

## Lidocaine medicated plasters

This is one of several bulletins supporting the implementation of [NHS England guidance on items which should not be routinely prescribed in primary care](#). The guidance classifies lidocaine medicated plasters as items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness. NHS England's recommendations do not apply to patients who have been treated in line with National Institute for Health and Care Excellence (NICE) guidance on chronic pain but are still experiencing neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia (PHN)).<sup>1</sup>

Approximately £36million annually is spent on prescribing lidocaine medicated plasters in England, Scotland, Wales, Isle of Man and Northern Ireland (NHSBSA England, Wales, Isle of Man, Northern Ireland (Nov23-Jan24), and Public Health Scotland (Oct-Dec23)).

Medicines optimisation projects can support quality improvement, value and sustainability in healthcare. For lidocaine medicated plasters specifically, the projects are aimed at ensuring the products are not routinely prescribed and are deprescribed in patients that do not meet the relevant exception criteria.

This bulletin relates to the use of lidocaine medicated plasters in indications that are most relevant to primary care prescribers, particularly neuropathic pain, including PHN. It does not cover secondary care indications such as post-operative pain, or palliative care, which are generally managed by specialist teams.

### Recommendations

- Be aware that current NICE guidance does not make a recommendation about the use of lidocaine medicated plasters for neuropathic pain (including PHN), as only very limited evidence on this treatment met their inclusion criteria. For neuropathic pain (except trigeminal neuralgia), NICE recommend:
  - » Amitriptyline, gabapentin, pregabalin or duloxetine for initial treatment (note that none of the duloxetine studies considered by NICE were in people with PHN).
  - » Consideration of capsaicin 0.075% cream for those with localised neuropathic pain who wish to avoid, or who cannot tolerate, oral treatments (however there is no licensed product available at present).
- For PHN, ensure that prescribing of lidocaine medicated plasters in primary care is restricted to those in whom other interventions are clinically inappropriate. This is in accordance with guidance from NHS England, the Scottish Medicines Consortium, the All Wales Medicines Strategy Group and the Strategic Planning and Performance Group in Northern Ireland (formerly the Health and Social Care Board).
- For unlicensed indications including localised neuropathic pain, lidocaine medicated plasters should, in general, not be prescribed in primary care. There are some differences in guidance in different countries of the UK, so consult the relevant national guidance (See 'National Guidance' section below).
- With the exception of patients with PHN in whom other interventions are clinically inappropriate, review patients prescribed lidocaine medicated plasters and consider alternatives appropriate to the indication.

## Recommendations

- Address patients' expectations of chronic pain treatments at an early stage. Medication is unlikely to completely eliminate pain. Realistic treatment expectations should focus on reducing pain and maintaining function, with a view to improving quality of life.
- **Where lidocaine medicated plaster treatment is considered appropriate:**
  - » Issue the initial supply as an acute prescription.
  - » Ensure patients have at least a 12 hour treatment free period every 24 hours.
  - » Advise those with intermittent symptoms that they only need to apply the plaster(s) when they are needed for pain.
  - » Ensure that no more than three plasters are used at a time.
  - » Ensure treatment is reviewed after two to four weeks and discontinued if it is ineffective.
  - » Treatment continued beyond four weeks can be added to the patient's repeat prescriptions.
  - » Reassess treatment at regular intervals e.g. four weekly initially, but longer intervals may be appropriate according to clinical judgement.
  - » Reviews should include an assessment of pain control, impact on lifestyle and daily activities (including sleep disturbance), physical and psychological wellbeing, adverse effects and continued need for treatment.
  - » When assessing continued need for treatment, consider if any of the following strategies are appropriate:
    - Attempting to reduce the amount of plaster(s) needed to cover the painful area (note that plasters can be cut) or increase the interval between plasters.
    - A 'trial without' e.g. asking the patient to remain lidocaine medicated plaster-free for 24 hours before their review appointment.
    - A trial of unmedicated physical protection (e.g. with a plastic wound dressing such as Opsite).

