



**Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)**

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

Application for change in traffic light colour classification

GREEN - Non-specialist drugs Primary care prescribers may take full responsibility for initiation and continuation of prescribing. Local prescribing guidelines or NICE guidance may apply.		
BLUE - Specialist Input WITHOUT Formal Shared Care Agreement Prescribing initiated and stabilised by a specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement. Please note that in some circumstances a specialist may recommend that prescribing can be started in primary care.		
AMBER - Specialist Initiation WITH Shared Care Guidelines Prescribing initiated and stabilised by a specialist but has the potential to transfer to primary care under a formal shared care agreement.		
RED - Specialist ONLY drugs Treatment initiated and continued by specialist clinicians.		
Non-formulary Not recommended for use in any health setting across the Surrey Heartlands health economy.		
Medicine details		
Name, brand name	Capsaicin (Qutenza)	
Manufacturer	Grunenthal Ltd http://www.grunenthal.co.uk	
Licensed indication	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	
Formulation	Cutaneous patch	
Usual dosage	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). Treatments may be repeated every 90 days, Re-treatment after less than 90 days can be considered for individual patients only after a careful assessment by the physician (see also section 5.1). A minimum interval of 60 days between treatments is to be observed.	
Traffic Light Status	Current Status	Proposed status
	Non-formulary	Red

Reason for requested change
<p>1. Specialist assessment to enable patient selection, initiation and continuation of treatment</p> <p>2. Long term specialist monitoring of efficacy and not suitable for shared care.</p> <p>3. A RED traffic light status would enable long-term, on-going specialist monitoring of toxicity</p> <p>4. Current usage by RSH, ASPH by specialist pains teams under non-formulary status.</p> <p>5. Cutaneous patch has not been prescribed in primary care in last 6 months (Apr 2024).</p> <p>6. RED status in other local ICBs only available via specialist pain teams: SWL, Frimley and Sussex</p> <p>7. No other similar product currently available on formulary.</p> <p>Please note that Capsaicin Cream, which is not considered within this application, it has a GREEN traffic light status on the PAD. It is currently unavailable and has been removed from the Drug Tariff. The shortage is expected to last until June 2026.</p>
Key Considerations
Cost implications to the local health economy
<p>Cost of product: £210.00 per patch (BNF and Drug Tariff June 2024). 14 cm x 20 cm (280 cm²) patch can be cut to size or multiple patches can be applied on various areas (maximum of 4 on patient).</p> <p>Annual cost per patient: 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 (i.e. 4 patches per treatment) = £40,320</p> <p>Please note; secondary care is subject to paying VAT on medicines, and there is no hospital contracted discount pricing.</p> <p>Availability of PAS and details (if appropriate): <i>No</i></p> <p>Availability of homecare service (if appropriate): <i>not applicable</i></p>
Impact to current prescriber or medication initiator
<p>Consideration at APC would allow addition to PAD and hospital formularies, to allow prescribing without using onerous non-formulary processes.</p>
Impact to proposed prescriber or medication initiator
<p>See above. Prescribing and supply is expected to continue in secondary care only.</p>
Impact to patients
<p>Patient may require multiple hospital /specialist appointments.</p> <p>Application requires a physician or healthcare professional, as they should determine the painful area and mark the skin prior to application. Re-treatment may be done every 60-90 days following a careful assessment, meaning the patient will have to revisit the hospital.</p>
Additional comments :

Commented [GR1]: Gillian, do these costs include VAT? I assume that DT costs don't, so 20% is required to be added to these costs??

Commented [GR2]: Might need to explain this statement

- Trusts will need to add capsaicin patches formally to their respective formulary systems, product will be added to PAD and Joint Formulary with the APC agreed traffic light status.
- Product is to be used within licensed indication and patient cohort only, so no additional patient information leaflet or clinician advice is required.
- Primary care prescribers should ensure that patient medication records include any medicine for which prescribing remains the responsibility of secondary or tertiary care. This will ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.
- A pathway for prescribing and referral processes for neuropathic pain might need to be developed (or adopted if one is available on CKS etc).

Identified lead for development of necessary documents e.g., shared care agreement

Name
Designation:
Organisation
Estimated date of preparation:

Equality Impact Assessment:

Protected characteristics Protected Characteristics - Information	Describe any considerations or concerns for each group.	Describe suggested mitigations to reduce inequalities.
Age	Non-adults will be affected by this decision (although product is not licensed for this age group).	Consideration of access to this product should be considered by Trusts on an off-label/one-off basis as per their internal processes
Disability	Individual patients may require carers to place and remove patches	Social/healthcare provision via carers may be required
Gender reassignment	None identified	
Marriage and civil partnership	None identified	
Pregnancy & maternity	Limited data is available for patients wishing to conceive or for during pregnancy.	Individual risk assessments will have to be made at time of prescribing decision as per usual medical practice.
Race	None identified.	There is nothing in the SPC to suggest that clinical adjustments are required due to skin colour.
Religion and belief	None identified	
Sex	None identified	
Sexual orientation	None identified	
Impact on any other vulnerable groups?	None identified	

References:

1. Glunenthal Ltd, 2024. *Qutenza 179mg cutaneous patch*. Maidenhead: Available from: [Qutenza \(Capsaicin\) 179mg cutaneous patch – Summary of Product Characteristics \(SmPC\) – \(emc\) \(medicine.org.uk\)](#) [Accessed 17th June 2024]
2. Joint Formulary Committee. (2024). *British national formulary* from: <https://www.medicinescomplete.com/#/browse/bnf> [accessed June 17th, 2024].
3. NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings <https://www.nice.org.uk/guidance/cg173> [accessed 23rd May 2024].
4. South West London ICB formulary <https://swlimo.southwestlondon.icb.nhs.uk/wp-content/uploads/2021/06/2020-21-SWL-Interface-Prescribing-Policy-App-1-Hospital-Specialist-Only-Drug-List-v1-260320.xlsx> [accessed 23rd May 2024].
5. Frimley ICS Medicines Optimisation Board Joint Formulary <https://www.frimleyhealthformulary.nhs.uk/chaptersSubDetails.asp?FormularySectionID=10&SubSectionRef=10.03.02&SubSectionID=C100> [accessed 26th May 2024].
6. Sussex Partner Formulary. <https://www.sussexformulary.nhs.uk/> [accessed 26th May 2024].

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	Gillian Sekadde-Kaluba	Pharmacist	26/7/24	None
Supported by				
Reviewed by	Georgina Randall	Senior Pharmacy Technician	30/07/24	None

Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1			Draft	Out for consultation
			Final	Out for clinical comment