

**South East London Area Prescribing Committee
Formulary recommendation**

Reference:	064
Intervention:	Clonidine patches (controlled release over 7 day period) for dystonia/dyskinesia in paediatrics (Clonidine is a centrally-acting α_2 -adrenergic agonist that works by stimulating receptors in the brain)
Date of Decision	March 2017
Date of Issue:	April 2017
Recommendation:	RED – suitable for prescribing and supply by hospital only
Further Information	<ul style="list-style-type: none"> • Clonidine patches are approved for the treatment of paediatric dystonia/dyskinesia as an alternative to clonidine liquid (unlicensed special) or clonidine tablets in whom transdermal delivery is more appropriate. • Clonidine patches may be useful in children whose symptoms are controlled on intravenous clonidine, where transition to alternative formulations (e.g. oral) is not possible (determined by the specialist on a case by case basis). The use of patches in these patients may also facilitate discharge from hospital. • Clonidine patches are for specialist paediatric neurology prescribing only. • Clonidine patches are available in 100 microgram/24 hour, 200 microgram /24 hour and 300 microgram /24 hour, 7 day (weekly) patches. Relatively high doses are often required to control dystonia symptoms. • Clonidine injection and oral clonidine (tablets or liquid) have been in use for some time for this indication. • Evidence for use of clonidine for paediatric dystonia is currently only in the form of case series, however there are no licensed treatments for this condition, and there is no strong evidence for any treatment used to treat dystonia in paediatrics. • This formulary decision and red rating will be subject to review in 6 months (October 2017). During this time the specialist paediatric neurology team is requested to produce an information support pack and a proposed framework for requesting primary care prescribing. This will include detailed information about this treatment and condition for healthcare professionals and patients/carers, and contact details for specialist support. This should be provided to the APC for consultation and approval before October 2017. • It should be noted that clonidine patch formulation is not licensed in the UK, but is an imported commercial product. The imported product is, however, licensed for the treatment of hypertension in its country of origin (it is not licensed for use in dystonia in its country of origin).
Shared Care/ Transfer of care required:	N/A – see above. Resources to support healthcare professionals and patients/carers to be developed.

Cost Impact for agreed patient group	<ul style="list-style-type: none"> As this treatment is an imported product, the price is subject to variation according to supply route. Data suggest that the cost of one 300 microgram patch can vary between £8 and £70 The application suggests that 3-4 patients per annum from SE London may be suitable for clonidine patches. If an average price of £50 per patch is assumed, at expected doses this would equate to approximately £19,000 costs per annum in South East London. There may also be savings from the use of the patches due to reduced hospital inpatient stay.
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> Develop support resources as outlined in the further information section. Monitor usage on a 6-monthly basis and report back to APC. Audit use upon request to ensure use is in line with this recommendation. <p>CCGs:</p> <ul style="list-style-type: none"> Monitor ePACT data Monitor exception reports from GPs if inappropriate transfer of prescribing to primary care is requested.
Evidence reviewed	<p>References (extracted from evidence evaluation)</p> <ol style="list-style-type: none"> Koy A, Lin JP, Sanger T et al. Advances in management of movement disorders in children. <i>Lancet Neurology</i> 2016; 15: p719–35 Kirkham F, Haywood P, Kashyape P et al. Movement disorder emergencies in childhood. <i>European Journal of Paediatric Neurology</i> 2011, vol. 15, p390-404 CG 145: Spasticity in under 19's: Management. National Institute of Health and Care Excellence 2012 (updated 2016). Available online here (accessed 05/03/2017) Dystonia: A Guide to Good Practice for Health and Social Care Professionals. The Dystonia Society November 2011. Available online here. (accessed 05/03/2017) Roubertie A, Mariani L, Fernandez-Alvarez E et al. Treatment of Dystonia in Childhood. <i>European Journal of Neurology</i> 2012 19 p1292-1299. McRea N. Childhood Dystonia. <i>Paediatric Neurology</i> 2013 13 (5) p18-20 Allen N, Lin JP, Lynch T. Status Dystonicus: a practice guide. <i>Developmental Medicine and Child Neurology</i> 2014 56: p105-112 Summary of Product Characteristics; Catapres ampoules (clonidine). Available online here (accessed 05/03/2017) The Evelina London Paediatric Formulary. Available online here. (accessed 05/03/2017) Boehringer Ingelheim - SPC; Catapres TTS. Available online here (accessed 05/03/2017) Safadieh L, Sharana-CHami R, Dabbagh O. Paroxysmal Autonomic Instability with Dystonia after Pneumococcal Meningoencephalitis. <i>Case Reports in Medicine</i> 2012 doi:10.1155/2012/965932 Sayer C, Lumsden D, Kaminska M et al. Outpatient clonidine management of severe secondary dystonia in childhood. <i>Developmental Medicine and Child Neurology</i> 2015 58 Supplement S1 p26 Barbone J, Thomas N, Kirkham F et al. Paroxysmal Autonomic Instability with Dystonia as a consequence of acquired brain injury. <i>Paediatric Neurology</i> 2009 13 Supplement 1 pS20. Nakou V, Williamson K, Hutchinson A et al. Use of enteral, intravenous and transdermal clonidine for the acute management of dystonia. <i>Developmental Medicine and Child Neurology</i> 2015 58 Supplement S1 p69-70 Lumsden D, Grigoratos D, Arenas S et al. Use of clonidine in the treatment of life threatening paediatric dystonia. <i>Movement Disorders</i> 26 Supplement 2 pS220 Jiao F et al. Clinical observation on treatment of Tourette syndrome in Chinese children by clonidine adhesive patch. <i>European Journal of Paediatric Neurology</i> 2016 20 p80-84 Du Y, Li H, Vance A et al. Randomised double-blind multicentre placebo-controlled clinical trial of the clonidine adhesive patch for the treatment of tic disorders. <i>Australian and New Zealand Journal of Psychiatry</i> 2008 42 p807-813. National Poisons Information Service "TOXBASE", clonidine monograph. Available online here (login required). (accessed 06/03/2017) Drug Tariff, March 2017, available here.

NOTES:

- Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.
- This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
- Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**