of High (1++) to Acceptable (1) quality consistently reported that in the short term steroids were more effective at reducing pain compared to: no intervention, NSAIDs, placebo (local anaesthetics: lidocaine, procaine, or saline), and autologous blood products.

***Long-term:** longer than six weeks*

Systematic reviews showed:

- Autologous blood product injections were more effective than steroid injections for treating pain (n = 3 SRs; 2 High Quality, 1 Acceptable Quality)
- No difference between corticosteroid injection or placebo after 6 weeks (3 High Quality SRs)
- Physiotherapy interventions were more effective than steroid injections (n = 1 HQ and n = 1 AQ SR)

Randomised controlled trials

Volume and quality of evidence:

Sixteen RCTs not covered in the SRs were included in the report. These RCTs compared the effectiveness of different corticosteroids (methylprednisolone acetate + prilocaine; triamcinolone + lidocaine; triamcinolone acetonide; lidocaine; depomedrol; and dexamethasone) against therapies including extracorporeal shock wave therapy; platelet-rich plasma; prolotherapy, physiotherapy, saline, NSAIDs, and botox.

Quality of these RCTS was graded as:

- *High quality (n = 2)*: Tahririan et al, 2014; and Guo et al, 2016

- *Acceptable quality (n = 8)*: Gunduz, 2012; Kucuksen et al, 2013; Murtezani et al, 2015; Stefanou et al, 2012; Yadav, 2015; Behera et al, 2015; Carayannopoulos et al, 2011; Weerakul and Galassi, 2012

- Low quality (n = 6): Beyazal and Devrimsel, 2015; Ahmed et al, 2012; Palacio et al, 2016; Khaliq et al, 2015; Lebiedzinski et al, 2015; Bellapianta et al, 2011.

Effectiveness (in terms of pain relief and/or improved function):

Findings were (as reported in the review):

***Short-term**: less than six weeks*

Three RCTs of high, acceptable and low quality found steroids were more effective than saline, NSAIDs (topical and oral) and muscle energy techniques[1].

***Long-term:** longer than six weeks*

Steroids were not as effective as muscle energy techniques in the longer term (1 AQ RCT).

No difference was seen in pain levels between steroids and saline (1 HQ RCT); steroids and botox (1 HQ RCT) or prolotherapy (1 AQ RCT).

In the long term plasma related products appear to provide better pain relieve than steroids (1 AQ, 2 LQ RCTs).

Higher concentrations of Triamcinolone (10mg) did not appear to be more effective than lower doses (5mg), and a single injection performed better in visual pain scores compared to 'peppering' Triamcinolone (10mg) (1 LQ RCT).

Safety and Risk

Volume and quality of evidence:

[1] Described as a series of isometric contractions against resistance. In this study (Kucuksen et al, 2013) the forearm is supinated and resistance is applied by tester against pronation at end of range of motion (ROM), or onset pain at joint in attempt to increase ROM at the joint

Seven systematic reviews reported adverse events associated with steroid injections for lateral epicondylitis. Two other reviews are excluded from this CJF as they are dated pre-2005. Adverse effects are outlined below. Reported serious effects were low, the most common adverse effects were post-injection pain at site that was reported to wear off, other effects were loss of skin pigmentation, and skin atrophy.

Table 1. Adverse effects associated with steroid injection for epicondylitis

Author	Comparisons	Effect
Nichols et al, 2005 ***(included studies 1986 – 2002)*** ***(N=43 included studies, 13 that investigated Lateral epicondylitis)***	*Group 1* Association of secondary complications after steroid injection *Group 2* Primary described adverse events associated with steroid injections	Local warmth (0.8% to total number participants included); Facial flush (4.7%); Local erythema (4.7%); Local bruising (6.2%); Post-injection pain (55%); skin atrophy (18.8%); minor reactions (6.2%); Tendon rupture - *Injections with triamcinolone acetonide appeared to develop more frequent mechanical structural defects than methylprednisolone, betamethasone or hydrocortisone.* - *Relative doses of corticosteroids administered and injection technique may influence on post treatment mechanical tendon properties.*
Brinks et al, 2010 ***(N = 87 studies; 9 prospective studies investigated LE, 1 prospective cohort on ME)***	Divided events into: Major (0 – 5.8%): needing intervention or not disappearing), and Minor (0 – 81%): transient, not requiring intervention.	Adverse events included: - Discolouration of skin (3.2 – 11%) - Increased elbow pain (18.5 - 81%) - Skin atrophy (1.5 – 40%) - Facial flush (0.5 – 3%) - Skin irritation (5%) - Red swollen elbow (3%)
Arirachakaran et al, 2016	Adverse events of using steroid injections compared to use of PRPs and Autologous Blood	Corticosteroid injections had lower associated risks than Autologous blood injections; PRPs had lower associated risk than both corticosteroid and autologous blood injections
Claesson et al, 2016	Adverse events at the injection site	5 out of 7 included studies reported adverse events: rash, fat atrophy, hypopigmentation. - Risk not significantly different from placebo
Coombes et al, 2010	23 / 28 trial (82%)included in the SR reported adverse events	- Site specific risks seen for corticosteroid injection atrophy to Achilles and patella tendon **not** seen at elbow - Pain reported more frequently after steroid injection than placebo - Gastrointestinal disorders, vertigo and rash more common after placebo combined with oral NSAIDS than corticosteroid. - Low frequency of serious events
Krogh et al, 2013	Injection therapies in patients with LE	- Most common side effect is pain after injection (12 /17 trials) - Only glucocorticoid and botulinum toxin were associated with drug-specific adverse effects - Skin atrophy and loss of pigment in minority of patients in 4 or 9 glucocorticoid injections
Qian et al, 2016	Steroid injections compared to Autologous blood products	- Post injection pain (subsided within 2 days - Discolouration at the injection site - ABP had higher post injection pain rate (60%) vs corticosteroid (26%) - Other: rash (n = 1), skin atrophy (n = 3)

Medial epicondylitis

Volume and quality of evidence:

Only two randomised control trials were found for this review, no systematic reviews were found. Both of these studies (Stahl and Kaufman, 1997; and Bahari et al, 2003) were reported in the original IPM guidance in 2005. One study was graded as Acceptable Quality (+), (Stahl and Kaufman, 1997) the other as Low Quality (Bahari et al, 2003)

Interpretation of this evidence was no different to how it was interpreted for the 2005 guidance. Both studies showed that steroid group had significantly less pain than saline within the short term: first six weeks in Stahl and Kaufman (1997); and at two months by Bahari et al, (2003). Both studies found no difference in pain scores after three to four months.

2. Cost

Where possible and reported in the published research literature any economic analysis of the new treatment is considered. Where possible the following will be considered; total costs of the new intervention and number of claimants likely to be affected are considered, along with comparison with the cost of current treatments or interventions, actuarial assessment of the impact of the intervention on scheme liability (including direct and indirect impact e.g. other services and access), expected "accrued benefit" in terms of quality of life, longer life or speedier return to the workforce, implications of cost to the wider health sector.

There are no procedures recorded for elbow under IN31 (injection with imaging).

Data extracted from ACC data warehouses showed between 2014 – 2016 (end of financial year) there have been n = 13 claims for IN30 procedures at the elbow. N = 10 were paid and cost from $53 to $104 for each procedure.

3. Equity

The extent to which the intervention reduces disparities in health status; in particular equity of access and health outcome.

No equity issues found

4. Consistency with the intent of the AC Act

Purchasing decisions made by ACC must be consistent with and reflect consideration of factors described in the AC Act, Schedule 1, clause 2(1 and 2) and these decisions must be defensible against this statutory requirement in respect of individual claimants.

5. Possible purchasing options

The options are:

1. Purchase,

2. Don't purchase, or

3. Purchase on a case by case basis on the decision of the Corporate Medical Advisor (or equivalent).

6. Evidence statements

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

Lateral epicondylitis

15 SRs of low to very high quality were found that reported the result of low to moderate quality primary studies on efficacy of corticosteroid injections for LE. 16 RCTs of low to high quality were also found. Evidence from these studies were largely consistent and the main findings were:

- Steroid injections are effective in the short term (<6 weeks) for reducing pain and improving function
- Steroid injections are not effective in the intermediate and long term (>6 weeks) for reducing pain and improving function.

Medial epicondylitis
The two RCTs presented in the review were previously reported in the 2005 IPM update. The authors of this review stated:

- Steroid injections are effective in the short term (<8 weeks) for reducing pain and improving function in patients with medical epicondylitis

7. Recommendation

The 2005 recommendations on lateral and medial epicondylitis do not need to change greatly. However, in light of recent evidence presented to PGAG on 13 February 2017, it is suggested that the wording be refined as follows.

***Purchase* under the following conditions:**

- Purchase injections of steroid with local anaesthetic for the treatment of adults for short term (<6 weeks) pain relief from ***lateral epicondylitis***
- Purchase injections of steroid with local anaesthetic for the treatment of adults for short term (<8 weeks) pain relief from ***medial epicondylitis***

Good practice point

- *These injections should not be purchased in isolation but as part of a wider rehabilitation pathway, for example to relieve pain to enable participation in a physiotherapy rehabilitation programme*

These recommendations were ratified by the Clinical Governance Committee in March 2017.