Original Effective Date: 07/01/2013
Current Effective Date: 06/23/2023
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C2809-A

Qutenza (capsaicin)

PRODUCTS AFFECTED

Qutenza (capsaicin)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Post-herpetic neuralgia, Diabetic peripheral neuropathy

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. POSTHERPETIC NEURALGIA (PHN):
1. Documented diagnosis of postherpetic neuralgia (PHN) that has persisted for at least 6 months following healing of herpes zoster rash
AND

2. Documentation of baseline Numerical Pain Rating Scale (NPRS)
   AND
3. Documentation member has experienced an inadequate treatment response, but was able to tolerate the side effect(s) to OTC topical capsaicin
   AND
4. Documentation member has experienced an inadequate treatment response, serious side effect(s) or contraindication to at least ONE drug from ALL classes of therapies indicated for the treatment of PHN: Gabapentin at maximally tolerated doses, generic tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine), pregabalin, and Lidoderm patches (lidocaine 5% transdermal patches)
   AND
5. Prescriber attests Qutenza will be administered/applied by a physician or healthcare professional

B. DIABETIC PERIPHERAL NEUROPATHY:

1. Documented diagnosis of diabetic peripheral neuropathy (DPN) of the feet
   AND
2. Documentation of baseline Numerical Pain Rating Scale (NPRS)
   AND
3. Documentation member has experienced an inadequate treatment response, but was able to tolerate the side effect(s) to OTC topical capsaicin
   AND
4. Documentation member has experienced an inadequate treatment response, serious side effect(s) or contraindication to at least ONE drug from ALL classes of therapies indicated for the treatment of DPN: Gabapentin at maximally tolerated doses, generic tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine), pregabalin, and Lidoderm patches (lidocaine 5% transdermal patches)
   AND
5. Prescriber attests Qutenza will be administered/applied by a physician or healthcare professional

CONTINUATION OF THERAPY:

A. POSTHERPETIC NEURALGIA AND DIABETIC PERIPHERAL NEUROPATHY OF THE FEET:

1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., severe application site reactions, hypertension)
   AND
2. Documentation member has experienced an improvement in pain of at least 30% from baseline Numerical Pain Rating Scale (NPRS)
   AND
3. Prescriber attests Qutenza will be administered/applied by a physician or healthcare professional

DURATION OF APPROVAL:

Initial authorization: 90 days, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified pain specialist (anesthesiologist, neurologist, physical medicine and rehabilitation physician) [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Maximum 4 patches every 90 days

PLACE OF ADMINISTRATION:

Drug and Biologic Coverage Criteria

The recommendation is that external medications in this policy will be for pharmacy or medical benefit coverage and the topical products administered in a place of service that is a non-hospital facility-based location. Only physicians or health care professionals are to administer.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Topical

DRUG CLASS:
Local Anesthetics – Topical

FDA-APPROVED USES:
Indicated for the treatment of neuropathic pain associated with post-herpetic neuralgia (PHN) and neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Qutenza™ (capsaicin) is the only prescription capsaicin product currently available and it is FDA- approved for the management of neuropathic pain associated with postherpetic neuralgia (PHN). Qutenza™ works by targeting certain pain nerves in the area of skin where pain is being experienced. It selectively binds to a transient receptor potential vanilloid 1 (TRPV1), a protein that resides on the membranes of pain and heat sensing neurons.

The capsaicin in Qutenza™ is a synthetic equivalent of the naturally occurring compound found in chili peppers. There are a variety of over the counter (OTC) topical capsaicin products available in lower strengths (0.025% up to 0.25%). These OTC formulations are used in the treatment of pain associated with arthritis and musculoskeletal conditions. Qutenza™ is available as an 8% topical patch. It must be used under the supervision of a healthcare professional, and the recommended dose is one 60- minute application of up to 4 patches which may be repeated no sooner than every 3 months. Qutenza™ represents another option in the treatment of PHN.

Pain relief occurs during the first week after the application and may last up to 3 months or more. Immediately after the application, the patient is sensitive to heat and should avoid hot showers, sun, and extreme exercise. 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 Commonly utilized agents in the treatment of PHN include analgesics, anesthetics, anticonvulsants, antivirals, corticosteroids, and tricyclic antidepressants. Lyrica® (pregabalin), Lidoderm® (lidocaine) and gabapentin are FDA-approved for the treatment of PHN. Qutenza™ was approved based on the results of two 12- week, double-blind, randomized, dose-controlled multicenter studies. Qutenza™ 8% was more effective than the capsaicin 0.04% comparator in both studies. There are currently no clinical trials directly comparing Qutenza™ to gabapentin, Lyrica® (pregabalin), or Lidoderm®.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Qutenza (capsaicin) are considered experimental/investigational and therefore, will

follow Molina's Off-Label policy. Contraindications to Qutenza (capsaicin) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:
Only physicians or health care professionals are to administer. Administer QUTENZA in a well-ventilated treatment area. Wear nitrile (not latex) gloves when handling QUTENZA and when cleaning treatment areas. Use of a face mask and protective glasses is advisable for healthcare professionals. Do not use QUTENZA on broken skin.

Special training is necessary for the application of Capsaicin (Qutenza®) including use of special gloves and disposal to avoid accidental contact. The area of pain is marked and anesthetized prior to application of the dermal patch. The patch is applied to the area identified that is painful for one hour. Pain and heat are experienced during the application and may require cold compresses and pain medication. The patient's BP should be monitored during the application since this substance tends to increase BP.

Patients may experience substantial procedural pain and burning upon application of QUTENZA and following removal of QUTENZA. Prepare to treat acute pain during and following the application procedure with local cooling (such as an ice pack) and/or appropriate analgesic medication.

Reductions in sensory function, which were generally minor and temporary, have been reported following administration of QUTENZA. All patients with sensory deficits should be assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory loss occurs, treatment should be reconsidered.

Capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin to the healthcare professional, patients, and others.
- Do not use near eyes or mucous membranes.
- Wear nitrile gloves and avoid touching items or surfaces that the patient may later touch.
- If irritation of eyes or airway occurs, flush the mucous membranes or eyes with water and provide supportive medical care for shortness of breath. Remove the affected individual (healthcare professional or patient) from the vicinity of QUTENZA. Do not re-expose the affected individual to QUTENZA if respiratory irritation worsens or does not resolve.
- If skin not intended to be treated comes into contact with QUTENZA, apply Cleansing Gel and then wipe off with dry gauze.
- Thoroughly clean all areas and items exposed to QUTENZA and dispose of properly.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J7336	Capsaicin 8% patch, per square centimeter

AVAILABLE DOSAGE FORMS:
Qutenza KIT 8%, Qutenza (2 Patch) KIT 8%, Qutenza (4 Patch) KIT 8%

REFERENCES

1. Qutenza Patch (capsaicin 8%) [prescribing information]. Morristown, NJ: Averitas Pharma, Inc; February 2023.
2. Backonja M, Wallace MS, Blonsky ER, et al. NGX-4010, a high-concentration capsaicin patch, for the treatment of postherpetic neuralgia: a 52andomized, double-blind study. Lancet Neurol 2008; 7: 1106–12.
3. R. M. Dubinsky, H. Kabbani, Z. El-Chami, C. Boutwell, H. Ali, Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2004 September 28;63(6) 959-965.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy	Q2 2024
REVISION- Notable revisions: Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations HCPCS Code and Description References	Q2 2023
REVISION- Notable revisions: Place of Administration Other Special Considerations References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file