Lancashire & South Cumbria Medicines Management Group

NHS Midlands and Lancashire Commissioning Support Unit

New Medicine Assessment

Qutenza (capsaicin) 179mg cutaneous patch

For the treatment of peripheral neuropathic pain in adults either alone or in combination with other medicinal products for the treatment of pain.

Recommendation:

Red RAG rating.

To be used as last line when all other alternative treatment options have been exhausted

- Medicine is supplied by the hospital for the duration of the treatment course.
- Primary care initiation or continuation of treatment is not recommended unless exceptional circumstances such as specialist GP.

Red medicines are those where primary care prescribing is not recommended. These treatments should be initiated by specialists only and prescribing retained within secondary care. They require specialist knowledge, intensive monitoring, specific dose adjustments or further evaluation in use. If however, a primary care prescriber has particular specialist knowledge or experience of prescribing a particular drug for a particular patient it would not always be appropriate for them to expect to transfer that prescribing responsibility back to secondary care. There should be a specific reason and a specific risk agreement, protocol and service set up to support this.

Primary care prescribers may prescribe Red medicines in exceptional circumstances to patients to ensure continuity of supply while arrangements are made to obtain on going supplies from secondary care.

Summary of supporting evidence:

Efficacy of a single 30-minute application of Qutenza to the feet has been shown in controlled clinical trials of 12 weeks duration conducted in patients with painful Human Immunodeficiency Virus – Associated Neuropathy (HIV-AN) and painful diabetic peripheral neuropathy (pDPN). Efficacy of a single 60-minute application of Qutenza to locations other than the feet has been shown in controlled clinical trials of 12 weeks duration conducted in patients with postherpetic neuralgia (PHN). The average pain reduction after single application of Qutenza compared to baseline at week 2 to 12 across the pivotal trials ranged between -22.8% and -32.3%, compared to a range of -10.7% to -25.0% for the control patches. Responder rates (response defined as a 30% decrease in average pain score from baseline) ranged between 34% and 47%, compared to a range of 18% to 36% for the control patches. These results were statistically significant versus low dose capsaicin (PHN and HIV-AN) or placebo (pDPN). Pain reduction was observed at week 1 in PHN, week 2 in HIV-AN and week 3 in pDPN. For all three aetiologies efficacy was maintained throughout the 12-week study period.

Consistent and reproducible efficacy and tolerability was demonstrated with repeated treatments during a 52-week period in two clinical trials (STRIDE and PACE). In these two trials, one in pDPN patients (PACE) and one in patients with HIV-AN, Post Traumatic Nerve Injury (PNI) and PHN (STRIDE), the mean time (Standard Deviation) to retreatment was 68.4 (23.31) and 107 (43.58) days respectively. In these trials 25% of patients had a retreatment time shorter than 61.5 and 78.8 days respectively and 25% of patients had a retreatment time longer than 64.6 and 118.7 days respectively. A frequency increase of up to approximately 5% of known application site reactions, such as pain and burning sensation, was reported in patients retreated with

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Qutenza earlier than 90 days.

The safety profile of Qutenza in diabetic patients was consistent with that seen in the non-diabetic population.

Qutenza has been shown to be effective when used alone or when used in combination with systemic medicinal products for neuropathic pain.

