

**Policy: MBP 269.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Qutenza (capsaicin topical system)**

**Applicable line of business:**

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

**I. Policy:**

Qutenza (capsaicin topical system)

**II. Purpose/Objective:**

To provide a policy of coverage regarding Qutenza (capsaicin topical system).

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

**Commercial**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicare**

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

**CHIP**

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**DESCRIPTION:** 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.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

Qutenza (capsaicin topical system) will be considered medically necessary for commercial, exchange, and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of postherpetic neuralgia OR diabetic peripheral neuropathy **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on pregabalin **AND**
- For diabetic peripheral neuropathy: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: gabapentin, tricyclic antidepressant (amitriptyline, nortriptyline, desipramine), duloxetine, venlafaxine, valproate sodium, capsaicin cream **OR**
- For postherpetic neuralgia: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: gabapentin, tricyclic antidepressant (amitriptyline, nortriptyline, desipramine), capsaicin cream, lidocaine patch

**AUTHORIZATION DURATION:** Initial approval will be given for a duration of 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**QUANTITY LIMIT:** 4 patches every 90 days (Facets RX count: 1120 units (J7336) per 90 days)

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Qutenza (capsaicin topical system) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of postherpetic neuralgia OR diabetic peripheral neuropathy **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AUTHORIZATION DURATION:** Initial approval will be given for a duration of 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**QUANTITY LIMIT:** 4 patches every 90 days (Facets RX count: 1120 units (J7336) per 90 days)

**LINE OF BUSINESS:**

**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

**REFERENCES:**

1. Qutenza [prescribing information]. Morristown, NJ: Averitas Pharma Inc; March 2023.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 9/20/22

**Revised:** 9/12/23 (Medicaid business segment), 12/28/23 (references added), 8/30/24 (LOB table, taglines)

**Reviewed:**

**MA UM Committee approval:** 12/31/23