NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Positional Plagiocephaly/brachycephaly in children, helmet therapy

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.

1.4 This policy is based on NHS England's Evidence-Based Interventions (EBI) recommendations see link to programme below - accurate at the point of publication https://www.aomrc.org.uk/ebi/clinicians/helmet-therapy-for-treatment-of-positional-plagiocephaly-brachycephaly-in-children/.

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. Summary of intervention

3.1 Non-synostotic/positional plagiocephaly and brachycephaly are distortions of the skull (flattening to the side or the back of the head) that most commonly become apparent in the first few months of life as a result of the amount of time a baby spends lying on their back. Non-synostotic/positional plagiocephaly and brachycephaly are very common, affecting up to 40% of infants (as opposed to synostotic conditions which are rare).

3.2 Cranial Moulding Orthosis – or 'helmet therapy' – is an intervention that claims to correct the shape of the head. A specially moulded solid helmet is created (with space to allow the flattened area to re-mould) that must be worn 23 hours a day. This helmet requires repeated adjustments as the baby grows.

3.3 **This guidance applies to children aged 2 years and under.**

4. Policy statement

4.1 Helmet therapy for positional plagiocephaly/brachycephaly in children is not routinely commissioned.

5. Exclusions

5.1 None

6. Rationale

6.1 As clinically evidenced by the four major designated supraregional craniofacial services in the UK (prior to the availability of Helmet therapy), the flattened area of the head usually self-corrects naturally, as a baby grows, develops and becomes more mobile with increased muscle strength, and spends less time lying in one position.

6.2 There is clear evidence and expert consensus that a helmet does not affect the natural course of skull growth and should not be used. Helmets may be associated with significant risks such as pain, pressure sores and may adversely affect the bond between baby and parents. They are also expensive. To reduce pressure on the flattened part of the head and encourage remoulding, the following simple interventions are suggested:

- 'Tummy time' – Allow baby to spend time lying on their front while awake, supervised and playing
- Change the position of toys / mobiles / cot in the room to encourage baby to move their head away from the flattened side
- Use a sling or a front carrier to reduce the amount of time baby spends lying on a firm flat surface
- Modify Parental lap "nursing" position to promote contact with less flattened side to parental chest.

6.3 All babies including those with non-synostotic/positional plagiocephaly or brachycephaly must be laid to sleep on their back. Sleeping in positions other than this is associated with an increased risk of Sudden Infant Death Syndrome or SIDS (formerly known as Cot Death). For the same reason, no pillows or props should be used to change a baby's sleeping position.

6.4 Non-synostotic/positional plagiocephaly is a mechanical distortion that corrects itself as the child grows. Studies have shown that helmet therapy is no more effective than leaving the head to remould naturally as the baby grows. Choosing Wisely UK and Choosing Wisely Canada have both advised against helmet therapy as an intervention for positional plagiocephaly and brachycephaly. In the guideline NG127 Suspected neurological conditions: recognition and referral published in May 2019 NICE does not refer to helmet therapy and recommends: For babies aged under 1 year whose head is flattened on one side (plagiocephaly):

- Be aware that positional plagiocephaly (plagiocephaly caused by pressure outside the skull before or after birth) is the most common cause of asymmetric head shape
- Advise parents or carers of babies with positional plagiocephaly that it is usually caused by the baby sleeping in one position and can be improved by changing the baby's position when they are lying, encouraging the baby to sit up when awake, and giving the baby time on their tummy.

6.5 The NICE committee discussed how measuring the distance between the tragus of the ear and the outer canthus of the eye is a useful adjunct to clinical inspection of the head shape of a child under 1 year and would help a clinician reassure parents that this was a benign condition. However, the committee acknowledged that this was not an absolute discriminator and that if there was uncertainty, referral for specialist assessment was appropriate.

6.6 In terms of positional plagiocephaly, the NICE committee recommend that once the flat area at the back of the head is relieved of pressure with changing position, and the child is spending more time sitting, natural growth of the head will reduce the flattening. The committee does not recommend referral for investigations or management for a condition that has an excellent prognosis over time. The committee recommends referral for assessment of developmental disorders if there is concern that delay in meeting early motor milestones – rolling, sitting – is contributing to degree or maintenance of plagiocephaly. The referral would be for diagnostic assessment as well as assessing the need for therapy and provision of equipment such as adapted seating.

6.7 Consider referral to physiotherapy if there is concern of neck muscle pathology.

7. Underpinning evidence

7.1 NHS information. Plagiocephaly and brachycephaly (flat head syndrome) https://www.nhs.uk/conditions/plagiocephaly-brachycephaly/.

7.2 NHS: Reduce the risk of sudden infant death syndrome (SIDS): https://www.nhs.uk/conditions/pregnancy-and-baby/reducing-risk-cot-death/.

7.3 NICE guidance (2019) Suspected neurological conditions: recognition and referral [NG127].

7.4 Wilbrand J-F et al. Complications of Helmet Therapy. Journal of Cranio-Maxillofacial Surgery Volume 40, Issue 4, June 2012, Pages 341-346.

7.5 Expensive helmets do not correct skull flattening in babies. BMJ. 2014;348:g3066. PMID: 24791750. doi: https://doi.org/10.1136/bmj.g3066

7.6 Tamber MS, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline on the Role of Cranial Molding Orthosis (Helmet) Therapy for Patients With Positional Plagiocephaly. Neurosurgery. 2016 Nov;79(5):E632-E633. doi: 10.1227/NEU.0000000000001430. PMID: 27776089.

7.7 van Wijk RM, et al. Helmet therapy in infants with positional skull deformation: Randomised controlled trial. BMJ. 2014;348:g2741. PMID: 24784879: doi: https://doi.org/10.1136/bmj.g2741.

7.8 Choosing Wisely UK. “Helmet therapy is not effective in the treatment of positional Plagiocephaly in children, other treatment options should be considered and discussed with your patient.” https://www.choosingwisely.co.uk/i-am-a-clinician/recommendations/

7.9 Choosing Wisely Canada. Pediatric Neurosurgery https://choosingwiselycanada.org/pediatric-neurosurgery/.

7.10 Rowland K, Das N et al. PURLs: Helmets for positional skull deformities: A good idea, or not? J Fam Pract. 2015 Jan; 64(1): 44–46. PMCID: PMC4294410. PMID: 25574506.

8. Force

8.1 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.

9. Coding

9.1 Office of Population Censuses and Surveys (OPCS)

None

9.2 International classification of diseases (ICD-10)

Q75.0 Brachycephaly
Q67.3 Plagiocephaly

10. Monitoring And Review

10.1 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

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

11. Quality and Equality Analysis

11.1 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.