Details of Review

Name of medicine (generic & brand name)**:** Qutenza (capsaicin) cutaneous patch[1]
Strength(s) and form(s): Each 280 cm^2 cutaneous patch contains a total of 179 mg of capsaicin or 640 micrograms of capsaicin per cm^2 of patch.
Dose and administration: The cutaneous patch should be applied to the most painful skin areas (using up to a maximum of 4 patches). Qutenza must be applied to intact, non-irritated, dry skin, and allowed to remain in place for 30 minutes for the feet (e.g. HIV-associated neuropathy, painful diabetic peripheral neuropathy) and 60 minutes for other locations (e.g. postherpetic neuralgia). Qutenza treatments may be repeated every 90 days, as warranted by the persistence or return of pain. Re-treatment after less than 90 days can be considered for individual patients only after a careful assessment by the physician. A minimum interval of 60 days between treatments is to be observed. It is recommended to treat sufficiently long and to reassess effectiveness on a case-by-case basis after 3 treatments.
BNF therapeutic class / mode of action: Analgesics / counter irritant
Licensed indication(s): Qutenza is indicated for the treatment of peripheral neuropathic pain in adults, either alone or in combination with other medicinal products for the treatment of pain.
Proposed use (if different from, or in addition to, licensed indication above): N/A
Course and cost: The NHS list price of Qutenza is 1 patch = £210.[2] 2 patch / 1 treatment = £420 4 patch / 1 treatment = £840 (maximum therapy) If 4 patches were to be used every 90 days for 4 treatments (per annum), then the total cost per patient would be £3,360. The annual cost for 12 patients at maximum dose (ie 4 patches per treatment) = £40,320.
Current standard of care/comparator therapies: NHS list price February 2024[2] Capsaicin 0.025% cream (Zacin) 45g = £17.71 Capsaicin 0.075% cream (Axsain) 45g = £14.58 Lidocaine 5% medicated plasters 30 = £72.40 Pregabalin 25mg-300mg capsules / tablets range from: 56 x 25mg capsules =£1.23 to 56 x 300mg tablets = £7.19 Gabapentin 100-800mg capsules / tablets range from: 100 x 100mg capsules = £1.97 to 100 x 800mg tablets = £26.91

Relevant NICE / OTHER guidance:

NICE CG173[3] -Neuropathic pain in adults: pharmacological management in non-specialist settings – for capsaicin patches states 'Do not start the following to treat neuropathic pain in non-specialist settings, unless advised by a specialist to do so'.

SMC 673/11[4] - capsaicin (Qutenza®) is accepted for restricted use within NHS Scotland. SMC restriction**:** to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments.

AWMSG 823[5] **-** Capsaicin patch (Qutenza®) is recommended as an option for restricted use within NHS Wales for the treatment of peripheral neuropathic pain (PNP) in non-diabetic adults in combination with other medicinal products for pain and in patients who have not received adequate benefit from, or are intolerant to, alternative conventional treatments. The company submission provided evidence on the cost effectiveness of capsaicin patch (Qutenza®) as an add-on treatment in patients who were refractory to or intolerant of usual first or second line treatments. AWMSG is of the opinion that capsaicin patch (Qutenza®) is suitable for specialist only prescribing within NHS Wales for the above indication. Capsaicin patch (Qutenza®) is not recommended for use alone for the treatment of peripheral neuropathic pain (PNP) in non-diabetic adults.

The North East and Cumbria (NTAG)[6] [vi] have a pathway in place, for the neuropathic pain patient group, which offers a 4th line trial of Qutenza in patients who have / are:

- Localised neuropathic pain which is not controlled by medications on the maximum tolerated dose
- Patients are experiencing significant side effects and not able to tolerate
- Patients have developed tolerance to anti-neuropathic medications
- Patients are not keen to take / continue the anti-neuropathic medications

All patients offered a trial of Qutenza are reviewed in 3-6 months and dependent on results treatment maybe continued / discontinued. All patients will be regularly reviewed if they require ongoing therapy.

Background and context

A request was submitted by a Consultant in Pain Management at Blackpool Victoria Hospital for Capsaicin patches to be reviewed and approved for use by LSCMMG.

The request is for the patches to be available for the treatment of peripheral neuropathic pain and it is felt that there will be a particular advantage in the specific patient group suffering from allodynia ("painful sensitive skin") due to neuropathic pain of any cause (not diabetes). These patients will have been through the NICE guidelines on treatment, will have been reviewed by the pain consultants and will have tried advanced pain pharmacology (combination double and triple neuropathic pain treatments with anticonvulsants, antidepressants and opiates), topical application of lidocaine plaster 5%, capsaicin 0.075%, TENS and acupuncture. This may also be associated with psychological treatments.

The estimated annual use is for 12 patients and they would commence treatment with 1 patch / treatment.

Capsaicin is a highly selective agonist for the transient receptor potential vanilloid 1 receptor (TRPV1) found on cutaneous nociceptors. The initial effect of capsaicin results in pungency and erythema. Following exposure to capsaicin, cutaneous nociceptors become less sensitive to a variety of stimuli, which is thought to be the mechanism of the analgesic effect of the drug.

