



Northern Treatment
Advisory Group

Lycra Garments for Neurological and Musculoskeletal Conditions

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Summary

- Lycra garments are a type of orthotic device which consist of sections of Lycra with strategically positioned reinforcement panels providing specific areas of resistance to stretch and aid corrective alignment of the body. The garments are made to measure and range from a glove for improved hand / upper limb function to a full body suit for whole body involvement.
- They are predominantly used in children with cerebral palsy but are also advocated for other neurological and musculoskeletal conditions such as muscular dystrophy, multiple sclerosis, stroke, scoliosis, and head injury.
- The garments are presumed to work by increasing sensory and proprioceptive awareness as well as producing a mechanical compressive effect. This in turn leads to reduction in abnormal tone, improved proximal stability, posture, movement and functional performance.
- Advantages of Lycra garments include the flexibility and breathability allowing freedom of movement, intimate skin contact and user comfort over conventional rigid/semi-rigid orthoses.
- The evidence base for clinical effectiveness of Lycra garments in the management of cerebral palsy and other neurological and musculoskeletal conditions is limited. Available studies which have mostly been in children with cerebral palsy tend to be lacking in quality and have many limitations (e.g. small patient numbers, mostly case studies/series, non-standardised and/or subjective outcome measures and short duration). Only one published small randomised controlled trial (n=16) was identified. Currently, academic studies evaluating effectiveness of Lycra suits for cerebral palsy and stroke are ongoing at Keele University and University of West of England, Bristol.
- The limited data which is inconclusive suggests that wearing Lycra garments may improve stability, movement and function in some children with cerebral palsy in the short term, but are not conclusive. The limitations of the evidence make it difficult to characterise whether there are patient groups that may benefit more than others and which if any benefits are sustained in the long term.
- Adverse effects reported in studies with various types of Lycra garments (full body suits, vests, shorts) include vomiting, cyanosis, hyperthermia, muscle weakness, inhibition of voluntary movement, respiratory compromise, constipation, friction sores and erythema. Long term safety is not known.
- Practical difficulties with putting on and taking off the suit, feeling hot and/or restricted and toileting have been reported. Careful assessment of the patient's need and designing the garment accordingly e.g. addition of extra zips may address these issues.
- No published cost-effectiveness studies were identified, Cost varies depending on the type of garment required and the manufacturer. Standard process for more commonly used garments range from about £90 to £3200.

- The garments have an average life span of about 12 months, but may need to be replaced more often in children as they grow. Alterations may be possible with some garments to make them bigger so that they don't have to be replaced as quickly.

Introduction and background

Lycra garments are a type of orthotic device - an externally applied artificial device or appliance used to support, align, prevent, or correct deformities or to improve musculoskeletal function.⁽¹⁾ They have been available for around 15 years and were originally developed as a treatment modality for improving movement, posture and function in children with cerebral palsy. They have since been employed in the management of other neurological and musculoskeletal conditions affecting movement and posture such as muscular dystrophy, multiple sclerosis, stroke, scoliosis, and head injury.⁽²⁻⁴⁾

Lycra garments are made to measure to conform to the shape of the wearer. They are made up of strategically positioned reinforcement panels, using specific tensions and directions of pull, which provide specific areas of resistance to stretch to aid corrective alignment of the body.^(5, 6) Plastic boning can be added to provide extra support if necessary.⁽⁷⁾ The extent to which the garment covers the body depends on the requirements of the individual and garments range from a glove for improved hand / upper limb function to a full body suit for whole body involvement.

In contrast to conventional orthoses which tend to be rigid or semi rigid, Lycra garments are breathable and flexible, allowing freedom of movement. Hence they are referred to as dynamic. They may be referred to as dynamic Lycra orthoses, dynamic Lycra splints or Dynamic Elastomeric Fabric Orthoses (DEFOs).^(5, 8, 9)

The mechanisms by which Lycra orthoses are presumed to work are a combination of physiological and biomechanical effects. The areas of high pressure provided by the close, tight fit of the Lycra garment are thought to increase sensory and proprioceptive awareness, and produce a mechanical compressive effect. This in turn leads to reduction in abnormal tone, improved proximal stability, posture, movement and functional performance.^(7, 9-11)