## Background

Neuropathic pain is a symptom that develops as a result of damage to, or disease of, the somatosensory system. It may be caused by a wide range of conditions affecting the peripheral nervous system or the central nervous system. The prevalence estimates for painful diabetic neuropathy is 16-26% of people with diabetes; PHN is 8% of people with herpes zoster when defined as pain three months after rash onset; chronic pain after surgery is 10-50% for many common operations.<sup>2</sup>

Neuropathic pain may be constant or intermittent, and spontaneous or provoked. The pain is typically described as shooting, stabbing, like an electric shock, burning, tingling, tight, numb, prickling, or itching. Some people may experience allodynia (pain caused by a stimulus that does not normally provoke pain e.g. pain in response to light touch/pressure), hyperalgesia (an increased response to a stimulus that is normally painful), anaesthesia dolorosa (pain felt in an anaesthetic area) or sensory gain or loss.<sup>2</sup>

Neuropathic pain is a complex condition that can be particularly difficult to treat. Response to drug treatment is often inadequate, with no more than 40–60% of people obtaining partial pain relief. There is a risk of adverse effects with the systemic treatments commonly used and some are associated with dependence and abuse.<sup>2</sup> It is important for health professionals to address expectations of chronic pain treatments at an early stage. Realistic treatment expectations should focus on reducing pain and maintaining function, with a view to improving quality of life.<sup>3</sup>

Topical lidocaine formulated as a medicated plaster has been licenced in the UK since 2007.<sup>4</sup> Two brands have been available (Versatis® and Ralvo®) with Grünenthal Limited hold the Marketing

Authorisation for both products. However the manufacturer has discontinued the Ralvo® brand and have launched Lidocaine Grunenthal 700 mg medicated plasters. Ralvo® will continue to be available during 2024 until stocks run out. Versatis® will continue to be available.<sup>5</sup>

Versatis® contains 700 mg lidocaine per medicated plaster (5% w/w). It is licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (PHN) in adults.<sup>6</sup> It not licensed for any other indication.

According to the manufacturer, lidocaine medicated plasters have a dual mode of action. The lidocaine component is thought to provide a local analgesic effect by stabilisation of neuronal membranes, which is thought to cause down regulation of sodium channels resulting in pain reduction. The hydrogel plaster itself provides physical protection to the hypersensitive area.<sup>6</sup>

The medicated plasters can be cut into smaller sizes with scissors prior to removal of the release liner if needed. Up to three plasters can be applied to a painful area once daily for a maximum of 12 hours within a 24 hour period.<sup>6</sup> The product information does not explain why each should be worn for no longer than 12 hours at a time, and it is not clear from published trials whether this results in breakthrough pain during the plaster-free time.<sup>4</sup>

Treatment outcome should be re-evaluated after two to four weeks. If there has been no response during the wearing time and/or during the plaster-free interval, treatment must be discontinued as potential risks may outweigh benefits. Treatment should be reassessed at regular intervals to decide whether the amount of plasters needed to cover the painful area can be reduced, or if the plaster-free period can be extended. The manufacturer does not specify a time-frame for such reassessment.<sup>6</sup>

## National guidance

This section focuses primarily on guidance in relation to lidocaine medicated plasters. For a wider consideration of prescribing for neuropathic pain see [PrescQIPP Bulletin 216: Neuropathic Pain](#).

**NICE guidance** on the management of chronic pain<sup>7</sup> recommends that neuropathic pain is managed in accordance with the NICE clinical guideline on neuropathic pain in adults: pharmacological management in non-specialist setting.<sup>8</sup>

NICE [CG173] recommends amitriptyline, duloxetine, gabapentin or pregabalin as initial treatment options for neuropathic pain (except trigeminal neuralgia, for which treatment recommendations differ).<sup>8</sup> Note that gabapentin but not pregabalin is included in the Northern Ireland formulary for neuropathic pain and there is a prescribing note which states that pregabalin and gabapentin can lead to dependence and may be misused or diverted.<sup>9</sup>

NICE state that capsaicin 0.075% cream should be considered for people with localised neuropathic pain who wish to avoid, or cannot tolerate, oral treatments. They note that capsaicin 0.075% cream (Axsain®)\* is licensed for PHN and painful diabetic peripheral polyneuropathy only, so use for other conditions would be off label.<sup>8</sup> The SPC states that this should only be used for painful diabetic peripheral polyneuropathy under the direct supervision of a hospital consultant who has access to specialist resources.<sup>8,10</sup> The recommended duration of use in the first instance is eight weeks.<sup>10</sup>

Regular clinical review is recommended, including an assessment of pain control, adverse effects and continued need for treatment.<sup>8</sup>

\*Note that Axsain® cream has been discontinued by the manufacturer<sup>12</sup> so there is no licensed product available at present. Further information on the current status of capsaicin cream supply issues and alternatives can be found in the [medicine supply tool](#) (NHS free access, registration required).

