West Yorkshire and Harrogate
Health and Care Partnership

West Yorkshire & Harrogate Joint Committee of Clinical Commissioning Groups

Summary report			
Date of meeting: 5 October 2021		Agenda item: 36/21	
Report title:	**Lidocaine plasters for the treatment of pain in children**		
Joint Committee sponsor:	Jo Webster		
Clinical Lead:	Dr James Thomas		
Author:	Gaye Sheerman-Chase, Catherine Thompson		
Presenter:	Catherine Thompson		
Purpose of report: (why is this being brought to the Committee?)			
Decision	✓	Comment	
Assurance			

Executive summary

Persistent and difficult to manage pain is a problem for a very small number of children. There is a limited number of treatment options and the prescription of lidocaine plasters in some instances would be a helpful addition to the management tools available to support these children. The limited amount of published data within paediatrics, in conjunction with anecdotal unpublished reports from other leading paediatric pain management centres would support the extrapolation of available adult data, that this treatment modality is both safe and effective for the management of discrete neuropathic pain in children. This is a licensed product, although we are proposing its use to be outside its specific licence.

Across the UK there are 13 tertiary paediatric pain centres (including Alder Hay and Great Ormand Street Hospital) all of whom prescribe lidocaine plasters for a specific cohort of children as first line for medical management of discrete neuropathic pain. Initiation of lidocaine plasters avoids or limits the use of systemic medicine and avoids hospital admission wherever possible. This is current practice at Leeds Teaching Hospitals NHS Trust but they cannot transfer the prescribing responsibility to primary care as it is not commissioned for use in primary care and implementation of this policy across WY&H HCP would improve access to care.

It is estimated that up to 20 patients per year would meet the criteria for and require lidocaine 5% plasters. From unpublished local and national data, most children are managed with a maximum of 2 plasters, with many children requiring less than 1 plaster, cut to appropriate size to cover the painful area. Children will be expected to continue treatment for a minimum of 1 month and an average of 3 months. Maximum treatment duration would be 2 years (across the WY&H HCP it is estimated only 1 child will require the full 2-year treatment).

The estimated cost per patient per year is £810.84 with an estimated total annual cost of £16,216.80. Up to six in-patient stays per year may be avoided through use of lidocaine patches for this indication.

Recommendations and next steps

The WY&H Joint Committee of CCGs is asked to recommend the commissioning statement for adoption as policy across all of the WY CCGs.

Delivering outcomes: describe how the report supports the delivery of STP outcomes (Health and wellbeing, care and quality, finance and efficiency)

Health and Wellbeing: The Health and Wellbeing of the children and young people affected by this commissioning statement will be improved with the addition of a more discreet, non-oral treatment alternative with very few, if any, side effects (only reported side effects are localised skin irritation) when compared to traditional pain management treatments and medications.

Care and Quality: Improvement in clinical outcomes and quality of care are expected for the children and young people affected by this commissioning statement.

Finance and Efficiency: The estimated annual cost is expected to be £16,216.80, however this is likely to be offset with the reduction in amount of in-patient stays and the use of other medications and analgesics for this cohort of patients.

Impact assessment (please provide a brief description, or refer to the main body of the report)

Clinical outcomes:	Paragraphs 1 to 9, Appendices 1, and 3
Public involvement:	Paragraphs 10 and 11, Appendix 2
Finance:	Paragraphs 14 to 19, Appendix 4
Risk:	Paragraph 20, Appendix 3
Conflicts of interest:	Jo Webster: Chief Officer of NHS Wakefield CCG Dr James Thomas: GP Chair of NHS Airedale, Wharfedale and Craven CCG; partner of Modality GP partnership; Dr Kate Thomas (spouse) is also a partner of Modality GP partnership. Gaye Sheerman-Chase: GP partner of Craven Road Medical Practice Catherine Thompson: Member of the AoMRC EBI Expert Advisory Group.

Lidocaine plasters for the treatment of pain in children: WY&H commissioning statement

1. Persistent and difficult to manage pain is a problem for a very small number of children. There is a limited number of treatment options and the prescription of lidocaine plasters in some instances would be a helpful addition to the management tools available to support these children.