The style and design of the Lycra garment is based on the individual's specific functional objectives. Detailed measurements are taken by a physiotherapist, occupational therapist or orthotist specifying the reinforcement that is required. The garments are also fitted and reviewed by the therapist/orthotist. The wearing time is usually increased gradually until the patient reaches their recommended wearing time which can be throughout the day in some cases. Night time wear is not advised unless specifically prescribed.^(3, 12, 13)

The garments have an average life span of about 12 months but may need to be replaced more often in children as they grow;⁽⁵⁾ although at extra cost, some garments may have the possibility to get altered e.g. by adding panels to make them bigger so that they don't have to be replaced as quickly.⁽¹⁴⁾ Patients typically receive one garment⁽¹⁴⁾ which can be washed according to the manufacturer's care instructions.^(3, 12, 15) Washing around twice weekly is usually recommended.^(3, 12)

The length of time that the garment will have to be worn varies between patients. For some people, wearing the garment for a few years may result in permanent functional

improvement, whereas for others reduction in use may result over a period of time. In general, it is usual to wear the garments for a number of years.^(3, 16)

Patient and carer commitment and motivation, and adherence to treatment are deemed to be essential components of treatment success.

In the UK, the main manufacturers of dynamic Lycra orthoses appear to be DM Orthotics Ltd, Jobskin and Second Skin. Garments from these manufacturers are CE marked.⁽¹⁷⁻¹⁹⁾ Specific construction and prescription varies between manufacturers.⁽⁵⁾

The NICE guidance on spasticity in children and young people with non-progressive brain disorders - last updated in November 2016 states that orthoses may be considered for children with spasticity based on their individual needs, and aimed at specific goals. However, there are many different types of orthoses and the guideline does not specifically address Lycra based orthoses.⁽¹⁾

The NICE guidance on stroke rehabilitation in adults – published in June 2013 gives recommendations on the use of orthoses for the upper limb but again, this guideline does not make a specific mention of Lycra based orthoses.⁽²⁰⁾

Lycra garments have been developed as another form of orthotic treatment. Their flexibility and breathability allowing freedom of movement, intimate skin contact and user comfort, are viewed as advantages over conventional rigid/static orthoses.

Clinical Evidence

The vast majority of studies investigating Lycra garments have been carried out in children with cerebral palsy. Hence, this has resulted as the main focus of the literature review. Most of the studies are case series/case reports with small numbers of patients. Only one published randomised controlled trial (RCT) on the effectiveness of Lycra garments was identified.

Lycra garments for cerebral palsy

Systematic reviews

Two systematic reviews on the effects of Lycra garments in patients with cerebral palsy were identified.

The first by Blackmore et al in 2006 was a systematic review of the effects of soft splinting (splints made of soft, pliable material such as neoprene and Lycra) on upper limb function in people with cerebral palsy. Five studies were included (all using Lycra), most of which were case series. One study included matched controls. All of the studies had small sample sizes ($n \leq 24$), included patients with different types of cerebral palsy and were mostly of short duration (<12 months). The review found that the evidence regarding soft splinting is very weak. The only study with matched controls found no significant differences in muscle strength (grip strength and abdominal strength) between children who had worn the Lycra splints and those who hadn't. This study was considered methodologically weak due to its

small sample size, a heterogeneous population (with no distinctions between types and severity of cerebral palsy), and inappropriate outcome measures. The conclusion was that there was no evidence to support the use of upper limb soft splinting in people with cerebral palsy and the need for high quality RCTs was highlighted.⁽¹⁰⁾

The second was a rapid review published in 2010 investigating whether Lycra garments improve function and movement in children aged 0-18 years with cerebral palsy. A total of eight studies were included, many of which were also included in the review by Blackmore et al. Most were case series/case studies and no RCTs were identified. Several methodological limitations were noted such as small patient numbers, inclusion of children with different types of cerebral palsy, and lack of objective outcome measures. The authors said that the available data suggest Lycra garments help to improve proximal stability and function in children with cerebral palsy, but the evidence is limited. The review concluded that more research is needed before an evidence based approach to using Lycra garments in the management of children with cerebral palsy can be implemented.⁽²¹⁾