NICE do not make a recommendation about the use of lidocaine medicated plasters for neuropathic pain due to insufficient evidence (see 'Clinical Effectiveness' below). The guideline development group felt that a research recommendation should be made to further investigate the use of this treatment for localised peripheral pain because it could be a potential alternative treatment for people who do not wish to, or are unable to, take oral medications.<sup>11</sup>

**NHS England** recommended that lidocaine medicated plasters should not routinely be prescribed in primary care. Lidocaine medicated plasters are categorised as an item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.<sup>1</sup> The recommendations state:

- Do not initiate.
- Deprescribe in patients currently prescribed this medicine.
- Prescribe only if no other item or intervention is clinically appropriate.
- Prescribe only if no other item or intervention is available.
- Prescribe only if for a named indication in this guidance.

Named exceptions and further recommendations are:

- Prescribe to patients who have been treated in line with NICE guidance on chronic pain but are still experiencing neuropathic pain associated with previous herpes zoster infection (PHN).
- Prescribe only if the decision has been made after a multidisciplinary team discussion.<sup>1</sup>

**The Scottish Medicines Consortium (SMC)** accepted lidocaine medicated plasters for restricted use within NHS Scotland in 2008. They are accepted for the treatment of neuropathic pain associated with previous herpes zoster infection (PHN). Use is restricted to those intolerant of first-line systemic therapies for PHN or where these therapies have been ineffective. The SMC noted that comparative data for lidocaine medicated plasters are limited, and comparative clinical effectiveness was unclear.<sup>13</sup>

**Scottish Intercollegiate Guidelines Network (SIGN)** guideline on chronic pain recommends topical lidocaine should be considered for the treatment of patients with PHN if first-line pharmacological therapies have been ineffective. It also states that they are the topical agent of choice (in the non-specialist setting) in patients with localised neuropathic pain who prefer a topical treatment.<sup>14</sup> An update to this SIGN guideline is expected in Summer 2025.

**The All Wales Medicines Strategy Group (AWMSG)** include lidocaine medicated plasters in guidance on [Medicines Identified as Low Priority for Funding in NHS Wales – paper 1](#). They note the limited evidence for lidocaine and state that any potential benefit of treatment needs to be balanced against its high cost compared to other treatment options available.

Within NHS Wales it is recommended that the prescribing of lidocaine medicated plasters in primary care should be restricted to the licensed indication of PHN in patients for whom alternative treatments have proved ineffective or where alternative treatments are contra-indicated.

- Patients on long-term therapy with lidocaine medicated plasters should be assessed for continued need, with the view to discontinuing treatment or having a longer plaster free period between applications.
- Off label use should only be initiated by pain specialists in secondary care and should be in line with MHRA guidance on the use of off label and unlicensed medicines.
- Patients being prescribed lidocaine medicated plasters for an unlicensed indication should be reviewed with the intention of discontinuing treatment or switching to a licensed alternative wherever possible.<sup>15</sup>

**The Strategic Planning and Performance Group in Northern Ireland** (formerly the Health and Social Care Board) includes lidocaine medicated plasters in their Limited Evidence List. Products on this list must not be routinely prescribed and should be reviewed to ensure that they are used only in approved circumstances. Lidocaine medicated plasters may be considered in PHN if the patient is intolerant of first line systemic therapies or where they have been ineffective or are contraindicated.<sup>16</sup>

**The British Pain Society** issued a position statement on the use of lidocaine medicated plasters for localised neuropathic pain in August 2018. They suggest that if a person is referred to a specialist pain service and their expert advice is to use lidocaine 5% medicated plasters then treatment should continue to be funded in primary care. People prescribed lidocaine 5% medicated plasters should have their treatment reviewed to assess efficacy. Where there is evidence of substantial benefit people should not be disadvantaged by prescribing being discontinued.<sup>17</sup>

International guidance from the **Neuropathic Pain Special Interest Group (NeuPSIG)** makes a weak recommendation for use and propose as a second line treatment for lidocaine medicated plasters (see 'Clinical Effectiveness' below).<sup>18</sup>