2. This paper presents a proposal for the prescription of Lidocaine 5% medicated plasters for the treatment of complex Regional Pain Syndrome (CRPS), Persistent Post-Surgical Pain (PPSP), Erythromelalgia and Isolated Neuropathic Pain in children where:
    - pain has not responded to usual non-pharmacological & pharmacological treatments (e.g., opioids, amitriptyline, gabapentin, pregabalin) or standard care medications are causing unacceptable side-effects / there are risks with other long-term conditions e.g. opioid side-effects/tolerance, cardiac risks of amitriptyline, risk of suicidal ideation with gabapentinoids, risks in overdose, risks of addiction.
    - pain is having significant impact on wellbeing and activities of daily living (ADL) e.g., unable to self-mobilise, pain affecting whole limbs, pain having significant longer-term impact on school attendance, pain having significant impact on mental wellbeing.
    - child is already receiving polypharmacy for their underlying condition, and/or those whose underlying condition impacts on renal and/or hepatic metabolism, where alternative systemic treatments pose a higher risk of side-effects.
    - to avoid 5-day/4-night admission to hospital for MDT treatment package (Including invasive analgesia which necessitates general anaesthetic and nerve block) plus 15-18 therapy sessions).

3. Lidocaine plasters may only to be considered for first line use in paediatric patients on specialist tertiary paediatric pain centre advice where the paediatric pain consultant considers lidocaine patches the most suitable therapy for an individual child to avoid the above complications. This would be by agreement with the patient / parent / carer and with an agreed protocol / process for review and decision regarding continuation or discontinuation of treatment.

4. Lidocaine 5% plasters are a topical local anaesthetic preparation. They are licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection in adults which is also referred to as Post-herpetic Neuralgia (PHN). PHN is not a disease of childhood but other types of neuropathic pain are encountered. The limited amount of published data within paediatrics, in conjunction with anecdotal unpublished reports from other leading paediatric pain management centres would support the extrapolation of available adult data, that this treatment modality is both safe and effective for the management of discrete neuropathic pain in children.

5. Lidocaine plasters are worn for 12 hours a day and can be applied in the morning or evening, depending on therapy advice, the patient's preference, and lifestyle. This will follow with a 12-hour plaster free period. Lidocaine plasters have minimal side-effects however local irritation is a recognised side-effect of the plasters. When it is first applied, it can initially be uncomfortable if the skin is already very sensitive. Once the patch is in place, this sensation usually resolves after 1-2 minutes. The manufacturer states that the plasters can be cut into smaller sizes with scissors. Patch size may vary depending on patient (Leeds current experience 0.25 to 1.5 patches).

6. Across the UK there are 13 tertiary paediatric pain centres (including Alder Hay and Great Ormand Street Hospital) all of whom prescribe lidocaine plasters for a specific cohort of children as first line for medical management of discrete neuropathic pain. Initiation of lidocaine plasters avoids or

limits the use of systemic medicine and avoids hospital admission wherever possible. This is current practice at Leeds Teaching Hospitals NHS Trust but they cannot transfer the prescribing responsibility to primary care as it is not commissioned for use in primary care.

7. The lidocaine plasters would be initiated by the tertiary referral service following assessment. Six weeks' medication would be prescribed by the hospital specialist consultant. This would be supplied by the hospital outpatient pharmacy. Further supplies would be prescribed by the patient's GP if treatment is successful and continues beyond the initial review.

8. Lidocaine plasters are not routinely prescribed in primary care in line with the 'Items which should not be routinely prescribed in primary care' guidance published by NHS England in November 2017 and adopted in the CCGs of West Yorkshire and Harrogate.

9. The proposed policy is included in Appendix 1

Engagement and Consultation

10. CCG Heads of Medicines optimisation, senior / specialist pharmacists from provider organisations, Consultant pain specialists and CCG GP prescribing leads from across WY&H HCP were engaged with in the development of this commissioning statement. Please see Appendix 2 for details of the comments received and amendments to the policy in response to engagement.

11. Local engagement and consultation hasn't been undertaken to date, and it is the opinion of the programme communications team that this is not required to agree the pathway. This commissioning position is already in place in many CCGs across the country and within other tertiary referral centres for children's pain management and adoption across the WY CCGs will reduce variation in access to care. We do not therefore believe any local public engagement is required.

Quality and Equality Impact assessment

12. The groups of people affected by this policy are:

    - a small cohort of children with chronic / severe pain who following assessment by the tertiary centre paediatric pain specialists (following referral from secondary care paediatricians/ general practitioners) would be expected to benefit from this therapy.
    - Tertiary care paediatric pain specialists, secondary care paediatricians and GPs looking after this group of patients.