Capsaicin patch is applied topically, and therefore avoids the central adverse effects and potential for drug-drug interactions that may occur with existing systemic treatments for PNP (peripheral neuropathic pain). Qutenza is longer lasting than other topical pain relief; avoids worries about addiction to oral medication which may lead to abandoning treatment and offers an alternative to existing treatments. It is applied as a single application to be repeated after 90 days, so may have an advantage in terms of compliance over systemic treatments administered daily.

Some patients experience rapid and long-lasting improvements in pain after a single local treatment of PNP with the capsaicin 179mg cutaneous patch, whereas others may follow a more progressive or incremental course of benefit in terms of pain, sleep, QOL and patient satisfaction. In the latter individuals, two or even three treatments 8 weeks apart are needed before a response is achieved. Slower responders appear to “catch up” with rapid responders over time. Repeat treatment may therefore be important to maximize efficacy in those who do not initially respond.

NTAG have a pathway for the use of Qutenza in the neuropathic pain patient group (2017),[6] which offers a 4th line trial of Qutenza in patients who meet certain criteria.

Summary of evidence

Summary of efficacy data in proposed use:

A phase IV open-label, randomised, multi-centre, non-inferiority study (**ELEVATE**) compared the efficacy and tolerability of capsaicin cutaneous patch with pregabalin in adult patients with peripheral neuropathic pain (PNP). Patients were eligible for the study if they were aged between 18 and 80 years with a documented diagnosis of probable or definite non-diabetic PNP in a localised and well-defined area suitable for treatment with capsaicin patch, including: post-herpetic neuralgia (PHN) with pain persisting at least six months since shingles vesicles crusting; peripheral nerve injury (PNI) including post-surgical or post traumatic neuropathic pain, persisting for at least three months; or non-diabetic painful peripheral polyneuropathy (PPN) with pain that had persisted for a minimum of three months. Patients must have had an average pain score ≥4 during the screening period over at least four consecutive days using the “average pain for the past 24 hours” Numeric Pain Rating Scale (NPRS) score and be naive to treatment with pregabalin or gabapentin or have had an inadequate trial of either of these medicines.

The primary endpoint was the proportion of patients in each group who achieved at least 30% decrease in the average NPRS score from baseline to week 8 (defined as “responders”), assessed in both the per protocol population and the full analysis set (FAS; which included all randomised patients who started study treatment). In the per protocol population, this was achieved in 58% (147/254) of patients receiving capsaicin patch and 58% (145/252) of patients in the pregabalin group; a difference (capsaicin minus pregabalin) of 0.3% (95% confidence interval [CI] -8.3% to 8.9%); odds ratio (OR) 1.03 (95% CI 0.70 to 1.5). In the FAS, the proportion of responders was 56% (157/282) for capsaicin patch and 55% (151/227) for pregabalin, a difference (capsaicin minus pregabalin) of 1.2%; OR 1.03 (95% CI: 0.72 to 1.50). Since the lower bound of the 95% CI of the OR was greater than the predetermined value of 0.693, non-inferiority of capsaicin versus pregabalin was demonstrated.[7]

Consistent and reproducible efficacy and tolerability was demonstrated with repeated treatments during a 52-week period in two clinical trials (**STRIDE and PACE**)[8]. In these two trials, one in pDPN patients (PACE) and one in patients with HIV-AN, Post Traumatic Nerve Injury (PNI) and PHN (STRIDE), the mean time (Standard Deviation) to retreatment was 68.4 (23.31) and 107 (43.58) days respectively. In these trials 25% of patients had a retreatment time shorter than 61.5 and 78.8 days respectively and 25% of patients had a retreatment time longer than 64.6 and 118.7 days respectively. A frequency increase of up to approximately 5% of known application site reactions, such as pain and burning sensation, was reported in patients retreated with Qutenza earlier than 90 days.

A prospective, non-interventional study on the tolerability and analgesic effectiveness of capsaicin patch in German centres (**QUEPP**)[9] recruited 1063 non-diabetic adult patients with PNP. Of these there was safety and effectiveness data for 1,044 patients over 12 weeks. The most frequently reported diagnoses were post herpetic neuralgia (32%), post-surgical neuralgia (23%, post-traumatic neuropathy (12%), polyneuropathy (14%) and mixed pain syndromes (17%) with a mean NPRS score at baseline of 6.3. The mean number of patches applied at the first visit was 1.4. The 30% responder rate for the period day 7-14 to week 12 was 41% (n=446).

