BSW Qutenza® patch (capsaicin 8%) for peripheral neuropathic pain in non-diabetic patients commissioning statement: Low priority intervention

Policy Statement

BSW clinical advisory group have determined that capsaicin patches may be used as a 4th line agent for peripheral neuropathic pain in non-diabetic patients only after conventional oral and topical therapies as described by NICE CG173 have proven unsuccessful. Qutenza® should only be prescribed by a pain specialist and applied in a specialist pain clinic by suitably trained staff. This policy will be reviewed with audit data from the local pain services using this treatment in February 2021.

There are considerations for the pain service in terms of clinic time and staff resources required for administration of the patch, monitoring the patient after application and management of application site reactions. This drug is not a Payment by Results drug exclusion and so all drug costs will be borne by Secondary Care. Commissioners should ensure that commissioned pathways reflect this and although a low priority for funding, there is a group of patients for whom this treatment might be appropriate.

Patient groups that qualify for treatment with Qutenza®:

1. Patients with localised neuropathic pain which is not controlled by medications on the maximum tolerated dose as per NICE CG173.
2. Patients who have developed tolerance to anti-neuropathic medications
3. Patients who are unable to fulfil work responsibilities due to side-effects of oral treatment options (e.g. heavy vehicle driver/machinery operator)

- The license for Qutenza® patches stipulates that up to 4 patches can be used per application, however this is unlikely to be cost-effective (see p3), hence the maximum number of patches that is commissioned to use is two per application.
- A baseline Numeric Pain Rating Scale (NPRS) score must be recorded at the start of treatment.

Commissioned review criteria:

Every patient who receives a trial of Qutenza® (Capsaicin 8%) will be reviewed within 4-6 months:

1) If patients get at least >30% relief in their Numeric Pain Rating Scale (NPRS) score from baseline, the specialist should:
    a. Review and wean down/stop other pain medications
    b. Review the pain relief and continue with Qutenza patches applied not more frequently than every 4 months (not 90 days as per the license, due to questionable cost-effectiveness)
    c. The number of administrations shall not exceed three applications.
2) If patients get <30% pain relief in their Numeric Pain Rating Scale (NPRS) score from baseline, the specialist should:
    a. Review all the medication and STOP using Qutenza patches

NOTES:

- *The European Medicines Agency (EMA) considers patients who experience a 30-50% reduction in the assessment scale from baseline as responders.*
- *Qutenza patches are an in-tariff drug so commissioners fund the activity costs but do not reimburse drug costs.*

Prescribing information and monitoring: (RED Traffic-light status on BSW formulary)

Indication: Capsaicin is indicated for the treatment of peripheral neuropathic pain in adults either alone or in combination with other medicinal products for pain.
Pharmacological action: Capsaicin is a highly selective transient receptor potential vanilloid 1 (TRPV1) receptor agonist.
Presentation: Cutaneous patch 14cm x 20 cm (280cm2) which contains a total of 179mg of capsaicin or 640 micrograms of capsaicin per cm2 of patch (8% w/w).
Dose: After pre-treatment with topical anaesthetic or oral analgesic, up to two patches (not four as per SPC) to be applied to intact non irritated dry skin and allowed to remain in place for 30 minutes for feet (e.g. in HIV associated neuropathy) and 60 minutes for other areas (e.g. in post-herpetic neuralgia). Treatment can be repeated after 120 days if necessary. It is important to ensure that precautions are taken by healthcare professionals before handling or administrating capsaicin. Precautions are needed on applying the patches and in ensuring that the skin is intact – specific instructions are provided in the SPC.

Cost comparison (for general comparison only – therapeutic equivalence is not implied);
28 days' supply for oral treatments (Drug Tariff Oct 19):

- Capsaicin 179 mg patch £210
- Axsain® (capsaicin 0.075%) cream 45g, £14.58
- Amitriptyline 75 mg daily £2.61
- Duloxetine 60 mg daily £2.34
- Carbamazepine 200 mg three times daily £3.83
- Gabapentin 600 mg three times daily £6.72
- Pregabalin 600 mg daily £5.34

Efficacy

A Cochrane review from 2017 suggests that good pain relief (moderate or substantial benefit for 2 to 12 weeks) is achieved by about 10% more people with Qutenza patches than control, after a single application[1]. However, these results should be interpreted with caution as the quality of the evidence was moderate or very low. High-concentration topical capsaicin is similar in its effects to other therapies for chronic pain.

