

Clinical Commissioning Policy

CMICB_Clin062

Idiopathic Facial Paralysis (Bell's Palsy) -Trophic Electrical Stimulation

Category 1 Interventions – Not routinely commissioned

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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 This intervention is not routinely commissioned.

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 <u>NHS England gender</u> <u>services programme</u> - <u>https://www.england.nhs.uk/commissioning/spec-services/npccrg/gender-dysphoria-clinical-programme/</u>

4. Rationale behind the policy statement

- 4.1 The primary research which has been published since the 2011 Cochrane systematic review on the use of electrotherapy in Bell's palsy, does not support a change in current commissioning position of not routinely commissioned.
- 4.2 National guidance published in North America does not support the use of electrostimulation.

5. Summary of evidence review and references

- 5.1 Bell's palsy (also called idiopathic facial palsy) is an acute disorder of the facial nerve which can produce full or partial paralysis of movement on one side of the face. ¹ It is characterised by an acute onset of unilateral, lower motor neuron weakness of the facial nerve in the absence of an identifiable cause. ² The incidence has been reported to be 11.5 40.2 cases per 100,000 per annum with a lifetime prevalence of 1 in 60.³ The major cause is likely to be an infection of the facial nerve caused by the herpes simplex virus which results in swelling and compression as the nerve passes through the temporal bone.
- 5.2 Most people make a full recovery, although 23% of people with Bell's palsy are left with either moderate to severe symptoms such as hemifacial spasm, partial motor recovery, crocodile tears (i.e. tears upon salivation), contracture or synkinesis (involuntary twitching of the face or blinking).¹
- 5.3 According to Facial Palsy UK, when the facial nerve is damaged, the muscle no longer receives its electrical impulses and as a result, the muscle becomes weak and floppy. Electrostimulation, electrical stimulation or trophic electrical stimulation attempts to mimic these missing electrical impulses which helps to restore muscle tone and growth.
- 5.4 The current Cheshire CCG policy is trophic electrical stimulation for Bell's palsy isn't routinely commissioned. The supporting evidence is a single article on physical therapy for Bell's palsy, published by the Cochrane collaboration in 2011.¹ The wide-ranging review examined a number of treatment modalities which included electrostimulation. It examined 4 trials (N = 313 participants) of patients on electrostimulation and found no benefit over placebo. The authors concluded there is insufficient evidence to decide whether electrical stimulation works or to identify risks. A literature search over the last 10 years was therefore performed to identify any new evidence which might affect this recommendation.
- 5.5 The mainstay of treatment is corticosteroids which should be initiated within 72 hours of symptom onset and these may or may not be combined with antiviral therapy. In addition to electrotherapy, other treatments have included acupuncture, physical therapy and surgical decompression.²
- 5.6 Confirmation of the significant benefit of corticosteroids is provided by a Cochrane review (2016) based on the available moderate to high quality evidence.⁴ In a separate systematic review and meta-analysis (2019), the efficacy and safety of high-dose corticosteroids (daily dose of 120mg 200 mg of prednisolone) was examined. Compared with the standard dosage, this achieved a significant benefit at 6 months with no severe adverse effects.⁵
- 5.7 The effectiveness of antiviral therapy has been reviewed in 2 other studies. The first (2015) was a systematic review which concluded that antiviral agents are not efficacious in increasing the proportion of people with Bell's palsy who achieve complete recovery, regardless of their baseline symptom severity.⁶ Another Cochrane review (2019) assessed the impact of antivirals plus other therapies for Bell's palsy. It concluded that the combination of antivirals and corticosteroids may have little or no effect on rates of incomplete recovery in comparison to steroids alone. Corticosteroids alone are probably more effective than antivirals alone and there is no clear benefit from antivirals alone over placebo.⁷
- 5.8 Early surgical decompression of the entrapped nerve is another option which has recently been examined in a 2021 Cochrane review. This concluded there is insufficient evidence to decide whether surgical intervention is beneficial or harmful. ⁸ Interestingly, the authors suggested that further research into this surgical intervention is unlikely because spontaneous or medically supported recovery occurs in most cases.

Electrostimulation

- 5.9 Only 2 studies were identified which were specifically focused on electrostimulation. The first, a 2016 prospective, randomised study in Korea of 60 patients provided low quality evidence of the benefit of electrostimulation. ⁹ All patients received either prednisolone alone, acyclovir alone or prednisolone + acyclovir. Patients in the intervention arm received electrostimulation in addition to pharmacotherapy. It is important to stress that the type of electrostimulation was a continuous low frequency output. No information on age, comorbidities or other potential confounders was supplied, neither was there detailed information on how the rate of recovery was measured. However, "recovery" occurred in 88% of controls and 96% in the intervention group i.e. a marginal difference of 8%.
- 5.10 The 2nd study, a systematic review (2020) evaluated electrotherapy for treating Bell's palsy in 7 studies in 131 intervention cases and 113 controls. This compared electrotherapy combined with other interventions such as hot wet facial napkins, massages and muscle reeducation. ¹⁰ Unfortunately, electrostimulation alone was not studied. The authors concluded because of the diverse methodologies and small patient numbers, the efficacy of electrotherapy for treating Bell's palsy could not be proved. More studies with larger samples and homogenous populations were required.

National guidelines

5.11 The American Academy of Otolaryngology Head and Neck Surgery (AAO-HNSF) guideline on management of Bell's palsy recommends against use of electrostimulation.¹¹ This is supported by the Bell Palsy Working Group of the Canadian Society of Otolaryngology which states that the available (very low quality evidence) provides little support for electrostimulation.³ In addition, Aetna, the American healthcare maintenance organisation considers electrical stimulation for Bell's palsy as experimental and investigational because its effectiveness for this indication has not been established.¹

Conclusion

5.12 In conclusion, the primary research which has been published since the 2011 Cochrane systematic review on the use of electrotherapy in Bell's palsy, does not support a change from Cheshire CCG's current commissioning stance of not routinely commissioned. Neither does national guidance published in North America support the use of electrostimulation. It is, therefore, recommended that the current policy statement should remain unchanged. This is consistent with the policy from Mersey CCG.

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¹ Aetna. Bell's palsy Clinical policy bulletin no. 0745. Oct 2018. <u>www.aetna.com</u>

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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: <u>https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/</u>

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: <u>http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx</u> and <u>http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx</u>

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
 - Prior approval process
 Post activity monitoring through
 - Post activity monitoring through routine data
 Dest activity monitoring through accepted and
 - 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 **OPCS-4 Procedure Codes** A338 Neurostimulation of cranial nerve Other specified

9.2 ICD-10 diagnosis code(s) G51.0 Bell palsy G83.6 Upper motor neuron facial paralysis

Document Control

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