# ARCHIVED 8/22/18

BlueCross BlueShield of Alabama

**Name of Blue Advantage Policy:**

## Qutenza® (capsaicin) 8% Patch

Policy #: 424
Category: Pharmacy

Latest Review Date: April 2010
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

## Background:

***Blue Advantage*** *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

**Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare*** *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## Description of Procedure or Service:

Qutenza® (capsaicin) 8% patch contains capsaicin in a localized dermal delivery system. The capsaicin in Qutenza 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 selectively 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 nociceptor nerve endings. Over the course of several months, there may be a gradual reemergence of painful neuropathy thought to be due to TRPV1 nerve fiber reinnervation of the treated area.

Qutenza® is indicated for the management of neuropathic pain associated with post-herpetic neuralgia.

Chickenpox is caused by an acute infection with varicella zoster virus (human herpes virus-3). After the acute phase, the virus remains dormant for many years in dorsal root nerve cells and cranial nerve ganglia. The virus may reactivate with advancing age or immunocompromised states and cause a painful skin eruption called shingles. The shingles rash heals in about two to four weeks, and the pain subsides. However, for 10% to 20% of shingles patients, the pain persists for months to years and is called post-herpetic neuralgia (PHN).

Qutenza is manufactured by Lohmann Therapie-Systems AG (LTS) of Andernach, Germany and distributed by Neuroges X, Inc of San Mateo, California.

## Policy:

**Effective for dates of service on or after November 17, 2009:**

**Blue Advantage** will treat **Qutenza®**, when used as the initial course of treatment, as a **covered** benefit for the treatment of neuropathic pain associated with post-herpetic neuralgia when the following conditions are met:

- It is administered by a physician or a healthcare professional under the close supervision of a physician.
- Before patch application, a physician must identify and mark the painful area, including areas of hypersensitivity and allodynia.
- Apply a topical anesthetic before patch application.
- Apply the patch to the most painful skin areas, using up to 4 patches.
- Apply the patch for 60 minutes and repeat every 3 months or as warranted by the return of pain (not more frequently than every 3 months).
- Treat acute pain during and following the procedure with local cooling and/or analgesics.
- Do not use the patch on broken skin.
- Do not use the patch near the eyes or mucous membranes.
- Monitor the blood pressure during and following the procedure.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## Key Points:

The efficacy of Qutenza was established in two, 12-week, double-blind, randomized, dose-controlled, multicenter studies. (N = 402 and N = 416). These studies enrolled patients with post-herpetic neuralgia (PHN) persisting for at least six months following healing of herpes zoster rash and a baseline score of 3 to 9 on an 11-point Numerical Pain Rating Scale (NPRS) ranging from 0 (no pain) to 10 (worst possible pain). Qutenza and a control patch were each applied as a single 60-minute application. The control used in these studies looked similar to Qutenza but contained a low concentration of the active ingredient, capsaicin, to retain binding regarding the known application site reactions of capsaicin, such as burning and erythema. The baseline mean pain scores were approximately six. Approximately half of patients were taking concomitant medications, including anticonvulsants, non SSRI antidepressants, or opioids.

The primary efficacy assessment for Qutenza was the percent change from baseline in average pain for the past 24 hours, measured at week eight using a NPRS. Other efficacy measures were the proportion of patients with ≥ 30% reduction in pain at weeks two through 12 and the proportion of patients achieving various percentage reductions in pain intensity at week 12.

In both trials, the group receiving Qutenza showed a greater reduction in pain compared to the control group at week wight (-18% vs. -29% ± 2% in PHN Study 1; -26% vs. -33% ± 2% in PHN Study 2). In these trials, 44% and 47% of patients, respectively, had an average reduction in pain of ≥ 30% at weeks two through 12.

In clinical trials, more than 1,600 patients received Qutenza. The most common adverse effects were site reactions from local application (e.g., redness, pain, itching, papules), which were mild or moderate. Serious adverse reactions included application site pain and increased blood pressure.

Patients with unstable or poorly controlled hypertension or a recent history of cardiovascular or cerebrovascular events may be at increased risk of adverse effects. Patients may experience substantial procedural pain. The pain should be treated with local cooling (such as a cold pack) and/or appropriate analgesic medications, such as opioids.

## Key Words:

Capsaicin, post-herpetic neuralgia (PHN), Qutenza®

## Approved by Governing Bodies:

In November 2009, Qutenza® was FDA approved for the management of neuropathic pain associated with PHN.

## Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

## Current Coding:

CPT Codes:

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|---|---|
| **64999** | Unlisted procedure, nervous system |

HCPCS:

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|---|---|
| **J7335** | Capsaicin 8% patch, per 10 square centimeters **(Effective January 1, 2011)** |

## Previous Coding:

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| **J3490** | Unlisted **(This code deleted January 1, 2011)** |
| **C9268** | Capsaicin patch, $10cm^2$ **(Effective July 1, 2010 - deleted January 1, 2011.)** |

## References:

1. Qutenza® (capsaicin) 8% patch, http://www.Qutenza.com.

## Policy History:

Medical Policy Group, April 2010
Available for comment May 7-June 21, 2010
Medical Policy Group, December 2010
Medical Policy Group, September 2012: **Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.**

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