13. The quality and equality impact assessment (see Appendix 3) demonstrated that the introduction of this pathway and policy will have a positive impact on patient experience, patient safety and clinical effectiveness. There will be some improvements in equality and workforce experience. Patients will benefit from an alternative/additional treatment option for the management of pain which has fewer unpleasant side effects and can avoid the need for a 5-day admission to the tertiary centre for trial of treatment interventions.

Impact of Implementation in WY&H HCP

14. It is estimated that up to 20 patients per year would meet the criteria for and require lidocaine 5% plasters. From unpublished local and national data, most children are managed with a maximum of 2 plasters, with many children requiring less than 1 plaster, cut to appropriate size to cover the painful area. Children will be expected to continue treatment for a minimum of 1 month and an average of 3 months. Maximum treatment duration would be 2 years (across the WY&H HCP it is estimated only 1 child will require the full 2-year treatment).

15. The estimated cost per patient per year is £810.84 with an estimated total annual cost of £16,216.80.

16. In 2018, six paediatric patients were admitted to Leeds Teaching Hospitals NHS Trust for a 5-day inpatient stay to receive invasive analgesia (necessitating a general anaesthetic) and intensive therapy/rehab. The cost of such admissions varies between £3000 - £6000 depending on the interventions required. In 2019 and 2020 there were no admissions, in part due to the introduction of lidocaine plasters in this cohort.

17. Advantages over existing therapies are avoidance of inpatient stay & invasive analgesia, avoidance of other medications with significant side-effect profiles and risks, few systemic side effects and the patches are well tolerated. There is no titration period. Efficacy takes up to 4 weeks to be apparent and the treatment would be stopped if it is not shown to be effective.

18. Fewer than 10% of paediatric patients using lidocaine plasters are transitioned into the adult service. Paediatric patients transitioning will be seen in a joint paediatric and adult pain clinic, which occurs 4-6 times a year.

19. A breakdown of the impact of implementation can be found at Appendix 4

Risks to Implementation

20. For the Paediatric pain specialists at the tertiary centre adoption of this policy would reduce risk as it would reduce variation in prescribing. For a small number of GP practices there would be a requirement to continue prescribing lidocaine plasters after the initiation and first review period and between reviews, potentially for up to 2 years. Communication and information requirements have been outlined in the commissioning statement to support this and mitigate the risk.

Implementation Plans

21. Implementation of the commissioning statement would be undertaken at place through the CCG medicines management teams, communicating the change in practice to the tertiary referral centre, place children's services and general practice.

Recommendation

22. The WY&H Joint Committee of CCGs is asked to recommend the commissioning statement for adoption as policy across all of the WY CCGs.

List of Appendices

Appendix 1: West Yorkshire and Harrogate Commissioning Policy
Appendix 2: Comments received and amendments to the policy in response to engagement
Appendix 3: West Yorkshire and Harrogate Combined Impact Assessment
Appendix 4: A breakdown of the impact of implementation

Appendix 1: West Yorkshire and Harrogate Commissioning Policy

Treatment	Lidocaine 5% medicated plasters (in paediatrics 0-18years)
For the treatment of	Children with: • Complex Regional Pain Syndrome (CRPS) • Persistent Post-Surgical Pain (PPSP) • Erythromelalgia • Isolated Neuropathic Pain
Commissioning position	Only to be considered for first line use in paediatric patients on specialist tertiary paediatric pain centre advice where paediatric pain consultant considers lidocaine patches most suitable therapy for individual child **to avoid**: • pain impacting on wellbeing and activities of daily living (ADL) e.g. unable to self-mobilise, pain affecting whole limbs, pain having significant longer term impact on school attendance, pain having significant impact on mental wellbeing; OR • use of alternative systemic treatments that pose a higher risk of side-effects if the child is already receiving polypharmacy for their underlying condition, and/or those whose underlying condition impacts on renal and/or hepatic metabolism; OR • use of standard care pain medications that may cause unacceptable side-effects e.g. opioid side-effects/tolerance, cardiac risks of amitriptyline, risk of suicidal ideation with gabapentinoids, risks in overdose, risks of addiction; OR • alternative 5-day/4-night admission to hospital for MDT treatment package (Including invasive analgesia which necessitates general anaesthetic and nerve block) plus 15-18 therapy sessions). **Other requirements:** 1. Agreement from patient/parent/carer to commence treatment 2. Agreement from patient/parent/carer to regular reviews with the paediatric pain team 3. Agree criteria for discontinuing lidocaine plasters if deemed ineffective 4. Tertiary pain team complete an audit form on initiation of lidocaine plasters and at end of treatment.
Date effective from	October 2021
Policy to be reviewed by	October 2023
Background information	Post-herpetic neuralgia, for which the product is licensed, is not a disease of childhood, in keeping with its underlying pathology, but other types of neuropathic pain are encountered.