Drug/class	NNT	95% confidence interval
Tricyclic antidepressants	3.6	3 to 4.4
SNRIs	6.4	5.2 to 8.4
Pregabalin	7.7	6.5 to 9.4
Gabapentin*	7.2	5.9 to 9.1
Tramadol	4.7	3.6 to 6.7
Strong opioids	4.3	3.4 to 5.8
Capsaicin 8% patch	10.6	7.4 to 19
Botulinum toxin type A	1.85	1.5 to 2.4

Table 1: Outcomes from systematic review of neuropathic pain treatments[2]

The clinical evidence derives from a phase IV open-label, randomised, multi-centre, non-inferiority study (ELEVATE)[3] comparing the efficacy and tolerability of capsaicin cutaneous patch with pregabalin in adult patients with PNP. The capsaicin 8% patch was non-inferior to pregabalin in achievement of a ≥30% mean decrease in NPRS score from baseline to Week 8. 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[4], the median time to retreatment (2nd application) was 191 days.

Cost-effectiveness

Qutenza patches were approved for use in Scotland by the Scottish Medicines Consortium (SMC)[5] after a re-submission in September 2014 and for use in Wales by the All Wales Medicines Strategy Group in March 2012[6].

A lot of the published cost-effectiveness studies were published a few years ago and used utility costs for administration that do not reflect real-world situations. Pregabalin is now available generically and costs 5p per 100mg capsule now whereas costs used a few years ago were at the Lyrica brand price (SMC used £64 per 28 days at BD dosage or £97 per 28 days for the TDS regimen). Now that the cost gap between qutenza patches and the main comparator from the clinical trials, pregabalin, is far greater, the cost-effectiveness of Qutenza is likely to be reduced.

The SMC report that the major driver in the cost-effectiveness calculations was the time to capsaicin retreatment (if the interval fell from 179 days to 117 days the Incremental Cost Effectiveness Ratio (ICER) tripled) and also the number of patches used also had an impact on the ICER. All Wales reported[6] that if patches were applied every 109 days, the ICER exceeded the NHS threshold of £30,000 cost per Quality Adjusted Life Year (QALY).

Hence if patients need several patches per treatment and receive the treatments very frequently (e.g. every 90 days), it is very unlikely to be cost-effective at today's costs.

Adverse effects

The patch is associated with a range of unpleasant but generally transient side-effects, including pain on application that may require strong analgesia to control it, and a need for blood pressure monitoring. In-hospital specialist supervision is required for safe use and this is best achieved in specialist pain clinics that have set up a service to apply Qutenza® patches.

AUDIT requirements: Local pain services providing Qutenza patches are required to undertake data collection in the next year to submit to commissioners for policy review purposes in February 2021.

Further information:

Electronic Medicines Compendium: https://www.medicines.org.uk/emc/product/573

References:

1.) Capsaicin applied to the skin for chronic neuropathic pain in adults. Cochrane review January 2017. https://www.cochrane.org/CD007393/SYMPT_capsaicin-applied-skin-chronic-neuropathic-pain-adults

2.) Finnerup NB, Attal N, Harotounian S et al. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet neurol 2015; 14:162-73

3.) Haanpää M, Cruccu G, Nurmikko TJ, et al. Capsaicin 8% patch versus oral pregabalin in patients with peripheral neuropathic pain. *Eur J Pain*. 2016;20(2):316–328. doi:10.1002/ejp.731

4.) Effectiveness of the capsaicin 8% patch in the management of peripheral neuropathic pain in European clinical practice: the ASCEND study. Colette Mankowski et al. BMC Neurol. 2017; 17: 80. Published online 2017 Apr 21. doi: 10.1186/s12883-017-0836-z https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5399813/

5.) Scottish Medicines Consortium Qutenza (capsaicin) advice Sept 2014 https://www.scottishmedicines.org.uk/medicines-advice/capsaicin-qutenza-resubmission-67311/

6.) All Wales Medicines Strategy Group Ref no. 823. March 2012. Capsaicin (Qutenza®) 179 mg cutaneous patch http://www.awmsg.org/awmsgonline/app/appraisalinfo/823