Randomised controlled trial

The first and only RCT found on Lycra garments in children with cerebral palsy was published in 2011. The Australian study was a randomised parallel group trial with waiting list control. A total of 16 children aged 8-15 years were randomised to either 3 months of wearing a Lycra arm splint combined with goal directed training (n=8) (group 1), or 3 months of goal directed training only (n=8) (group 2). After 3 months, group 2 then received 3 months of wearing the Lycra arm splint combined with goal directed training. The Lycra splints were worn during school hours, approximately 6 hours per day, 5 days per week. The goal directed training involved 25 minutes of active practice of task specific activities related to the child's functional goals. Assessments were done at baseline, initial splint application, 3 months after wearing the splint and immediately after removing the splint.

The results of this RCT were published in two separate papers. The first publication⁽²²⁾ focused on the fluency of movement following Lycra splint wear. Fluency in this context was defined as the ability of the movement to flow smoothly and freely without jerkiness or tremor. All participants completed the fluency section of the Melbourne Assessment of Upper Limb Function at each assessment session. This assessment involved performing 16 common upper limb tasks which a typically developing child of 5 years can easily complete. Additionally, movement substructures of the motion of the wrist joint centre (WJC) were analysed.

There was no change in movement fluency based on the Melbourne assessment between baseline and 3 months of splint wear for the entire cohort (p=1.00). There were significant improvements in 5 out of 6 of the movement substructures analysed including movement time, percentage of time in primary movement, normalised jerk, percentage of jerk in primary movement and percentage of jerk in the secondary movement. The conclusion was that children's movements were faster, more efficient and required less secondary corrections following splint wear, and Lycra splinting has the potential to improve movement outcomes for children with cerebral palsy.

The second publication⁽²³⁾ focused on the effects of the combination of Lycra splinting with goal directed training, compared with goal directed training alone. The Goal Attainment Scale (GAS), a tool used to detect discreet changes in movement performance of importance to the child was administered to all children at each assessment. Additionally, using 3D motion analysis, maximum joint movement and range of movement (RoM) were assessed in three or four joints during four different upper limb tasks including reach forwards to an elevated position, reach sideways to an elevated position, supination/pronation and hand to mouth.

Following 3 months of splint wear and goal directed training, 7/8 children achieved the expected level (for 3 months of training) of change in goal attainment (a change in GAS score ≥ 50), while only 1/8 receiving goal directed training alone achieved this level. When the entire cohort had received training and splint wear, 15/16 children achieved their movement related goals after 3 months and on average, achieved a 25% increase in movement proficiency related to their goals (statistical analysis not performed).

A total of 28 assessments of maximum joint movement/RoM were completed. Immediately upon splint wear, there were significant improvements in only 4/28 assessments. After wearing the splint for 3 months combined with goal directed training, significant improvements were observed in 11 assessments across three of the upper limb tasks. No significant improvements were observed in the pronation/supination task, although there was a trend towards improvement. Few improvements (4/11) were evident upon immediate removal of the splint.

It was concluded that Lycra splints combined with goal directed training can result in the achievement of movement goals and have a positive effect on selected maximum range of movement and joint kinematics in children with cerebral palsy. The splints were found to be most effective when worn although there may be small carry over improvements in movement compensations following splint removal.

Non-systematic reviews

A number of non-systematic reviews on the effectiveness of Lycra garments for cerebral palsy have also been published. In 2002, the National Horizon Scanning Centre (NHSC) published a review on "*Lycra Garments for Cerebral Palsy and Movement Disorders*" which included five primary studies. Overall the review concluded that there may be some short term benefit from the use of Lycra splints, however there was no evidence to determine long term benefit or whether there are patient groups that may benefit more than others.⁽¹¹⁾

A 2004 review by Attard and Rithalia including nine primary studies concluded that Lycra garments are useful in improving proximal stability in children with cerebral palsy leading to improved functional abilities particularly when combined with a multidisciplinary team approach. However noted that further research was required to learn more about how they work.⁽⁹⁾

