<u>Place of Service</u> Office Administration Outpatient Facility Infusion Administration Infusion Center Administration

HCPCS: J7336 per 1 cm² (1 patch is 280 billable units)

Condition listed in policy (see criteria for details)

- Diabetic peripheral neuropathy
- Postherpetic neuralgia

AHFS therapeutic class: External Analgesic

Mechanism of action: Topical administration of capsaicin causes an initial enhanced stimulation of cutaneous nociceptors that may be associated with painful sensations. This is followed by pain relief thought to be mediated by a reduction in nociceptive nerve endings.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s) All requests for Qutenza[®] (capsaicin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Diabetic peripheral neuropathy (DPN)

- 1. Either of the following:
 - a. *Effective through 4/29/2023*: Inadequate response, intolerable side effect(s), or contraindication to a self-administered product (e.g., lidocaine patch, capsaicin cream) used for DPN, **OR**
 - b. *Effective 4/30/2023 and after*. Inadequate response, intolerable side effect(s), or contraindication to a self-administered topical preparation (e.g., capsaicin cream) used for DPN

AND

2. If patient is less than 65 years old: Inadequate response, intolerable side effect(s) or contraindication to at least two oral drugs (e.g., tricyclic antidepressants, SNRIs, anticonvulsants) used to treat DPN

Covered Doses

Up to 4 patches per treatment session, and not more frequently than every 3 months

Coverage Period

Cover for 3 months, initially.

Reauthorization yearly, based upon continued response to treatment.

ICD-10: E11.21

Postherpetic neuralgia (PHN)

- 1. Inadequate response, intolerable side effect(s), or contraindication to self-administered topical patch (e.g lidocaine patch) used for PHN, **AND**
- 2. If patient is less than 65 years old: Inadequate response, intolerable side effect(s) or contraindication to at least two oral drugs (e.g. tricyclic antidepressants and anticonvulsants) used to treat PHN

Covered Doses

Up to 4 patches per treatment session, and not more frequently than every 3 months

Coverage Period

Cover for 3 months, initially.

Reauthorization yearly, based upon continued response to treatment.

ICD-10: B02.21-B02.24, B02.29

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice

All requests for Qutenza[®] (capsaicin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

PHP Medi-Cal

Capsaicin (Qutenza®)

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety</u> <u>Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed</u> <u>indication.</u>

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

Qutenza patch contains 8% capsaicin (640 mcg/cm²) 280 cm². Each patch contains a total of 179 mg of capsaicin.

1 patch = 280 units

Administration of Qutenza:

- Only physicians or health care professionals under the close supervision of a physician are to administer Qutenza
- Use only nitrile (not latex) gloves when handling Qutenza and when cleaning treatment areas.
- Burning and erythema reported in majority of patients treated with Qutenza.

Consensus guideline-recognized (AAN¹) oral alternatives for DPN:

- SNRI: duloxetine, venlafaxine, desvenlafaxine
- Gabapentinoid: gabapentin, pregabalin
- Sodium channel antagonist/blocker: oxcarbazepine, lamotrigine, lacosamide, valproic acid
- Tricyclic antidepressant: amitriptyline
- Topical: capsaicin

Consensus guideline-recognized (AAN^{2,} EFNS³, AAFP⁴) oral and topical alternatives for PHN:

- Tricyclic antidepressants: amitriptyline, nortriptyline, desipramine
- Anticonvulsants: gabapentin, pregabalin
- Opioids (oxycodone or morphine sulfate, controlled release)
- Topical: lidocaine patch

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex[®]. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- Qutenza[®] (capsaicin) [Prescribing information]. Morristown, NJ: Averitas Pharma, Inc., 8/2022.
- Price R, Smith D, Franklin G, et al. Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline Update Summary – Report of the AAN Guideline Subcommittee. Neurology 2022; 98:31-43.
- 2. Dubinsky RM, Kabbani H, El-Chami C, et al. Practice Parameter: Treatment of postherpetic neuralgia: An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2004;63;959-965.
- 3. Attal N, Cruccu C, Baron R, et al. EFNS guidelines on pharmacological treatment of neuropathic pain: 2010 revision. European Journal of Neurology 2010, 17: 1113–1123.
- 4. Saguil A, Kane S, Mercado M, et al. Herpes Zoster and Postherpetic Neuralgia: Prevention and Management. Am Fam Physician 2017; 96:656-663.

(7) Policy Update

Date of last review: 1Q2023 Date of next review: 1Q2024 Changes from previous policy version:

PHP Medi-Cal

Effective: 03/01/2023

• Section (2): Diabetic peripheral neuropathy - Clarified prerequisite therapy to include topical capsaicin. Effective 4/29/2023, will remove lidocaine patch as a qualifying prerequisite therapy *Rationale: 2021 American Academy of Neurology (AAN) guideline for treatment of Painful diabetic neuropathy*

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

PHP Medi-Cal

Effective: 03/01/2023

Capsaicin (Qutenza®)