## Clinical Effectiveness

### Neuropathic pain (including PHN)

In their original evidence review for [CG173] in 2013, NICE included only one small crossover study on topical lidocaine for post-surgical pain after surgery for cancer, which showed no effect on pain reduction.<sup>11</sup>

Guideline surveillance in 2017 identified two additional studies. The first was a crossover RCT (n=46) investigating pain relief with lidocaine 5% medicated plaster vs. placebo in localised peripheral neuropathic pain in relation to pain phenotype. Patients with neuropathic pain due to nerve injury or postherpetic neuralgia were randomised to four week treatment periods of lidocaine 5% patch or placebo. Lidocaine reduced pain and sleep disturbance significantly more than placebo. There was no significant interaction between treatment and phenotype, but there was a significant interaction for pain paroxysms and deep aching pain.<sup>19</sup>

The second was a Cochrane systematic review assessing the analgesic efficacy of topical lidocaine for chronic neuropathic pain in adults (see below). The NICE surveillance report stated that there was no convincing evidence that topical lidocaine is effective for treating neuropathic pain and they judged new evidence to be insufficient to trigger an update of the topic and the addition of new recommendations. The research recommendation was retained based on evidence of research activity in this area.<sup>19</sup>

A 2014 Cochrane systematic review found no evidence from good quality RCTs to support the use of topical lidocaine to treat neuropathic pain in adults. The review included randomised, double-blind studies of at least two weeks' duration comparing topical lidocaine (medicated plaster, cream, gel or spray) with placebo or another active treatment in chronic neuropathic pain. Twelve studies (508 participants) were identified:

- Six studies enrolled participants with moderate or severe PHN, four of which investigated the lidocaine 5% medicated plaster formulation.
- Six studies enrolled different, or mixed, neuropathic pain conditions, including trigeminal neuralgia and post-surgical or post-traumatic neuralgia.

All 12 studies were judged to be at high risk of bias because of the small size or incomplete outcome assessment, or both. Very low quality evidence indicated that lidocaine was better than placebo for some measures of pain relief, in all but one study (which showed no difference between topical lidocaine and placebo).<sup>20</sup>

Several studies included in the Cochrane review were excluded from the evidence review for NICE [CG173]. Reasons for exclusion included having a study duration of less than four weeks or using an enriched population,<sup>21</sup> where those randomised into the study had already been identified as responders to lidocaine medicated plaster treatment.

Two enriched design studies were the main phase III studies used to assess efficacy in the licence application for Versatis®. The Medicines and Healthcare Products Regulatory Agency (MHRA)

expressed concerns about the use of enriched populations in these studies. They also stated that the manufacturer was not able to define prospectively which patients would respond to the medicated plasters and that it is not clear how many patients will derive benefit.<sup>22</sup>

A 2015 systematic review of pharmacotherapy for neuropathic pain was used as the basis for the updated NeuPSIG recommendations. The systematic review, which included RCTs of least three weeks duration, identified one small negative study of lidocaine medicated plasters in postsurgical neuropathic pain and two enriched enrolment studies in PHN (likely to be those used for the Versatis® licence application, but they are not referenced). The smaller study (n=32) was positive, the larger study (n=263) was negative in the intention to treat population, but positive in the per protocol population.<sup>18</sup>

The authors of the systematic review note the weak final quality of evidence. However, owing to the safety profile, paucity of alternative well tolerated and safe medications, and short term positive studies, they made a recommendation for lidocaine medicated plaster use as generally second line for peripheral neuropathic pain. They state that future studies of pharmacotherapy for neuropathic pain should take into account the limited efficacy, large placebo responses, heterogeneous diagnostic criteria, and poor phenotypic profiling that probably account for modest trial outcomes.<sup>18</sup>

In addition to the RCTs considered in the Cochrane review, the evidence base for lidocaine medicated plasters for PHN include a number of open-label studies. These are summarised in a [review of lidocaine 5% medicated plasters for PHN](#) undertaken by Specialist Pharmacy Service in 2017.

