Qutenza (capsaicin)
Policy Number: C2809-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
7/1/2013	3/1/2019	3/1/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J7335	RxPA	Q2

PRODUCTS AFFECTED:
Qutenza KIT 8% Qutenza (2 Patch) KIT 8%

DRUG CLASS:
Local Anesthetics - Topical

ROUTE OF ADMINISTRATION:
External

PLACE OF SERVICE:
Specialty Pharmacy

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

FDA-APPROVED USES: indicated for management of pain associated with post-herpetic neuralgia.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: post-herpetic neuralgia.

REQUIRED MEDICAL INFORMATION:

A. POSTHERPETIC NEURALGIA(PNH):
   1. Documented diagnosis of PNH that has persisted for at least 6 months following healing of herpes zoster rash
      AND
   2. Documented 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, intolerable 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 (TCA), Lyrica(pregabalin) and Lidoderm patches (lidocaine 5% transdermal patches)

DURATION OF APPROVAL: Initial authorization: 90 days, Continuation of therapy: 12 months

QUANTITY: 4 patches every 90 days

PRESCRIBER REQUIREMENTS: Prescribed by a board-certified pain specialist (anesthesiologist, neurologist, physical medicine and rehabilitation physicians) or in consultation with a board-certified pain specialist

AGE RESTRICTIONS: 18 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. POSTHERPETIC NEURALGIA(PNH):
   1. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe application site reactions, hypertension
      AND
   2. Patient has experienced an improvement in pain of at least 30% from baseline Numerical Pain Rating Scale (NPRS)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Qutenza (capsaicin) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:
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

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®

APPENDIX: None

REFERENCES:

1. QUTENZA® [package insert]. Ardsley, NY; Acorda Therapeutics, Inc.; July 2013. Accessed November 2017.
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. 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.