An evidence note by NHS Quality Improvement Scotland (QIS) in 2005 (EN11) mainly based on the reviews by NHSC, and Attard and Rithalia concluded that Lycra® garments may improve functional abilities in the short term in some children with cerebral palsy. However, suitability needs to be decided on a case by case basis and further research is required to

determine the long term effects and if there are patient groups or specific disabilities that may benefit more than others.⁽⁸⁾

A Technologies Scoping Report by Healthcare Improvement Scotland in 2013 was published as an update to EN11 looking at the clinical and cost effectiveness of dynamic Lycra splinting for cerebral palsy. This review found that the evidence base is limited both in quantity and quality with little development since the publication of EN11 and concluded that further research, with larger numbers, longer follow ups and homogeneity in terms of type of garment and manufacturers' design, is required to determine the effects of Lycra splinting in cerebral palsy.⁽⁵⁾

Also in 2013, the Peninsula Cerebra Research Unit reviewed the evidence on Lycra orthoses for cerebral palsy and made similar conclusions to previous reviews stating that there haven't been enough well conducted studies of the same garment in groups of children with the same condition to be able to say that the evidence clearly shows that they do work. Also, the lack of long term studies makes it impossible to provide dependable advice about any lasting benefit once a garment is no longer worn.⁽²⁾

It is worth noting that these reviews include or refer to many of the same studies as each other as well as the systematic reviews discussed earlier.

A research project evaluating the effects and functional outcomes of Lycra garments to the upper limb in children with cerebral palsy supported by Jobskin is ongoing at Keele University.⁽¹⁸⁾

Lycra garments for other conditions

The use of Lycra garments in other conditions has been studied to a much lesser extent.

There are few reports on the use of Lycra garments for treatment and/or prevention of scoliosis. Lycra garments are considered to offer the advantage of deformity correction without the bulk and discomfort of rigid braces conventionally used for scoliosis. A recent retrospective audit of clinical notes obtained from five NHS paediatric physiotherapy departments was used to ascertain current orthotic management of children with neuropathic scoliosis. Of the total sample (n=180), 77 had confirmed scoliosis 39 of whom used a Lycra garment, and 43 had a spinal curve developing 22 of whom used a Lycra garment. The remaining 60/180 had no report of spinal curvature but used a Lycra garment as a preventive measure. Cobb angles (a standard measurement used to determine and track the progression of scoliosis) were regularly monitored in 26 children. Scoliosis improved in 6/26 children, 3 of which no longer required intervention. These 3 were managed with Lycra suits. In a further 5 children who wore Lycra suits, there was no progression of their scoliosis over an average of 1 year 4 months. The data suggested that Lycra garments are currently used in the management of mild to moderate scoliosis due to a range of neuromuscular conditions, predominantly in cerebral palsy; and may have a potential role in prevention and/or treatment of neuropathic scoliosis but further robust research is needed in this area.⁽⁶⁾

A case study involving a 7 year old with thoracic scoliosis reported that wearing a Lycra scoliosis suit reduced the Cobb angle by half from 33° to 15° and subsequent X-rays showed that the curve was maintained at 20°C for 30 months even without the suit being worn.⁽²⁴⁾ A case series involving 7 patients with scoliosis due to various conditions including

spinal injury, cerebral palsy, and agenesis of the corpus callosum reported that improved alignment and reduction in Cobb angle were observed with Lycra suits. This was available only as a conference abstract with no further details regarding the magnitude of effect.⁽²⁵⁾

A small study (n=8) published as a conference abstract examined whether Lycra sleeves are effective for glenohumeral subluxation (GHS) which is reported to occur in up to 81% of patients post stroke. Patients wore the sleeve for 7 hours a day on 7 consecutive days. GHS was assessed by ultrasound prior to application of the sleeve, immediately after application on day 1, and on day 8. A reduction in GHS was observed on both day 1 and day 8 by 0.21 cm and 0.28 cm respectively (statistical significance not reported). Three patients experienced decreased pain, 3 found the sleeve easy to wear and 4 reported that the sleeve was beneficial.⁽²⁶⁾