More recent data for lidocaine medicated plasters in PHN is available from a placebo-controlled, four week RCT (n=240) undertaken in Chinese patients. At week 4, patients in the lidocaine group had a greater mean decrease in pain score compared with the placebo medicated plaster group. More patients in the lidocaine group achieved a 30% decrease of analogue scale score value.<sup>23</sup>

For neuropathic pain, newer RCTs include:

- A small single-blind RCT (n=63) in chronic post-thoracotomy neuropathic pain, in which lidocaine medicated plasters demonstrated a statistically significant reduction in Numeric Rating Scale pain scores after one and two months of treatment, compared with placebo plasters.<sup>24</sup>
- A small double-blind RCT (n=36) in localised neuropathic pain after knee surgery, which demonstrated a statistically significant difference in response to treatment favouring lidocaine medicated plasters compared with placebo plasters over a three month period.<sup>25</sup>

### Comparative studies for neuropathic pain

Comparative data for lidocaine medicated plasters versus existing treatments are very limited. An open label, non-inferiority RCT for four weeks duration compared lidocaine medicated plasters with pregabalin in people with PHN (n=96) or diabetic polyneuropathy (n=204). In the full analysis set, a similar proportion of participants in the lidocaine medicated plaster group and pregabalin group were considered responders (66.4% and 61.5% respectively). In those with PHN, more participants responded to lidocaine medicated plaster treatment than to pregabalin (62.2% vs 46.5% respectively).<sup>26</sup> However, this is a non-inferiority study so superiority of lidocaine cannot be extrapolated and the open-label design as well as the short duration and small size are limitations to the findings.<sup>27</sup>

A further study was undertaken in this cohort to investigate if those not sufficiently responding to monotherapy with lidocaine medicated plaster or pregabalin could benefit from combination therapy. An improvement in reported pain intensity was reported with combination therapy.<sup>28</sup> Both comparative studies were excluded from the evidence considered by NICE for [CG173] because of their open label design.<sup>21</sup>

A systematic review and network meta-analysis (which combines direct evidence and indirect evidence for particular pairwise comparisons) investigating lidocaine medicated plaster vs. pregabalin in peripheral neuropathic pain was published in 2020.<sup>29</sup> It included 43 RCTs, only one of which was

a direct head-to-head comparison (by Baron et al above).<sup>26</sup> The authors reported no clear difference in efficacy between treatments and some advantages for lidocaine medicated plasters vs. pregabalin in terms of adverse effects. They stated that the findings support the recommendation of lidocaine medicated plasters for any peripheral neuropathic pain as a safe alternative to pregabalin. However they acknowledge limitations of the network meta-analyses and also recommend further high-quality RCTs to comparing these treatments given the large amount of uncertainty.<sup>29</sup>

### Non-neuropathic pain

There has been interest in the use of lidocaine medicated plasters for non-neuropathic pain, including various types of musculoskeletal pain. Even where RCTs have been published, such as in chronic back pain,<sup>30</sup> rib fractures,<sup>31,32</sup> and myofascial pain,<sup>33-35</sup> studies are often limited by small size or negative findings. It has been reported that topical lidocaine can penetrate no deeper than 8-10 mm,<sup>36</sup> which would limit the types of pain that it could potentially have a role in managing.

### Precautions and adverse effects

Contraindications to lidocaine medicated plasters include hypersensitivity to the active substance, the excipients or other amide-type local anaesthetics e.g. bupivacaine, etidocaine, mepivacaine and prilocaine. The plasters must not be applied to inflamed or injured skin such as active herpes zoster lesions, atopic dermatitis or wounds.<sup>6</sup>

Lidocaine medicated plasters should be used with caution in people with severe cardiac impairment, severe renal impairment or severe hepatic impairment. They should not be applied to mucous membranes and eye contact with the plaster should be avoided.<sup>6</sup>

Approximately 16% of patients can be expected to experience localised adverse reactions, which are most commonly administration site reactions and include burning, dermatitis, erythema, pruritus, rash, skin irritation and vesicles. Anaphylactic reactions and hypersensitivity have been reported very rarely (<1/10,000).<sup>6</sup>

Systemic adverse reactions following the appropriate use of lidocaine medicated plasters are unlikely due to very low systemic absorption. They must however be used with caution in patients receiving Class I antiarrhythmic medicinal products (e.g. tocainide, mexiletine) and other local anaesthetics since the risk of additive systemic effects cannot be excluded.<sup>6</sup>

In an open-label comparative RCT, lidocaine medicated plasters were associated with improved tolerability compared with pregabalin.<sup>26</sup> There are no direct comparative data with other commonly used agents for post-herpetic neuralgia.