A meta-analysis of the Qutenza Clinical Trials Database (2013)[10] combined individual patient data from randomized, controlled studies of Qutenza in peripheral neuropathic pain (1458 subjects treated with approved doses of Qutenza or control patches; 1120 with PHN and 338 with HIV-AN). These 7 studies had similar designs and were performed with the high-dose 8% capsaicin Qutenza patch and a 0.04% low-dose control patch. The difference between treatment groups for the primary efficacy end point of percentage change from baseline to weeks 2 to 12 on pain intensity score was calculated. Response was defined as a ⩾30% decrease in mean pain intensity score during weeks 2 to 12. The overall between-group difference in percentage change from baseline in pain intensity was 8.0% (95% confidence interval 4.6, 11.5; $P < .001$), which statistically significantly favoured Qutenza over low-dose control. Qutenza superiority was demonstrated for both PHN and HIV-AN patients for the primary end point and the end point proportion of 30% pain reduction response, and for PHN patients for the end point of proportion of 50% pain reduction response. These results confirm that Qutenza is effective for the treatment of both PHN and HIV-AN compared to low-dose control patch.

ASCEND[11] was an open-label, non-interventional study of patients with non-diabetes-related PNP who received capsaicin 8% patch treatment, according to usual clinical practice, and were followed for ≤52 weeks. Co-primary endpoints were percentage change in the mean numeric pain rating scale (NPRS) 'average daily pain' score from baseline to the average of Weeks 2 and 8 following first treatment; and median time from first to second treatment. The primary analysis was intended to assess analgesic equivalence between post-herpetic neuralgia (PHN) and other PNP aetiologies. Health-related quality of life (HRQoL, using EQ-5D), Patient Global Impression of Change (PGIC) and tolerability were also assessed. Following first application, patients experienced a 26.6% (95% CI: 23.6, 29.62; n = 412) reduction in mean NPRS score from baseline to Weeks 2 and 8. Equivalence was demonstrated between PHN and the neuropathic back pain, post-operative and post-traumatic neuropathic pain and 'other' PNP aetiology subgroups. The median time from first to second treatment was 191 days (95% CI: 147, 235; n = 181). Forty-four percent of all patients were responders (≥30% reduction in NPRS score from baseline to Weeks 2 and 8) following first treatment, and 86.9% (n = 159/183) remained so at Week 12. A sustained pain response was observed until Week 52, with a 37.0% (95% CI: 31.3, 42.7; n = 176) reduction in mean NPRS score from baseline. Patients with the shortest duration of pain (0-0.72 years) experienced the highest pain response from baseline to Weeks 2 and 8. Mean EQ-5D index score improved by 0.199 utils (responders: 0.292 utils) from baseline to Week 2 and was maintained until Week 52. Most patients reported improvements in PGIC at Week 2 and at all follow-up assessments regardless of number of treatments received. Adverse events were

primarily mild or moderate reversible application site reactions. The study concluded that the capsaicin 8% patch provided effective and sustained pain relief, substantially improved HRQoL, improved overall health status and was generally well tolerated in a heterogeneous PNP population.

There is also a Randomized, Double-Blind, Placebo-Controlled Study Capsaicin 8% Patch in Painful Diabetic Peripheral Neuropathy study[12]: This 12-week study evaluated the efficacy and safety of capsaicin 8% patch versus placebo patch in painful diabetic peripheral neuropathy (PDPN). Patients aged 18 years or older with PDPN were randomized (1:1) to one 30-minute treatment (capsaicin 8% patch or placebo patch) to painful areas of the feet. Overall, 369 patients were randomized (capsaicin 8% patch, n = 186; placebo patch, n = 183). Percentage reduction in average daily pain score from baseline to between weeks 2 through 8 (the primary end point) was statistically significant for capsaicin 8% patch versus placebo (−27.4% vs −20.9%; *P* = .025); improvements in pain were observed from week 2 onward. Versus placebo, patients treated with capsaicin 8% patch had a shorter median time to treatment response (19 vs 72 days) and modest improvements in sleep interference scores from baseline to between weeks 2 through 8 (*P* = .030) and weeks 2 through 12 (*P* = .020). Apart from application site reactions, treatment-emergent adverse events were similar between groups. No indications of deterioration in sensory perception of sharp, cold, warm, or vibration stimuli were observed. In patients with PDPN, capsaicin 8% patch treatment provided modest pain relief and sleep quality improvements versus a placebo patch, similar in magnitude to other treatments with known efficacy, but without systemic side effects or sensory deterioration.

