Medical Policy:

Qutenza® (capsaicin 8% patch)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.162	February 24, 2025	

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Qutenza is a TRPV1 channel agonist indicated for the management of neuropathic pain associated with postherpetic neuralgia (PHN). The capsaicin in Qutenza (capsaicin) 8% patch is a synthetic equivalent of the naturally occurring compound found in chili peppers. Capsaicin 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. 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.

Length of Authorization

Coverage will be provided for 3 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 4 patches (1120 billable units) every 90 days

Guideline

I. INITIAL APPROVAL CRITERIA

Qutenza *may be considered medically necessary if the below conditions are met*:

1. **Management of neuropathic pain associated with postherpetic neuralgia (PHN)**
   A. Patient is 18 years of age or older; **AND**
   B. Patient has postherpetic neuralgia that has persisted for at least 6 months following healing of herpes zoster rash; **AND**
   C. Documented baseline Numerical Pain Rating Scale (NPRS); **AND**
   D. 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**
   E. Patient had an inadequate response (or contraindication) to **ALL** of the following:
      i. Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine)
      ii. A gabapentinoid (e.g., pregabalin or gabapentin)
      iii. Lidocaine 5% patch

2. **Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet**
   A. Patient is 18 years of age or older; **AND**
   B. Documented baseline Numerical Pain Rating Scale (NPRS); **AND**
   C. Patient has painful, distal, symmetrical, sensorimotor polyneuropathy due to diabetes that has persisted for at least 1 year prior to screening; **AND**
   D. All other causes of pain in the feet have been ruled out; **AND**
   E. Patient had an inadequate response (or contraindication) to **ALL** of the following:
      i. Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine)
      ii. A gabapentinoid (e.g., pregabalin or gabapentin)
      iii. Lidocaine 5% patch

II. RENEWAL CRITERIA

Authorizations can be renewed based on the following criteria:

1. Patient continues to meet criteria identified under INITIAL APPROVAL CRITERIA; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe application site reactions, hypertension;-**AND**
3. Disease response with treatment as defined by improvement in pain based on the Numerical Pain Rating Scale (NPRS) compared to baseline

Dosage/Administration

Indication	Dose
Postherpetic Neuralgia	Health care professional administration: Single, 60-minute application of up to four patches. May be repeated every three months or as warranted by the return of pain (not more frequently than every three months)
Diabetic Peripheral Neuropathy	Health care professional administration: single, 30-minute application on the feet of up to four patches. May be repeated every three months or as warranted by the return of pain (not more frequently than every three months)

Applicable Procedure Codes

Code	Description
J7336	Capsaicin 8% patch, per square centimeter: 1 billable unit = 1 cm^2

Applicable NDCs

Code	Description
72512-0929-01	Qutenza 8% kit
72512-0928-01	Qutenza 8% kit
72512-0930-01	Qutenza 8% kit
72512-0920-00	Qutenza 8%

ICD-10 Diagnoses

Code	Description
B02.22	Postherpetic trigeminal neuralgia
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
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy
E11.40	Type 2 diabetes mellitus with diabetic neuropathy
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	02/24/2025	Annual Review: Initial Criteria: Management of neuropathic pain associated with postherpetic neuralgia (PHN) : Added: "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" Under: Patient had an inadequate response (or contraindication) to ALL of the following: Reworded the following: removed gabapentin and pregabalin to combine to:" A gabapentinoid (e.g., pregabalin or gabapentin)" Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet: Added: "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 Under: Patient had an inadequate response (or contraindication) to ALL of the following: Reworded the following: removed gabapentin and pregabalin to combine to:" A gabapentinoid (e.g., pregabalin or gabapentin)" Renewal Criteria: Removed: "Patient has experienced an improvement in pain of at least 30% from baseline Numerical Pain Rating Scale (NPRS)" replaced with: "Disease response with treatment as defined by improvement in pain based on the Numerical Pain Rating Scale (NPRS) compared to baseline" Added: 72512-0920-00, Removed: B02.23 and E13.41, added: E09.42
EmblemHealth & ConnectiCare	1/12/2024	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	5/15/2023	Annual Review: added codes E0.8.40, E08.42, E10.40, E11.42, E13.40, E13.41and E13.42.
EmblemHealth & ConnectiCare	10/13/2022	Transferred policy to new template

<table>
<tr>
<td>EmblemHealth & ConnectiCare</td>
<td>7/28/2020</td>
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1. Added new FDA indication of Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
2. Added following criteria:

Patient is 18 years of age or older; AND
Documented baseline Numerical Pain Rating Scale (NPRS); AND
Patient had an inadequate response (or contraindication) to ALL four of the following:

Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine)
Gabapentin
Pregabalin
Lidocaine 5% patch

2. Added the following to Dosage/Administration chart:
<table>
<tr><td>Diabetic Peripheral Neuropathy</td><td>Health care professional administration: single, 30-minute application on the feet of up to four patches. May be repeated every three months or as warranted by the return of pain (not more frequently than every three months)</td></tr>
</table>
3. Added the following ICD- 10 codes:
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<tr><td>E11.40</td><td>Type 2 diabetes mellitus with diabetic neuropathy</td></tr>
<tr><td>E10.42</td><td>Type 1 diabetes mellitus with diabetic polyneuropathy</td></tr>
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References

1. QUTENZA® [package insert]. Ardsley, NY; Acorda Therapeutics, Inc.; July 2013. Accessed March 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.