One case study evaluated the effects of a Lycra glove on arm function in a 70 year old man with late stage acquired brain injury. Although improvements in some measures were seen, the results were equivocal and some changes were noted irrespective of introduction of intervention. Therefore it was unclear whether the Lycra glove was entirely responsible for the changes seen.⁽²⁷⁾

Another case study found improvements in movement and coordination skills in a 5 year old with developmental coordination disorder who wore a Lycra body suit for 12 weeks which was sustained after removal although no measurable effect on proprioception was observed. The authors noted that the improvement could have been the result of natural maturation through the normal development process and it was difficult to differentiate between this and the effect of the Lycra suit.⁽²⁸⁾

Jobskin is currently supporting University of West of England in Bristol in evaluating effects of Lycra sleeves on upper limb in patients after stroke.⁽¹⁸⁾

Summary of clinical evidence

There is limited evidence on which to base the clinical effectiveness of Lycra garments in the management of cerebral palsy and other neurological/musculoskeletal conditions. Several factors make it difficult to draw solid conclusions including:

- Lack of high quality studies – mostly case studies/ case series; only one RCT was identified
- Small patient numbers
- Inconsistent outcome measures – many studies used non-standardised assessments with some creating their own, and many did not use objective outcome measures, making comparison difficult
- Variation in the types of cerebral palsy treated
- Variation in the types and design of orthoses used (e.g. glove, body suit)
- Lack of adequate comparator
- Short duration

Overall, the limited data available suggest that wearing Lycra garments may improve stability, movement and function in some children with cerebral palsy in the short term, but are not conclusive. The limitations of the evidence make it difficult to characterise whether there are patient groups that may benefit more than others and which if any benefits are

sustained in the long term. Furthermore, it is not known the extent to which any benefits obtained may impact the patient's quality of life. All reviews agree that there is a need for well-designed RCTs to properly evaluate the effectiveness of Lycra garments.

Safety

Similar to clinical effectiveness, limited data are available regarding the safety of Lycra garments.

Contraindications to Lycra garments documented in the literature include absence/unavailability of adequate monitoring and supervision, compliance and behavioural issues, severe epilepsy, chronic respiratory problems, and intractable peripheral cyanosis associated with hypoactivity.⁽⁷⁻¹¹⁾ Since patient motivation is considered to be a major influence on the success of the garment, it has been suggested that the wearer needs to have a capacity for purposeful intent and participation in daily activities for optimum benefit.^(9, 11)

Adverse effects that have been reported in studies with various types of Lycra garments (full body suits, vests, shorts) include vomiting, cyanosis, hyperthermia, induced muscle weakness, inhibition of voluntary movement, respiratory compromise, rubbing, constipation, friction sores between legs and at zip sites and erythema.⁽¹⁰⁾

Studies have reported practical issues with the garments. Some experience difficulties with putting on and taking off the garments. Temperature can also be an issue leading to feeling hot and restricted in the garment. There may be problems with toileting, and some may find it difficult to breathe with full body suits. In some studies, the discomfort and inconvenience were bad enough to affect adherence or lead to discontinuation.^(2, 8, 13, 21)

These problems may be alleviated to some extent by considering the needs of the child during assessment. For example, more zips can be added to relevant areas and/or reinforcements/boning can be altered, and the wearing regimen can be altered during hot weather.⁽⁹⁾

The long term effects of wearing Lycra garments remain unknown. Reviewers have recommended further research to determine whether the pressure being applied to the skin can be harmful in the long term, whether it can cause muscle fatigue or atrophy, what other physiological changes are taking place at the interface between the patient and the garment, and whether circulation is being affected.⁽⁹⁾

Relevant Guidance

The NICE clinical guideline CG145 on the management of spasticity in under 19s (2012) gives recommendations on the use of orthoses, but does not specifically mention Lycra based orthoses. The guideline recommends the following:⁽¹⁾

- Consider orthoses for children and young people with spasticity based on their individual needs and aimed at specific goals, such as: improving posture, improving

upper limb function, improving walking efficiency, preventing or slowing development of contractures or hip migration, relieving discomfort or pain and preventing or treating tissue injury.