Summary of safety data:

Safety data from the ELEVATE study have not been published and are taken from the clinical study report. In the ELEVATE study, the proportion of patients with any treatment-emergent adverse event (TEAE) was higher for capsaicin patch than pregabalin (74% versus 64%). Adverse events (reported by ≥5%) that were more frequent in the capsaicin patch compared with pregabalin included application site pain (24% versus 0%), erythema (21% versus 0.4%), burning sensation (16% versus 0.4%) and application site erythema (8.9% versus 0%). However, the proportion of patients without drug-related TEAEs was similar for both treatment groups (capsaicin patch 38.7% vs. pregabalin 45.5%). Adverse events that were reported less frequently with capsaicin patch compared with pregabalin included dizziness (2.5% versus 20%), somnolence (0.7% versus 16%), headache (14% versus 18%) and nausea (5% versus 13%). Adverse events reported for capsaicin patch in the ELEVATE study were consistent with the summary of product characteristics for capsaicin patch.

In the QUEPP study, adverse events considered related to capsaicin patch by the investigator were reported in 10% of patients (n=106), of which the most frequent were pain or erythema at the application site.

The SPC lists the most commonly reported adverse reactions as transient local application site burning, pain, erythema and pruritus.

All adverse reactions, listed in the SPC which occurred at an incidence greater than control and in more than one patient in controlled clinical trials in patients with postherpetic neuralgia (PHN), painful Human Immunodeficiency Virus – Associated Neuropathy (HIV-AN) and painful diabetic peripheral neuropathy, are listed by system organ class and frequency: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100) and not known (cannot be estimated from the available data) are as follows:

System organ class and frequency	**Adverse reaction**
Infections and infestations	

Uncommon	Herpes zoster
Nervous system disorders	
Common	Burning sensation
Uncommon	Dysgeusia, hypoaesthesia
Eye disorders	
Uncommon	Eye irritation
Cardiac disorders	
Uncommon	First degree atrio-ventricular (AV) block, tachycardia, palpitations
Vascular disorders	
Common	Hypertension
Respiratory, thoracic and mediastinal disorders	
Common	Cough
Uncommon	Throat irritation
Gastrointestinal disorders	
Common	Nausea
Skin and subcutaneous tissue disorders	
Common	Pruritus
Musculoskeletal and connective tissue disorders	
Common	Pain in extremity, muscle spasms
General disorders and administration site conditions	
Very common	Application site pain, application site erythema
Common	Application site pruritus, application site papules, application site vesicles, application site oedema, application site swelling, application site dryness, peripheral oedema
Uncommon	Application site urticaria, application site paraesthesia, application site dermatitis, application site hyperaesthesia, application site inflammation, application site reaction, application site irritation, application site bruising
Investigations	
Common	Increased blood pressure
Injury, poisoning and procedural complications	
Not known	Application site burns (including second-and third-degree burns), accidental exposure (including eye pain, eye and throat irritation and cough)

Strengths and limitations of the evidence:

Strengths

- Non-inferiority of capsaicin versus pregabalin was demonstrated **(ELEVATE).**
- Relatively large number of patients across all the trials
- Meta analysis demonstrated that Qutenza is effective for the treatment of both PHN and HIV-AN compared to low-dose control patch
- Consistent and reproducible efficacy and tolerability was demonstrated with repeated treatments during a 52-week period in two clinical trials (**STRIDE and PACE**)
- **ASCEND** was a 52 week study which demonstrated effective and sustained pain relief, substantially improved HRQoL, improved overall health status and was generally well tolerated in a heterogeneous PNP population.