One lidocaine metabolite has been shown to be genotoxic and carcinogenic in rats. Secondary metabolites have been shown to be mutagenic. The manufacturer states that clinical significance of this finding is unknown. Long-term treatment is therefore only justified if there is a therapeutic benefit.<sup>6</sup> This underscores the need for regular reassessment.

### Costs

There is a significant difference in cost between treatments available for PHN and other neuropathic pain, illustrated in Table 1, overleaf. Drug costs for lidocaine medicated plasters are more costly than all other treatment options.

**Table 1: Product and price comparison of treatments for post-herpetic and other neuropathic pain**

| Drug preparation                                                           | Dose range <sup>37</sup>                                                                 | Cost per 28 days <sup>38,39</sup>                                                                                                                   | Comments <sup>37</sup>                                                                                                                            |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Nortriptyline tablets                                                      | 10mg – 75mg at night                                                                     | £0.46 - £1.56<br>(Using 3 x 25mg tablets for 75mg dose)<br>£0.46 - <del>£56.88</del><br>(Using 1 x 25mg tablet plus 1 x 50mg tablets for 75mg dose) | Unlicensed use                                                                                                                                    |
| Amitriptyline tablets                                                      | 10mg – 75mg at night                                                                     | £0.63 - £1.46<br>(Using 1 x 25mg plus 1 x 50mg for 75mg dose)                                                                                       | Licensed for neuropathic pain                                                                                                                     |
| Pregabalin capsules                                                        | 150mg – 600mg daily<br>(in 2 or 3 divided doses)                                         | £1.32 - £2.43 (Twice daily dosing)<br>£1.66 - £2.57 (Three times daily dosing)                                                                      | Licensed for peripheral and central neuropathic pain<br>If prescribed by brand name, or as tablets, the price increases (sometimes substantially) |
| Duloxetine gastro-resistant capsules                                       | 60mg – 120mg daily                                                                       | £2.34 - £4.68<br>(Using 2 x 60mg capsules for 120mg dose)<br>£2.34 - <del>£21.94</del><br>(Using 1 x 120mg capsule for 120mg dose)                  | Licensed for diabetic neuropathy                                                                                                                  |
| Gabapentin capsules                                                        | 300mg – 1.2g three times daily                                                           | £1.93 - £7.69<br>(Using 3 x 400mg capsules for the 1.2g dose)                                                                                       | Licensed for peripheral neuropathic pain                                                                                                          |
| Tramadol immediate release capsules                                        | 50mg - 100mg every 4 to 6 hours up to a maximum of 400mg/24 hours – acute short term use | £2.65 - £5.31<br>(Using 50mg capsules and a 200mg - 400mg daily dose)                                                                               | Licensed for moderate to severe pain                                                                                                              |
| Ralvo® 700mg medicated plasters* (Lidocaine)                               | Apply 1 – 3 medicated plasters once daily for up to 12 hours                             | <del>£57.44</del> - <del>£172.31</del>                                                                                                              | Licensed for PHN                                                                                                                                  |
| Lidocaine 5% medicated plasters (prescribed as generic or Versatis® brand) | Apply 1 – 3 medicated plasters once daily for up to 12 hours                             | £67.57 - £202.72                                                                                                                                    | Licensed for PHN                                                                                                                                  |

\*The Ralvo® brand is discontinued but supplies will be available in 2024 until stock runs out.

## Prescribing review

There are several options available for reviewing treatment with lidocaine medicated plasters. Individual review is essential and should include consideration of indication, past treatments, co-morbidities and use of evidence based treatments.

Organisations considering a review of prescribing should ensure that the process is agreed locally by all key stakeholders including GPs, pain specialists and other relevant healthcare professionals.

They should ensure local guidelines on the management of neuropathic pain and other types of chronic pain are available, as well as specific guidance on the use of lidocaine medicated plasters. Where such guidance is not already in place or requires updating, it will need to be developed/revised taking into account relevant national guidance, which differs across the UK (see 'National Guidance p.3-5).

Reviews of lidocaine medicated plasters will need to be undertaken by healthcare professionals with the appropriate knowledge and skills in pain management.

