**LETTER OF MEDICAL NECESSITY**

**[To be completed by prescriber and printed on letterhead]**

[Date]

[Name of Health Insurance Company]

[Attn:]

[Address]

[City, State, Zip]

Re: Letter of Medical Necessity for QUTENZA (capsaicin) 8% Topical System

Patient: [Patient Name]

Group/policy Number: [Number]

Date(s) of service: [Dates]

Diagnosis: [Code & Description]

Dear [Insert contact name or department]:

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with QUTENZA (capsaicin) 8% Topical System.

The Centers for Medicare and Medicaid Services (CMS) has established a permanent Healthcare Common Procedure Coding System (HCPCS) code for QUTENZA® (capsaicin) 8% topical system, which was effective in 2015. The code for QUTENZA is J7336 and J7336 JW (Drug amount discarded/not administered to any patient). These codes should replace any previous J-Codes or miscellaneous codes that have been previously used, such as J7335, as they are no longer valid.

QUTENZA (capsaicin) 8% topical system has received approval for the treatment of the following two indications in adults:

* Neuropathic pain associated with Postherpetic Neuralgia (PHN)
* Neuropathic pain associated with Diabetic Peripheral Neuropathy (DPN) of the feet

QUTENZA (capsaicin) 8% topical system, non-opioid, non-systemic, non-steroidal medical benefit product that can be used with or without any adjunct procedure and treatment, is an agonist for the transient receptor potential vanilloid-1 receptor (TRPV1), which is an ion channel-receptor complex expressed on nociceptive nerve fibers in the skin. Topical administration of capsaicin causes an initial enhanced stimulation of the TRPV1-expressing cutaneous nociceptors that may be associated with painful sensations. This is followed by pain relief thought to be mediated by a reduction in TRPV1- expressing nociceptive nerve endings [see USPI section Clinical Pharmacology (12.2)]. Over the course of several months, there may be a gradual re-emergence of painful neuropathy thought to be due to TRPV1 nerve fiber reinnervation of the treated area.

* The recommended dose of QUTENZA for neuropathic pain associated with postherpetic neuralgia is a single, 60-minute application of up to four topical system.
* The recommended dose of QUTENZA for neuropathic pain associated with diabetic peripheral neuropathy of the feet is a single, 30-minute application on the feet of up to four topical system.

This letter serves to document that [PATIENT NAME] has a diagnosis of [DIAGNOSIS] and needs treatment with QUTENZA, and that QUTENZA is medically necessary for [him/her] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatment.

Patient Medical History and Diagnosis:

[PATIENT NAME] is a [AGE]-year-old [MALE/FEMALE] diagnosed with [DIAGNOSIS]. [NAME OF PATIENT] has been in my care since [DATE]. As a result of [DIAGNOSIS], my patient [ENTER BRIEF DESCRIPTION OF PATIENT HISTORY]. Additionally, [PATIENT] has tried [PREVIOUS THERAPIES] and [OUTCOMES]. The attached medical records document [PATIENT NAME]’s clinical condition and medical necessity for treatment with QUTENZA.

Based on the above facts, I am confident that you will agree that QUTENZA is indicated and medically necessary for this patient. The plan of treatment is to start the patient on QUTENZA and monitor and follow up as appropriate.

Please consider coverage of QUTENZA on [PATIENT NAME]’s behalf and approve use and subsequent payment for QUTENZA as planned. Please refer to the enclosed Prescribing Information for QUTENZA. If you have any further questions regarding this matter, please do not hesitate to call me at [PHYSICIAN TELEPHONE NUMBER]. Thank you for your prompt attention to this matter.

Sincerely,

[PHYSICIAN NAME]

[PROVIDER IDENTIFICATION NUMBER]

Enclosures: (Attach as appropriate)

*Prescribing Information (PI)* <https://www.qutenza.com/pdfs/Qutenza_Prescribing_Information.pdf>

*Clinic notes & labs*

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