

Qutenza® (capsaicin 8%) (Topical Patch)

Document Number: IC-0221

Last Review Date: 08/04/2020

Date of Origin: 09/30/2014

Dates Reviewed: 09/2014, 07/2015, 07/2016, 01/2017, 01/2018, 01/2019, 01/2020, 08/2020

I. Length of Authorization

Coverage will be provided for three months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 4 patches every 90 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1120 billable units (4 patches) every 90 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has a documented baseline Numerical Pain Rating Scale (NPRS) score; **AND**

Management of neuropathic pain associated with postherpetic neuralgia (PHN) † ⊕ ^{1,2}

- Patient has postherpetic neuralgia that has persisted for at least 6 months following healing of herpes zoster rash (i.e., crusting of the skin vesicles); **AND**
- Painful areas to be treated are not located on the face, above the hairline of the scalp, and/or in proximity to mucous membranes; **AND**
- Patient had an inadequate response (or contraindication) to ALL of the following:
 - Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine, etc.)
 - A gabapentinoid (e.g., pregabalin or gabapentin)

Treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet † ^{1,3}

- Patient has painful, distal, symmetrical, sensorimotor polyneuropathy due to diabetes that has persisted for at least 1 year prior to screening; **AND**
- All other causes of pain in the feet have been ruled out; **AND**
- Patient had an inadequate response (or contraindication) to ALL of the following:
 - An antidepressant (e.g., duloxetine, venlafaxine, amitriptyline, nortriptyline, maprotiline, desipramine, etc.)
 - A gabapentinoid (e.g., pregabalin or gabapentin)

† FDA Approved Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria ¹

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe application site pain and burning, hypertension, decrease in sensory function, etc.; **AND**
- Patient has experienced an improvement in pain based on the Numerical Pain Rating Scale (NPRS) compared to baseline

V. Dosage/Administration

Indication	Dose
Postherpetic neuralgia	Health care professional administration: apply Qutenza for 60 minutes (up to four patches) to the most painful skin areas and repeat every 3 months or as warranted by the return of pain (no more frequently than every 3 months). Do not use on broken skin.
Diabetic peripheral neuropathy of the feet	Health care professional administration: apply Qutenza for 30 minutes (up to four patches) to the feet and repeat every 3 months or as warranted by the return of pain (no more frequently than every 3 months). Do not use on broken skin and assess feet prior to application to detect skin lesions related to underlying neuropathy or vascular insufficiency.

VI. Billing Code/Availability Information

HCPCS Code:

- J7336 - Capsaicin 8% patch, per square centimeter: 1 billable unit = 1 cm²

NDC:

- Qutenza 8% kit (1 patch and 50 g tube of cleansing gel): 72512-0928-xx
- Qutenza 8% kit (2 patches and 50 g tube of cleansing gel): 72512-0929-xx

VII. References

1. QUTENZA® [package insert]. Ardsley, NY; Acorda Therapeutics, Inc.; July 2020. Accessed July 2020.
2. Backonja M, Wallace MS, Blonsky ER, et al. NGX-4010, a high-concentration capsaicin patch, for the treatment of postherpetic neuralgia: a randomised, double-blind study. *Lancet Neurol* 2008; 7: 1106–12.
3. Simpson DM, Robinson-Papp J, Van J, et al. Capsaicin 8% Patch in Painful Diabetic Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Study. *J Pain*. 2017;18(1):42-53. doi:10.1016/j.jpain.2016.09.008.
4. Ortega E (2019). Postherpetic neuralgia. In Shefner JM, Goddeau RP (Eds.), *UpToDate*. Available from <https://www.uptodate.com/contents/postherpetic-neuralgia#H7>.
5. Feldman EL (2020). Management of diabetic neuropathy. In Shefner JM, Nathan DM, Goddeau (Eds.), *UpToDate*. Available from <https://www.uptodate.com/contents/management-of-diabetic-neuropathy#H1815763146>.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
B02.22	Postherpetic trigeminal neuralgia
B02.23	Postherpetic polyneuropathy
B02.29	Other postherpetic nervous system involvement
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC