NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin111
Chronic Pelvic Pain Syndrome in Men, Hyperthermia, Extracorporeal Shockwave Therapy and Sacral Neuromodulation

Category 1 Interventions – Not routinely commissioned

Contents

Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 The following interventions for chronic pelvic pain syndrome in men are not routinely commissioned:

- Hyperthermia (transrectal thermotherapy)
- Extracorporeal shockwave therapy (ESWT)
- Sacral neuromodulation

2. Exclusions

2.1 None.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 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 expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 There is limited evidence on the effectiveness of these interventions in the short term and very little (if any) evidence in the long term.

5. Summary of evidence review and references

5.1 Prostatodynia is more commonly referred to in the literature as chronic pelvic pain syndrome. The term is used when symptoms of prostatitis are present, but there is no evidence of prostate infection or inflammation. The pain may be perceived at various sites: the base of the pelvis, the perineum, in the testes, in the pubis/bladder area, at the penile tip, while urinating (dysuria) or when ejaculating[1]. International consensus was reached in 1995 defining chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and classifying it into 4 categories[2] and led to the development of a validated symptom index tool, the NIH Chronic Prostatitis Symptom Index (CPSI) to allow objective and quantifiable response to treatment[3] CP/CPPS remained a difficult entity to manage. Randomized controlled trials of various treatment modalities failed to show significant improvements in measured outcomes[4].

5.2 Twenty years on it is now treated as a pain syndrome by international bodies such as the European Association of Urology. Pain must have been continuous or recurrent for at least three months to be considered chronic in ICD11 (International Classification of Disease, 11th Edition). "The pain syndromes are defined by a process of exclusion. In particular, there should be no evidence of infection or inflammation. Investigations by end-organ specialists should therefore be aimed at obtaining a differential diagnosis; repeated, unnecessary investigations are detrimental in the management of chronic pain syndromes"[5].

5.3 There is no adequate data on incidence[5]. Across the world chronic pain is prevalent, seriously affecting the quality of people's social, family, and working lives, with differences between countries attributable to multiple causes, including study methodology, but no credible estimate of CPPS in the UK was found.

5.4 The aetiology and pathogenesis of CP/CPPS remains poorly understood, the patient presentation is varied and it seems that some sub-groups benefit from various treatment modalities, but even the 4 classifications referred to above were not helpful in identifying who might benefit from which treatment. A phenotypic approach was developed, UPOINT, using existing clinical assessment to plot patients along 6 domains, Urinary, Psychosocial, Organ-specific, Infection, Neurologic and Tenderness, and produce individualised clinical treatment strategies[1].

5.5 Adverse Childhood Experiences (ACEs) such as sexual and physical violence, serious illness, and bereavement have been linked to number of chronic pain conditions in adulthood, and specifically to urologic chronic pelvic pain syndrome (UCPPS). A cohort-controlled study found ACEs was most strongly associated with complex chronic pain, including more diffuse pain, co-morbid functional symptoms/syndromes, and worse perceived physical well-being[6].

5.6 The prevalence of psychosocial symptoms and "pain catastrophising" was high in a recent Chinese study. The authors suggested that there might be a link between pain catastrophizing and somatic symptoms in CPPS[7].

5.7 Myalgia is too often overlooked as a form of chronic pelvic pain. The pelvic floor and adjacent muscles are used in an abnormal way. Repeated or chronic muscular overload can activate trigger points in the pelvic floor muscles. A report from the Chronic Prostatitis Cohort Study showed that 51% of patients with prostatitis and only 7% of controls had any muscle tenderness. Tenderness in the pelvic floor muscles was only found in the CPPS group[8].

5.8 Although antimicrobials are very widely prescribed for CPPS, often long-term, infective organisms are not commonly found. A 2017 study in Croatia obtained samples from 254 previously diagnosed and treated CPPS patients who had tested negative in urethral swab, urine and prostate samples by prostatic massage and reported that 13% of patients had positive infections. 10% of the men were infected with sexually transmitted organisms (Chlamydia, mycoplasma and Trichomonas) not previously detected[9].

Treatments

5.9 Treatment is often more about controlling symptoms rather than effecting an immediate cure. NICE Clinical Knowledge Summary states options include paracetamol and/ or a nonsteroidal anti-inflammatory drug, not opioids. For suspected neuropathic pain seek advice from a pain specialist. An alpha-blocker for 4 – 6 weeks if significant lower urinary tract symptoms (LUTS). Targeted Cognitive Behaviour Therapy, counselling, and anti-depressants for men with psychosocial problems. A single course of anti-biotics if symptoms have been present for less than six months. A stool softener if defaecation is painful. Acupuncture[10].

5.10 The European Guidelines place stronger emphasis on pain education and physiotherapy for the pelvic floor muscles or myofascial pain[5]. A Cochrane Review published in 2018 reviewed non-pharmacological interventions for treating CPPS, based on the findings of the moderate quality evidence they concluded that acupuncture and Extracorporeal Shock Wave Therapy were likely to result in a decrease in prostatitis symptoms and may not be associated with a greater risk of an adverse event[11].