	Advantages over existing therapies are avoidance of inpatient stay & invasive analgesia, avoidance of other medications with significant side-effect profiles and risks, few systemic side effects and the patches are well tolerated. There is no titration period. Efficacy takes up to 4 weeks to be apparent and the treatment can be stopped if it is not shown to be effective. The product is licensed in the UK for adults, therefore quality is assured. Nationally across the UK there are 13 tertiary paediatric pain centres (including Alder Hay and GOSH) all of whom prescribe lidocaine plasters for a specific cohort of children as first line for medical management of discrete neuropathic pain. Initiation of lidocaine plasters avoids or limits the use of systemic medicine and avoids hospital admission wherever possible. In 2018, 6 paediatric patients were admitted to LTHT for a 5-day inpatient stay to receive invasive analgesia (necessitating a general anaesthetic) and intensive therapy/rehab. No admissions in 2019 and 2020 to date as using plasters as first line instead. Maximum treatment duration would be 2 years (across the ICS it is estimated only 1 child will require the full 2 year treatment). Children account for 23% (570,000) of the total West Yorkshire and Harrogate population.[1] Across West Yorkshire & Harrogate ICS, we expect 20 paediatric patients per year at a cost of £ 16,200 per year.
Summary of evidence/rationale	The limited amount of published data within paediatrics, in conjunction with anecdotal unpublished reports from other leading paediatric pain management centres would support the extrapolation of available adult data, that this treatment modality is both safe and effective for the management of discrete neuropathic pain in children. Collated published UK data from the 13 tertiary pain centres showed, of 115 children treated with lidocaine plasters, 69% showed benefit and only 7% developed localised side-effects e.g. skin irritation. From unpublished local and national data, most children are managed with a maximum of 2 plasters, with many children requiring less than 1 plaster, cut to appropriate size to cover the painful area. Children will be expected to continue treatment for a minimum of 1 month and an average of 3 months. The manufacturer states that the plasters can be cut into smaller sizes with scissors. Patch size may vary depending on patient. Based on our current paediatric patient population, size varies between 0.25 -1.5 patches. We would expect the 6 weeks to be prescribed by the hospital specialist consultant, following advice from the paediatric chronic pain team. This would be supplied by the hospital outpatient pharmacy. We would then expect further supplies to be prescribed by the patient's GP if this is suitable. This is a licensed product, although we are proposing its use to be outside its specific licence.

	Lidocaine plasters are worn for 12 hours a day and can be applied in the morning or evening, depending on therapy advice, the patient's preference and lifestyle. This will follow with a 12 hour plaster free period. Lidocaine plasters have minimal side-effects however local irritation is a recognised side-effect of the plasters. When it is first applied, it can initially be uncomfortable if the skin is already very sensitive. Once the patch is in place, this sensation usually resolves after 1-2 minutes. Feedback from patients/parents/carers includes improved quality of life, reduced trips to doctors and pharmacies and reduced appointments/stays at GPs and hospitals. Patients are able to integrate back into schools with an improved mental health state as they are in less pain and more mobile. <u>Transition</u> Less than 10% of paediatric patients using lidocaine plasters are transitioned into the adult service. These cases are very rare and are reviewed thoroughly by the paediatric pain service to manage the patient's condition and pain. In 2020, 1 patient transitioned from paediatric to adult pain services whilst continuing with lidocaine plasters. Paediatric patients transitioning will be seen in a joint paediatric and adult pain clinic, which occurs 4-6 times a year. These patients will be managed in line with the above recommendations and for the maximum treatment length stated within this policy.
Contact for this policy	Leeds Commissioning of Medicines Group leedsccg.medsoptcommissioningteam@nhs.net

References

1. West Yorkshire and Harrogate Health and Care Partnership. Children, Young People and Families Programme. < Accessed 28.05.2021 >

Appendix 2: Comments received and amendments to the policy in response to engagement