- When considering an orthosis, discuss with the child or young person and their parents or carers the balance of possible benefits against risks. For example, discuss its cosmetic appearance, the possibility of discomfort or pressure sores or of muscle wasting through lack of muscle use.
- Assess whether an orthosis might cause difficulties with self-care or care by others, difficulties in relation to hygiene or be unacceptable to the child or young person because of its appearance.
- Ensure that orthoses are appropriately designed for the individual child or young person and are sized and fitted correctly. If necessary seek expert advice from an orthotist within the network team.
- Be aware when considering a rigid orthosis that it may cause discomfort or pressure injuries in a child or young person with marked dyskinesia. They should be monitored closely to ensure that the orthosis is not causing such difficulties.
- The network team should review the use of orthoses at every contact with the child or young person. Ensure that the orthosis is still acceptable to the child or young person and their parents or carers, remains appropriate to treatment goals, is being used as advised, remains well fitting and in good repair, and is not causing adverse effects such as discomfort, pain, sleep disturbance, injury or excessive muscle wasting.

The guidance also gives recommendations on specific uses of orthoses, including which types of orthoses may be used to achieve specified objectives.

The NICE clinical guideline CG162 on stroke rehabilitation (2013) gives the following recommendations on the use of orthoses for the upper limb (without specifically mentioning Lycra):⁽²⁰⁾

- Do not routinely offer wrist and hand splints to people with upper limb weakness after stroke.
- Consider wrist and hand splints in people at risk after stroke (for example, people who have immobile hands due to weakness, and people with high tone), to:
 - maintain joint range, soft tissue length and alignment
 - increase soft tissue length and passive range of movement
 - facilitate function (for example, a hand splint to assist grip or function)
 - aid care or hygiene (for example, by enabling access to the palm)
 - increase comfort (for example, using a sheepskin palm protector to keep fingernails away from the palm of the hand).

In 2011, consensus recommendations on the orthotic management of cerebral palsy were published by an international multidisciplinary group of healthcare professionals and researchers convened by the International Society for Prosthetics and Orthotics. The group reached the following conclusion regarding Lycra orthoses:⁽¹³⁾

Several types of Lycra based orthoses have appeared in the last ten years, with designs ranging from full body suits to smaller garments such as sleeves/gloves and leggings. Some children with cerebral palsy appear to experience functional gains by using Lycra based

orthoses; however, others experience difficulties with donning and doffing, feel hot and/or restricted, have problems with toileting in full suits, or experience compromised respiratory function. Synthesis of evidence from studies evaluating Lycra based orthoses is made difficult by the heterogeneity of the orthoses investigated, the various types of cerebral palsy treated and outcomes measured. Hence the characteristics of people who may benefit from using Lycra garments are not well defined in the literature. The effectiveness of Lycra based orthoses to improve function is not established, and should be evaluated carefully, in a research context.

A number of NHS commissioning group policies on the use of Lycra garments were identified from an online search. The recommendations of some of these are summarised in the table below:

Table 1. Summaries of selected NHS commissioning group policies on Lycra garments

Group	Recommendation	Date
Scarborough and Ryedale CCG Lycra Dynamic Splinting for Children with Neurological Impairment ⁽²⁹⁾	<ul style="list-style-type: none"> • Requests for funding will only be considered on an individual patient basis by the CCG Individual Funding Request (IFR) Panel. • The referral needs to come from a local lead specialist physiotherapist or occupational therapist. The expected benefits for that patient over other treatments must be clearly quantified. • Provision of subsequent garments will depend on clear, quantifiable demonstration of benefit for the individual patient which has been set upfront. 	December 2015 (Was due to be reviewed in 2017, but has not yet been reviewed)
Gloucestershire CCG Lycra splinting for paediatric patients with cerebral palsy/movement disorders ⁽³⁰⁾	Lycra splinting services is commissioned for paediatric patients who meet the following criteria: <ul style="list-style-type: none"> • children aged between 3 and 18 years* with a diagnosis of cerebral palsy or other neurological condition • following multidisciplinary team assessment by the Occupational Therapist and Physiotherapist and support from a Consultant Paediatrician that the child is likely to achieve an improvement in (or maintain) functional abilities regarding balance or movement control • where the child and family/carers are motivated to support the introduction and maintenance of use of the intervention. Regular monitoring at appropriate intervals by the multidisciplinary team (including Physiotherapist, Occupational Therapist and Consultant Paediatrician) to assess progress or maintenance of functional ability is required. Use of the splint will be discontinued if benefits cease to be achieved or maintained. *Replacement splints will be funded automatically to the age of 16. Requests for new or replacement splints for children aged 17-18 will be considered by the Effective Clinical Commissioning	October 2015 (Was due to be updated in 2017. Update not yet done)