## Unlicensed indications

The General Medical Council (GMC) has guidance for prescribers relating to unlicensed medicines. When prescribing an unlicensed medicine the prescriber must:

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.
- Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so.
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.<sup>40</sup>

Where lidocaine medicated plasters are prescribed for an unlicensed indication (e.g. neuropathic pain that is not PHN, pain in myalgic encephalomyelitis or musculoskeletal pain) review the need for continued treatment. Assess for suitability to change to an alternative treatment appropriate to the indication. [PrescQIPP Bulletin 216: Neuropathic Pain](#) and [PrescQIPP Bulletin 284: Chronic pain](#) are available to support prescribing. Consider making a referral to a specialist pain clinic if alternative treatments are clinically inappropriate.

## PHN

National guidelines outline specific circumstances in which lidocaine medicated plaster prescribing is appropriate i.e. in patients treated in accordance with NICE guidance on chronic pain but are still experiencing PHN,<sup>1</sup> or those with PHN in whom alternative treatments are contraindicated, not tolerated, or ineffective.<sup>13,15,16</sup>

If lidocaine medicated plasters have been commenced outside of these recommendations e.g. if they have been initiated without appropriate exploration of usual first-line options, treatment should be reviewed and changed if clinically appropriate.

Where lidocaine medicated plaster treatment is considered appropriate:

- Issue the initial supply as an acute prescription.
- Ensure treatment is used correctly and that patients have at least a 12 hour treatment free period every 24 hours.
- Advise those with intermittent symptoms that they only need to apply the lidocaine medicated plaster(s) when needed for pain.
- Ensure that no more than three plasters are used at a time. Plasters can be cut into smaller sizes if necessary.<sup>6</sup>

- Ensure treatment is reviewed after two to four weeks and discontinued if it is insufficiently effective.
- Treatment continued beyond four weeks can be added to the patient's repeat prescriptions, but should be reassessed at regular intervals.<sup>6</sup> The frequency of reassessment is not specified in the product literature. It may be reasonable to continue four weekly monitoring initially, which could be adjusted to longer intervals according to clinical judgement in the individual circumstances.
- As for any neuropathic pain treatment, review should include an assessment of pain control, impact on lifestyle and daily activities (including sleep disturbance), physical and psychological wellbeing, adverse effects and continued need for treatment.<sup>8</sup>
- When assessing continued need for treatment, consider if any of the following strategies are appropriate:
  - » Attempting to reduce the amount of plaster(s) needed to cover the painful area (note that plasters can be cut) or increase the interval between plasters.<sup>6</sup>
  - » A 'trial without' e.g. asking the patient to remain lidocaine medicated plaster-free for 24 hours before their review appointment.
  - » A trial of unmedicated physical protection (e.g. with a plastic wound dressing) as described below.

Self-care advice for all people with PHN includes the following:

- Wear cotton or silk fabrics, as these may cause the least irritation.
- Protect sensitive areas by applying a protective layer (such as a firm bandage, compression clothing, cling film, or a plastic wound dressing such as Opsite®).
- Consider frequent application of cold packs, unless this causes pain (allodynia).<sup>41</sup>

## Patient information

PrescQIPP resources include [patient leaflets](#) that explain why certain medicines (including lidocaine medicated plasters) are included in the NHS England Items which should not routinely be prescribed in primary care guidance.

## Sustainability

A number of strategies can be deployed to support a reduction in the medicine carbon footprint. Examples specific to lidocaine medicated plaster use include projects focused on:

- Reducing inappropriate use e.g. raising awareness of guidance with prescribers and practice audits
- Regular review of treatment e.g. after two to four weeks and then at regular intervals, using a 'trial without'/extending plaster free interval/reducing amount of plaster used
- Minimisation of waste e.g. cutting plasters where appropriate, using acute issues initially and issuing suitable quantities.

See [PrescQIPP bulletin 340. Sustainability in medicines optimisation](#) for a broader consideration of sustainability issues and reducing the carbon footprint of medicines.