Name	Role and Organisation	Comment
Fozia Lohan	Spectrum	No further comments to make
Dr Bob Phillips	Honorary Consultant in Paediatric Oncology Leeds Children's Hospital	Thank you – this is clear for me.
Jane Otter	Prescribing Advisor Pharmacist - Leeds Teaching Hospital	No comments to add
Andreanna Kosmirak	Paediatric LTHT specialist pharmacist	No comments to add.
Lyndsay Clayton	Wakefield CCG	• Not clear on age range – what does paediatrics refer to – 0-18? 0-12? • It is not clear where lidocaine patches sit in the pathway – is it 1st line or after the patient has tried gabapentinoids, opioids and amitriptyline and treatment not effective? • Treatment options section – only lists gabapentinoids and lidocaine – what about opioids and amitriptyline? Why are they excluded from this section? I think there needs to be a treatment pathway which indicates visually when lidocaine patches should be considered.
Dr Jordache Myerscough	Prescribing Lead GP Wakefield CCG	I would echo Lyndsey's comments / concerns about the wording and reference to the place / role of other analgesics. My next question is a "why? given the very small numbers, it's use off-licence and the complex Paediatric indications why does the prescribing needed to be handed over to GPs at all? I would argue this extra step or agreement could add confusion and is not particularly safe.
Lisa Murray	Meds Optimisation Pharmacist Wakefield CCG	Does the fact that the plasters are only to be considered for paediatric patients on Leeds specialist tertiary paediatric pain centre advice mean our local pain service has to refer children into this service creating more referrals? Could this statement apply to local pain services? If it doesn't then is this inequitable? A pathway would be better. There's no shared-care agreement to check alongside this statement which would be helpful

2nd draft Circulated to ICS APC members	30th November 2020
Comments from ICS APC members on 2nd draft by	11th December 2020
Date of next draft	
Agreement & Comments on next draft by	*If applicable*
On agenda for ICS APC meeting date:	*28th April 2021*

West Yorkshire and Harrogate
Health and Care Partnership

Appendix 3: West Yorkshire and Harrogate Combined Impact Assessment

Title of Scheme/Project:	Lidocaine 5% plasters in children

Project Manager:	Helen Higgins and Kirsty Shuttleworth
Clinical Lead:	Alison Bliss
Programme Lead:	
Senior Responsible Officer: (SRO)	Gaye Sheerman-Chase
Quality Lead:	Sarah Mackenzie - Cooper
Equality Lead:	Sarah Mackenzie - Cooper

Proposed Change
Prescribe lidocaine 5% plasters in children, for the treatment of Complex Regional Pain Syndrome (CRPS) / Persistent Post-Surgical Pain (PPSP) / Erythromelalgia / Isolated Neuropathic Pain

Which areas are impacted:					
NHS Airedale, Wharfedale and Craven CCG	☑	NHS Harrogate and Rural Districts CCG	☑	Acute services	☐
NHS Bradford City CCG	☑	NHS Leeds CCG	☑	Yorkshire Ambulance Service	☐
NHS Bradford Districts CCG	☑	NHS North Kirklees CCG	☑	Independent Sector	☐
NHS Calderdale CCG	☑	NHS Wakefield CCG	☑	Primary Care	☐
NHS Greater Huddersfield CCG	☑	Community services	☐	Mental Health services	☐
				Third sector	☐

Summary of engagement activity:
Prescribing of lidocaine 5% plasters only to be considered for paediatric patients on specialist tertiary pain centre advice where: • pain has not responded to usual non-pharmacological & pharmacological treatments (e.g. opioids, amitriptyline, gabapentin, pregabalin) or standard care medications are causing unacceptable side-effects / there are risks with other long term conditions e.g. opioid side-effects/tolerance, cardiac risks of amitriptyline, risk of suicidal ideation with gabapentinoids, risks in overdose, risks of addiction • pain is having significant impact on wellbeing and activities of daily living (ADL) e.g. unable to self-mobilise, pain affecting whole limbs, pain having significant longer term impact on school attendance, pain having significant impact on mental wellbeing; • child is already receiving polypharmacy for their underlying condition, and/or those whose underlying condition impacts on renal and/or hepatic metabolism, where alternative systemic treatments pose a higher risk of side-effects. • to avoid 5-day/4-night admission to hospital for MDT treatment package (Including invasive analgesia which necessitates general anaesthetic and nerve block) plus 15-18 therapy sessions).