5.11 Treatments which were commonly used in a cohort of 1,310 CPPS patients over a 16-year period, published in 2018, from a Canadian out-patient department were medication: alpha-blockers (62%), anti-depressants (15%), gabapentinoids (6%) and physiotherapy (2.5%) for pelvic floor pain. Phytotherpy (using extracts of natural origin) was very common - Quercetin, a plant flavonol found in many fruits, vegetables and seeds, and available as an over-the-counter supplement, was “prescribed” for a third of the patients by their physicians. [Bee pollen is also popular although not mentioned in this study.] Antibiotics were used in 22% of the patients. Less than 1% had used acupuncture[1].

5.12 A systematic review and network analysis completed nearly a decade ago found 262 studies of drug treatments of CPPS, of which 23 were eligible trials. They found patients receiving alpha-blockers, antibiotics and combinations of these therapies achieved the greatest improvement in clinical symptom scores compared with placebo. Anti-inflammatory medications have a lesser but measurable benefit on selected outcomes. However, the authors note that the beneficial effects of alpha-blockers may be overestimated because of publication bias[12].

5.13 As many patients do not respond conventional treatment such as anti-inflammatory medications, antibiotics, and alpha-blockers they turn to alternative therapies such as acupuncture. Acupuncture is commonly used in traditional Chinese medicine for chronic pain. A recent publication[13] reviewed the literature on acupuncture, exploring its effect on the NIH Chronic Prostatitis Symptom Index (NIH-CPSI), Quality of Life (QoL) and various biomarkers – one example cited was a randomised trial of acupuncture versus sham acupuncture – same number of needles but placed away from true acupuncture site – reported improvement in 73% of the acupuncture group compared to 47% of the sham control group. At 24 week follow up the results were 32% acupuncture and 13% sham still showed improvement.

5.14 In addition to the previously mentioned therapies, one finds hyperthermia, and invasive sacral neuromodulation discussed in the literature. A systematic review of the efficacy of low-intensity extracorporeal shockwave therapy (ESWT) for patients with CPPS was published in March 2021. They found 6 studies analysing 317 patients from 2009 to 2019. They examined the results at 1, 12 and 24 weeks and found NIH-CPSI scores, QoL and urinary symptom scores improved at 12 weeks, but not 1 or 24 weeks – they concluded that ESWT may transiently improve symptoms in CPPS[14]. Another systematic review published 2 years earlier included more of the Chinese literature and found 12 RCTs involving 838 patients and concluded that low-intensity ESWT showed a significantly higher rate of overall effectiveness and a positive correlation between number of shock waves and better therapeutic effect, but the follow-up period was not stated. This review may have also included females with chronic pelvic pain.

5.15 A small RCT tested radial ESWT (rESWT) on patients with CPPS, both control and intervention group treated to same schedule, but the control group had the device's probe turned off. A statistically significant decrease was determined in the pain domain, urine score, quality of life, and the total NIH-CPSI score of the rESWT group at all post-treatment time points. All domains and the total score of the NIH-CPSI at all three follow-up time points decreased more significantly in the rESWT group as compared to the control group[15].

5.16 Therefore, there is moderate evidence that ESWT may be effective at improving the symptoms of CPPS in the short and medium term, but no evidence about its long-term impact on this chronic condition.

5.17 Hyperthermia treatment for CPPS could only be found referred to as transrectal thermotherapy. The Cochrane review[11] cited previously identified two relevant studies (237 participants) which, based on short-term follow-up, concluded that transrectal thermotherapy alone or in combination with medical therapy may decrease prostatitis symptoms slightly when compared with medical therapy alone. One included study reported that participants may have experienced transient adverse events, but they found no information regarding sexual dysfunction, quality of life, depression or anxiety. A device called URO-Dr™ was referred to, but a Google search found no results when URO-Dr™ was entered.

5.18 A systematic review and meta-analysis of the benefits and harms of electrical neuromodulation for chronic pelvic pain found 8 randomised controlled trials covering 1099 patients, but meta-analysis was only possible for patients receiving transcutaneous nerve stimulation (as opposed to via an implant), for Sacral Neuromodulation they could only undertake a narrative synthesis which concluded that it appeared to reduce pain, but many of the studies showed high risks of bias and confounding[16].

5.19 Note that Sacral Neuromodulation is effective and appropriate for some conditions including urinary and faecal incontinence, for which is it NICE-approved and commissioned by NHS England – it is only it use in Chronic Pelvic Pain Syndrome which is being discussed here.

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6. Advice and Guidance

6.1 **Aim and Objectives**

- 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.

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

- 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.

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

- 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.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- 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.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- 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 available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 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

6.5 **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.

6.6 **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.

7. Monitoring and Review

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.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 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

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

8. Quality and Equality Analysis

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

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**
None

9.2 **International classification of diseases (ICD-10)**
None

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