Limitations

- The ELEVATE, ASCEND, STRIDE and PACE studies were open-label,
- The ELEVATE study was of a short duration (8 weeks), so longer term efficacy is uncertain and time to retreatment was not determined. In the supportive ASCEND study, the median time to retreatment was 179 days.
- The patient population in the ELEVATE study is broader than that suggested by the licence (i.e. patients who have not achieved adequate pain relief from or have not tolerated conventional first- and second-line treatments). Patients with HIV were excluded. Therefore the comparative efficacy of capsaicin versus pregabalin in patients with HIV associated neuropathy is not known. The ELEVATE study included patients with PHN (22% in the capsaicin group and 26% in the pregabalin group).
- The comparator in the ELEVATE study was pregabalin and the patients needed to be naive to treatment with pregabalin or gabapentin or have had an inadequate trial of either of these medicines. However, it would be thought that pregabalin would be used earlier in the treatment pathway than capsaicin patch in clinical practice. There are no comparative data of capsaicin patch with any other systemic or topical treatments for PNP.

Summary of evidence on cost effectiveness:

The Scottish Medicines Consortium (SMC) carried out an economic analysis of Qutenza®.[1]

The utilities resulted from the data collected from ELEVATE study. Patients on capsaicin cutaneous patches achieved a faster increase in quality of life from a quicker onset of action and had an additional utility gain on response compared to a responder on pregabalin. Medicines costs, follow up costs, resource use costs, and the treatment of intolerable adverse events costs, were included. Capsaicin cutaneous patches were assumed to be administered in an outpatient setting by a nurse and 1.38 patches assumed per patient with retreatment after 179 days. The base case results show that capsaicin cutaneous patches dominated pregabalin based on incremental savings of £11 and a quality adjusted life year (QALY) gain of 0.049.

This QALY gain was mainly derived from the time of onset differences, the small utility advantage associated with a response on capsaicin cutaneous patches and from the intolerable adverse event (AE) differences between both interventions. One-way and two-way sensitivity analysis, threshold analysis, scenario analysis, and probabilistic sensitivity analysis (PSA) were undertaken. The analyses showed that the major driver was the time to capsaicin retreatment and this raised the incremental cost effectiveness ratio (ICER) to £7,951 if reduced from 179 days to 117 days. Scenario analysis which removed differences in terms of time to response, discontinuations and utility gain on response showed the treatment was still dominant (zero utility gain but a saving of £36).

If 1.51 patches were assumed to be used, the ICER changed from dominant to £1,188.

A number of uncertainties were identified as follows:

- The base case assumes that pregabalin patients would be treated in the secondary care setting. This may overestimate the pregabalin resource use costs given that pregabalin is also prescribed in primary care.
- There were some further concerns relating to the impact of assuming a reduction in pain relief over time with capsaicin and the submitting company provided some scenario analysis which took this into account, alongside changed assumptions to account for the potential use of pregabalin in primary care and capsaicin in secondary care settings. This produced a revised base case ICER of £4,297 per QALY. Increasing the number of patches to 1.51 increased this figure to £8,498, or £25,331 if it was assumed that the retreatment interval fell to 117 days. There was some further upward uncertainty in the ICERs if the use of topical anaesthesia was allowed for in the analysis; however, the submitting company indicated that this is no longer a requirement of the product licence.
- The New Drugs Committee debated the choice of comparator as current guidelines suggest that pregabalin may be used earlier in the treatment pathway therefore other comparators may be relevant.

Despite these weaknesses, the economic case was demonstrated.

Prescribing and risk management issues:

A minimum interval of 60 days between treatments is to be observed.

It is recommended to treat sufficiently long and to reassess effectiveness on a case-by-case basis after 3 treatments.

There are precautions to be taken before handling or administering the medicinal product ie Nitrile gloves should be worn at all times, use of a mask and protective glasses is recommended, particularly during application and removal of the patch.

Patients experiencing pain during and after patch application should be provided with supportive treatment.

Blood pressure should be monitored during the treatment procedure.

Used and unused patches and all other materials that have been in contact with the treated area should be disposed of immediately after use by sealing them in a polyethylene medical waste bag and placing in an appropriate medical waste container.

References

[1] SPC Qutenza 179mg cutaneous patch (Feb 2024) https://www.medicines.org.uk/emc/product/573
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[12] Simpson D.M. et al: Capsaicin 8% Patch in Painful Diabetic Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Study. The Journal of Pain, Volume 18, Issue 1, January 2017, Pages 42-53 https://www.sciencedirect.com/science/article/pii/S1526590016302449