Summary of impacts graph - This will automatically populate from the impact score on each tab

Note that scores above zero indicate positive impact and below zero indicate negative impact

Links to each area for further detail:

Patient Experience

Patient Safety

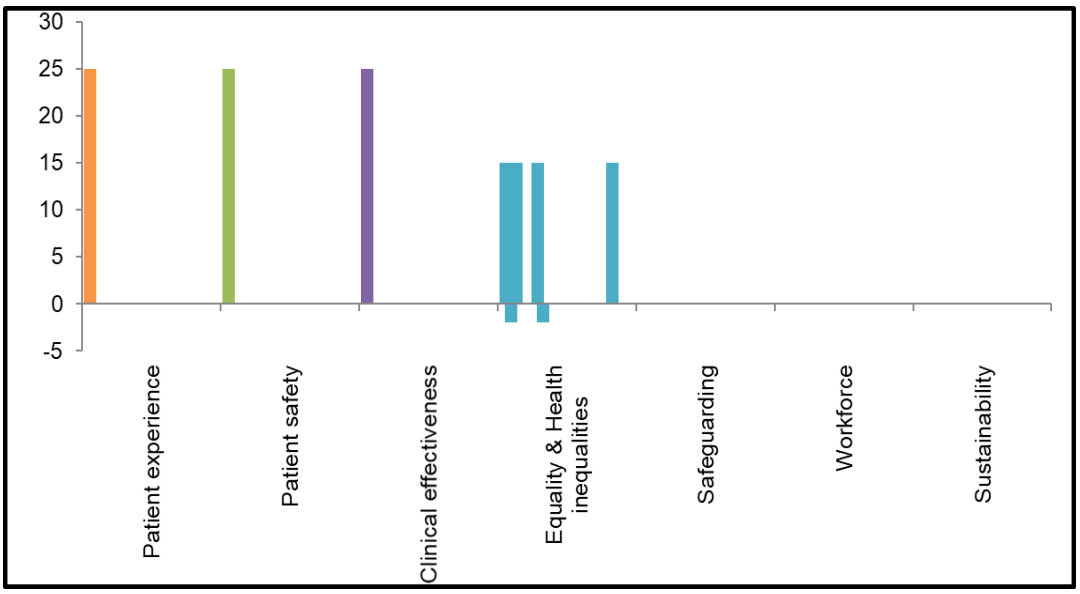
Clinical Effectiveness

Safeguarding

Equality and Health Inequality

Workforce

Sustainability



Summary of findings:

QEIA completed by (name, role and organisation):	Helen Higgins, Medicines Commissioning Pharmacist, NHS Leeds CCG
Date QEIA completed:	10/11/2020

QEIA signed off by:	Name	Date
Senior Responsible Officer:		
Committee		

Appendix 4: A breakdown of the impact of implementation

Anticipated paediatric patient no per annum across ICS	**Estimated no** Chronic Regional Pain Syndrome (CRPS)	**Estimated no** Persistent Post-Surgical Pain (PPSP)	**Estimated no** Erythromyalgia	**Estimated no** Isolated Neuropathic Pain
20	**6**	**6**	**2**	**6**

Anticipated paediatric patient no per annum across ICS	**Estimated no who receive 1 month treatment**	**Estimated no who receive 3 month treatment**	**Estimated no who receive 6 month – 1 year treatment**	**Estimated no who receive 2 year treatment**
20	**8**	**7**	**4**	**1**

From ONS - April 2019, there were approximately 1.3million children across Yorkshire and Humber

Cost effectiveness / resource impact:

Anticipated paediatric patient no per annum across ICS	**Estimated cost per patient per year**	**Estimated annual total cost across ICS**
20	**£810.84**	**£16,216.80**

Alternative Treatment Options	Cost per patient per month	Cost per patient per year
Amitriptyline tablets (50mg ON)	**£2.01**	**£24.12**
Amitriptyline liquid (50mg ON)	**£17.92**	**£215.04**
Gabapentin capsule (300mg TDS) **Schedule 3 Controlled Drug**	**£2.71**	**£32.52**
Gabapentin liquid (300mg TDS) **Schedule 3 Controlled Drug**	**£227.76**	**£2733.12**
Pregabalin capsules (25mg TDS) **Schedule 3 Controlled Drug**	**£3.78**	**£45.36**
Pregabalin liquid (25mg TDS) **Schedule 3 Controlled Drug**	**£22.08**	**£264.96**
Lidocaine plaster	**£67.57**	**£810.84**
Cost of 5-day inpatient stay for invasive analgesia & therapy per patient		**£3000-6000**

Based on Drug Tariff price from BNF on 26/02/2020 and 1 month is counted as 28 days.
N.B. Drug prices may vary between BNF prices, CCG prices and hospital prices.