	Policies Group.	
Greater Manchester Shared Services Greater Manchester EUR Policy Statement: Lycra Body Suits ⁽³¹⁾	<ul style="list-style-type: none"> Lycra body suits (sometimes referred to as lycra orthoses) are not routinely commissioned. Clinicians can submit an individual funding request outside of this guidance if they feel there is a good cause for clinical exceptionality. Requests on the grounds of clinical exceptionality should be submitted with all relevant supporting evidence which must be provided with the request. 	May 2017
East and North Hertfordshire CCG Lycra Dynamic Splinting for Children with Neurological Impairment ⁽³²⁾	Requests for funding should only be considered on an individual patient basis by exceptional treatment panels. The referral needs to come from a local lead specialist physiotherapist or occupational therapist. The expected benefits for that patient over other treatments must be clearly quantified. Provision of subsequent garments will depend on clear demonstration of benefit for the individual patient.	February 2016
Mid and South Essex Sustainability and Transformation Partnership CCG Joint Committee Policy Statement of Dynamic Lycra Splinting ⁽³³⁾	Dynamic Lycra Splinting is provided for a small cohort of people with cerebral palsy as part of some commissioned community health care services, but is not funded separately.	April 2018
Midlands & Lancashire CSU Criteria Based Clinical Treatments 2018-19 covering the following CCGs: NHS Halton, NHS Knowsley, NHS Liverpool, NHS Southport and Fromby, NHS South Sefton, NHS St Helens, NHS Warrington ⁽³⁴⁾	<ul style="list-style-type: none"> Lycra Suits are not normally commissioned for postural management of cerebral palsy. Evidence does not support routine commissioning of Lycra suits in management of cerebral palsy. Any application for exceptional funding should include a comprehensive assessment of the child's postural needs with clear outcome goals and time frames. 	February 2018
Wakefield CCG Lycra Garment Commissioning Policy: Children & Adults ⁽³⁵⁾	<p>Given the lack of clinical evidence available, particularly for adults, and the issues identified with patient compliance it is felt that referrals should be considered on a case by case basis through IFRs. It is recommended that Lycra garments are not commissioned for new adult referrals.</p> <p>Criteria for Funding</p> <ul style="list-style-type: none"> Patient registered with local GP. Patient must be on local physiotherapy/occupational therapy/orthotics caseload and must have been referred by one of these. Patient should have cerebral palsy or similar condition with significantly abnormal postural muscle tone. 	March 2014 (Policy Expired. New policy issued with recommendations valid for Wakefield, Huddersfield, North Kirklees and Calderdale – see below)

	<ul style="list-style-type: none"> • There are no contraindications present. • Referral should identify the specific significant benefits offered by the therapy for this patient. • Evidence provided that other therapies have been considered but were deemed to be insufficient. • Evidence of the patient/carer's willingness to comply with treatment (e.g. signed agreement or previous successful use). • If the patient is over 18, successful previous use of Lycra garments and benefits evidenced. • Requests for replacement garments should include a user or professional evaluation of benefits to add to the evidence base on this technology. 	
<p>NHS Greater Huddersfield, NHS North Kirklees & NHS Calderdale Commissioning Policy for Individual Funding Requests⁽³⁶⁾</p>	<p>Lycra garments are not routinely commissioned. Cases may be considered on an exceptional basis for example:</p> <ul style="list-style-type: none"> • The patient should have cerebral palsy or similar condition • There are no contraindications present (contraindications stated within the policy) • Referral should identify significant benefits offered by the therapy for this patient • Evidence provided that other therapies have been considered but were deemed to be insufficient • Evidence of the patient's / carer willingness to comply with treatment (e.g. signed arrangement or previous successful one) • If the patient is over 18, successful previous use of Lycra garments and benefits evidenced • Requests for replacement garments should include a user or professional evaluation of benefits. <p>Funding requests for replacement garments will be required to evidence on-going clinical benefit. Funding for a replacement garment will not normally be agreed within:</p> <ol style="list-style-type: none"> 1. 12 months from last approval for children aged up to 18 or 2. 12 months to 2 years from last approval for patients aged 18+ 	June 2018

