NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin071
Lycra™ Suits and Orthotics (dynamic elastomeric fabric orthoses)

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 Lycra™ Suits and orthotics (dynamic elastomeric fabric orthoses) are not routinely commissioned for postural management of cerebral palsy or any other condition.

2. Exclusions

2.1 Elastomeric garments (e.g. Lycra sleeves and gloves) may be used to treat lymphoedema by specialist lymphoedema services and are thus excluded from this policy.

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 The evidence to support the effectiveness of these garments is limited and of low quality.

5. Summary of evidence review and references

5.1 Lycra™ is an elastomeric fabric which is strong, but flexible and allows skin to breathe, hence its popularity in certain high-performance sports, including its use as supports/splints for various parts of the body. It has been used in the management of some medical conditions for more than two decades.

5.2 Lycra™ garments, including body suits, may offer generic support e.g. improved muscle tone but are not supportive of any particular function. They may be custom made (bespoke) to the individual patient, or "off the peg".

5.3 Dynamic Lycra™ orthotic garments have sections of Lycra™ of varying thicknesses stitched together using specific tensions and directions of pull to act as a form of splint or brace. They are designed to move with the wearer and hence referred to as dynamic. These orthoses are made-to-measure, therefore requiring individual assessment, and designed specifically to fit the shape of the wearer and ostensibly support a specific function. Dynamic splinting may be used in whole body suits, vests, trousers, gloves and socks. Lycra™ garments can be used alongside other types of splints or replace them completely and are likely to be used as an adjunct to other therapy, e.g. physiotherapy. Manufacturers suggest, to achieve optimal effect, the Lycra™ garment should be worn between 6–12 hours per day, 5–6 days per week, but not while sleeping.

5.4 Lycra™ orthoses have been used to ostensibly improve motor function and prevent deformity due to spasticity (contracture) particularly in children with neuromuscular conditions, cerebral palsy, multiple sclerosis, muscular dystrophy. Their use has also been suggested for improved postural management in Parkinson's disease when it coexists with Pisa syndrome (spinal curvature - scoliosis, kyphosis) and in stroke and lymphoedema.

5.5 An evidence review of the use Lycra™ Suits in Cerebral Palsy and Multiple Sclerosis[1] was conducted by Public Health Registrars in Cheshire in 2014 which found 14 studies/review articles, none of which were Randomised Controlled Studies, all had a very small number of participants (generally fewer than 10) with no long-term follow up. The results were variable, some showed a beneficial effect, others negative or detrimental and many participants withdrew because the garments were uncomfortable. They concluded that the evidence did not support routine commissioning of Lycra™ suits in the management of Cerebral Palsy. This was the evidence used in the current policy.

5.6 Lycra™ is an elastomeric fabric which is strong, but flexible and allows skin to breathe, hence its popularity in certain high-performance sports, including its use as supports/splints for various parts of the body. It has been used in the management of some medical conditions for more than two decades.

5.7 Lycra™ garments, including body suits, may offer generic support e.g. improved muscle tone but are not supportive of any particular function. They may be custom made (bespoke) to the individual patient, or "off the peg". Dynamic Lycra™ orthotic garments have sections of Lycra™ of varying thicknesses stitched together using specific tensions and directions of pull to act as a form of splint or brace. They are designed to move with the wearer and hence referred to as dynamic. These orthoses are made-to-measure, therefore requiring individual assessment, and designed specifically to fit the shape of the wearer and ostensibly support a specific function. Dynamic splinting may be used in whole body suits, vests, trousers, gloves and socks. Lycra™ garments can be used alongside other types of splints or replace them completely and are likely to be used as an adjunct to other therapy, e.g. physiotherapy. Manufacturers suggest, to achieve optimal effect, the Lycra™ garment should be worn between 6–12 hours per day, 5–6 days per week, but not while sleeping.

5.8 Lycra™ orthoses have been used to ostensibly improve motor function and prevent deformity due to spasticity (contracture) particularly in children with neuromuscular conditions, cerebral palsy, multiple sclerosis, muscular dystrophy. Their use has also been suggested for improved postural management in Parkinson's disease when it coexists with Pisa syndrome (spinal curvature - scoliosis, kyphosis) and in stroke and lymphoedema.