## Spend and savings

In England, Scotland, Wales, Isle of Man and Northern Ireland approximately £36million annually is spent on prescribing lidocaine medicated plasters (NHSBSA England, Wales, Isle of Man, Northern

**Table 2: Lidocaine medicated plaster annual spend and spend per 100,00 population NHSBSA England, Wales, Isle of Man, Northern Ireland (Nov23-Jan24), and Public Health Scotland (Oct-Dec23).**

| Country          | Lidocaine medicated plasters annual spend | Lidocaine medicated plasters spend per 100,000 registered patients |
|------------------|-------------------------------------------|--------------------------------------------------------------------|
| Scotland         | £17,553,924                               | £293,577                                                           |
| England          | £14,601,358                               | £23,140                                                            |
| Northern Ireland | £2,169,706                                | £105,794                                                           |
| Wales            | £1,608,387                                | £48,808                                                            |
| Isle of Man      | £33,512                                   | £37,558                                                            |
| <b>Total</b>     | <b>£35,966,877</b>                        | <b>£48,267</b>                                                     |

Any savings will depend on what stage of the neuropathic pain treatment pathway a person is on, how many medicated plasters are used at a time and whether an alternative treatment needs to be prescribed. The following examples in table 3 illustrate the potential annual savings per patient.

**Table 3. Potential annual savings per year\***

| Change to treatment                                               | Potential annual saving per patient using: |                  |                    |
|-------------------------------------------------------------------|--------------------------------------------|------------------|--------------------|
|                                                                   | One plaster/day                            | Two plasters/day | Three plasters/day |
| Lidocaine medicated plasters discontinued, no alternative started | £878.41                                    | £1756.82         | £2635.23           |
| Lidocaine medicated plasters discontinued, amitriptyline started  | £858.52                                    | £1736.93         | £2615.34           |
| Lidocaine medicated plasters discontinued, pregabalin started     | £843.57                                    | £1721.98         | £2600.39           |

\*The potential savings described are based on patients using lidocaine medicated plaster(s) every day. Savings will be lower for patients with intermittent symptoms who do not use lidocaine medicated plaster(s) every day.

Table 4 illustrates the 12 months cost avoidance that can be achieved through discontinuing lidocaine medication plasters or switching to amitriptyline tablets or pregabalin capsules for England, Scotland, Wales, Isle of Man and Northern Ireland (NHSBSA England, Wales, Isle of Man, Northern Ireland (Nov23-Jan24)), and Public Health Scotland (Oct-Dec23).

**Table 4. Potential 12 months cost avoidance by discontinuing or switching lidocaine medication plasters to alternatives**

|                                      | Lidocaine medicated plaster discontinued in 50% of patients 12 months cost avoidance | Lidocaine medicated plasters switched to amitriptyline tablets in 25% of patients 12 months cost avoidance | Lidocaine medicated plasters switched to pregabalin capsules in 25% of patients 12 months cost avoidance |
|--------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| England                              | £7,300,679                                                                           | £3,650,340                                                                                                 | £3,504,326                                                                                               |
| Isle of Man                          | £16,756                                                                              | £8,378                                                                                                     | £8,043                                                                                                   |
| Northern Ireland                     | £1,084,853                                                                           | £542,427                                                                                                   | £520,729                                                                                                 |
| Scotland                             | £8,776,962                                                                           | £4,388,481                                                                                                 | £4,212,942                                                                                               |
| Wales                                | £804,193                                                                             | £402,097                                                                                                   | £386,013                                                                                                 |
| <b>TOTAL</b>                         | <b>£17,983,444</b>                                                                   | <b>£8,991,722</b>                                                                                          | <b>£8,632,053</b>                                                                                        |
| <b>Saving per 100,000 population</b> | <b>£24,134</b>                                                                       | <b>£12,067</b>                                                                                             | <b>£11,584</b>                                                                                           |

## Summary

The place in therapy of lidocaine medicated plasters is currently unclear. Evidence supporting both their licensed use in PHN and in other unlicensed indications is limited. Lidocaine medicated plasters are a relatively costly treatment option. Several other neuropathic pain treatments with a greater evidence base and a lower acquisition cost are recommended by NICE; they should be preferred where they are clinically suitable. Significant savings are available by reviewing treatment and discontinuing lidocaine medication plasters if they are ineffective or inappropriately prescribed.

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## Additional PrescQIPP resources

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|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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| Implementation tools |                                                                                                                                                                                                                                                                                 |
| Data pack            | <a href="https://data.prescqipp.info/views/B350_Lidocaineplasters/FrontPage?%3Aembed=y&amp;%3Aiid=1&amp;%3AisGuestRedirectFromVizportal=y">https://data.prescqipp.info/views/B350_Lidocaineplasters/FrontPage?%3Aembed=y&amp;%3Aiid=1&amp;%3AisGuestRedirectFromVizportal=y</a> |

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