Specialist opinion

Specialists with experience in using Lycra garments based at The Newcastle upon Tyne Hospitals NHS Foundation Trust were in agreement that the evidence base is limited. They reported no change in practice and prescribing of Lycra garments since this document was first published. However, therapists reported that they have witnessed improvements in patients' function as a result of Lycra garment wear, and positive feedback is often received from patients and their families. It was suggested that from experience, Lycra garments may be beneficial for children with truncal weakness (poor core strength) to improve trunk stability and fine manipulative skills; children with dystonia to limit the range of involuntary movements at joints and improve joint stability; and for joint positioning (e.g. at the wrist, thumb or elbow).⁽³⁷⁾

will vary for each individual and may depend on their clinical presentation, functional goals and progress.

There is a lack of robust information from which to deduce the number of patients that would be eligible for Lycra garments in the NTAG region.

Between November 2016 and May 2017, a total of 22 IFR applications were made for Lycra garments to various CCGs based in North East England, except Darlington CCG. Out of these, 13 (59%) IFRs were approved. Individual CCG data is included in table 3 below.

Table 3: Lycra Garments IFR Approvals and Refusals Nov. 2016 to May 2017

CCG	Approved	Declined	% of approved
North Durham	2	5	28%
Durham Dales, Easington and Sedgefield	2	2	50%
Hartlepool and Stockton	2	0	100%
South Tees	1	1	50%
Sunderland	3	0	100%
Darlington	0	0	0
South Tyneside	3	1	25%

Approvals and total applications figures for Newcastle Gateshead CCG, North Tyneside CCG and Northumberland CCG are not available between November 2016 and May 2017.

Between June 2017 and July 2018, a total of 166 IFR applications were made for Lycra garments to various CCGs based in North East England. Out of these, 154 (92%) IFRs were approved. Individual CCG data is included in table 4 below

Table 4: Lycra Garments IFR Approvals and Refusals May 2017 to July 2018

CCG	Approved	Declined	% of approved
North Durham	7	0	100%
Durham Dales, Easington and Sedgefield	9	1	90%
Hartlepool and Stockton	7	4	63%
South Tees	0	1	0%
Sunderland	7	0	100%
Darlington	0	1	0%
South Tyneside	1	1	50%
Newcastle Gateshead	59	2	96%
North Tyneside	19	4	82%
Northumberland	44	0	100%

Points to consider

- The overall clinical benefit of Lycra garments is difficult to estimate based on the available evidence.
- Available studies are mostly case studies/series with small numbers of patients and have a number of limitations. Synthesis of the evidence is made difficult due to the differences in the types of orthoses worn (e.g. glove/body suit), manufacturers' designs, types of cerebral palsy treated and outcomes measured in studies.
- The only RCT identified found that Lycra garments have the potential to improve movement outcomes in children with cerebral palsy particularly in combination with goal directed therapy, but this was only a small trial (n=16).
- It is not clear from the available data whether there are some patients that will benefit more than others and whether any benefits are sustained in the long term. Long term safety is also not known.
- Practical issues with putting on and taking off the garment, feeling hot and/or restricted and toileting have been reported in studies.
- Patient and carer commitment and motivation, and adherence to treatment are deemed to be essential components of treatment success.
- No published evidence on the cost-effectiveness of Lycra garments was identified and so any cost savings with regards to increased mobility and reduced care needs cannot currently be quantified.
- NICE guidelines on spasticity in children and young people and stroke rehabilitation in adults give recommendations on the use of orthoses but do not specifically address Lycra based orthoses.
- A number of other commissioning groups have issued recommendations on the use of Lycra garments. Most of these do not routinely commission Lycra garments but consider funding on an individual basis through individual funding requests.

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