5.9 The Peninsula Cerebra Research Unit published a review of Lycra™ Orthoses for Cerebral Palsy[2] which found one randomised controlled trial, which reported that Lycra™ orthoses had the potential to improve movement outcomes for children with cerebral palsy but that it only

included 18 children, so had to conclude that the lack of long-term studies makes it impossible to provide dependable advice about whether there is a risk of weakened muscles or any lasting benefit once a garment is no longer worn.

5.10 A retrospective audit of the use of dynamic elastomeric fabric suits in children with neuropathic onset scoliosis[3] reported in 2016. The findings were that many children with existing or at high risk of scoliosis were being fitted with these suits, but no data on outcome was reported, and in fact there was not even consistent measurement.

5.11 NICE guidelines on spasticity in children and young people[4] give recommendations on the use of orthoses but do not specifically address Lycra™ based orthoses, apart from one mention of dynamic orthoses to improve hand function, for example a non-rigid thumb abduction splint to allow some movement with a thumb in palm deformity. It does not refer to any specific dynamic material or construction. Similarly, NICE guidance on stroke rehabilitation in adults[5] makes recommendations on the use of orthoses but does not specify Lycra™ or other elastomeric fabrics.

5.12 A small randomised controlled trial examined the use of a Lycra™ sleeve in stroke patients[6] with upper limb motor dysfunction early in their rehabilitation, whilst they reported improved outcomes in the experimental group, the final results being based on just 15 participants meant that the evidence is not reliable. A search in October 2019 for a specific IFR case (scoliosis secondary to Parkinson's disease in an adult) found no published research on use of Lycra™ in adult skeletal deformity.

5.13 Use of dynamic elastomeric fabrics in the form of compression garments for lymphoedema (e.g. Lycra sleeves) are an acceptable replacement for other types of compression hosiery and bandages, and can be used for areas difficult to bandage, such as the digits. Lycra gloves are particularly useful.

REFERENCES

1 Use of Lycra Suits in the Management of Cerebral Palsy and Multiple Sclerosis. Literature Review. Liu A, Bolton-Maggs D (in conjunction with Hampson JP). CHAMPS, Public Health Collaborative Service. 2014. https://www.liverpoolccg.nhs.uk/media/1075/public-health-lycra-suits-paper.pdf

2 What's the Evidence? Lycra Orthoses for Cerebral Palsy. Peninsula Cerebra Research Unit. Childhood Disability Research. University of Exeter. Published April 2013. http://www.pencru.org/media/universityofexeter/medicalschool/subsites/pencru/pdfs/WTE_Lycra_orthoses_April_2013.pdf

3 The use of dynamic elastomeric fabric orthosis suits as an orthotic intervention in the management of children with neuropathic onset scoliosis: A retrospective audit of outline clinical case notes. Matthews M, Blandford S, Marsden J et al. Scoliosis and Spinal Disorders (2016) 11:14. https://scoliosisjournal.biomedcentral.com/track/pdf/10.1186/s13013-016-0073-z

4 National Institute for Health and Care Excellence. NICE clinical guideline CG 145. Spasticity in under 19s: management. Published July 2012. Last updated November 2016. Accessed via https://www.nice.org.uk/guidance/cg145/chapter/1-Guidance#orthoses on 30/07/20.

5 National Institute for Health and Care Excellence. NICE clinical guideline 162 (June 2013) Stroke rehabilitation in adults. Accessed via https://www.nice.org.uk/guidance/cg162 on 30/07/20.

6 The Effectiveness of Lycra Compression Garments on the Upper Limb in Patients with Stroke. Naubereit C. Masters dissertation, MSc Occupational Therapy. 2017. Johannesburg. http://wiredspace.wits.ac.za/bitstream/handle/10539/23260/Carene%20Naubereit%20307148%20Research%20report%20titled%20-%20The%20effectiveness%20of%20Lycra%20Compression%20Garments%20on%20the%20upper%20limb%20in%20patients%20with%20stroke%20.pdf?sequence=1&isAllowed=y

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

Document Control

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