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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Topical Products	**Original Policy Date:**	June 26, 2020
Subject:	Qutenza	**Page:**	1 of 4

Last Review Date: September 8, 2023

Qutenza

Description

Qutenza (capsaicin) patch

Background
Qutenza (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 (1).

Regulatory Status
FDA-approved indication: Qutenza is indicated for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet (1).

Qutenza should not be dispensed to patients for self-administration or handling. Only physicians or health care professionals under the close supervision of a physician are to administer and handle Qutenza (1).

The recommended dose of Qutenza is a single application of up to four patches. Treatment with Qutenza may be repeated every three months or as warranted by the return of pain (not more frequently than every three months) (1).

The safety and effectiveness of Qutenza in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

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

Qutenza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Neuropathic pain associated with postherpetic neuralgia (PHN)
2. Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet

AND the following:

1. Inadequate treatment response, intolerance, or contraindication to **ALL** of the following:
   a. A topical lidocaine product
   b. Another topical capsaicin product

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Neuropathic pain associated with postherpetic neuralgia (PHN)
2. Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet

AND the following:

1. Patient has not been treated with Qutenza patches in the past 90 days

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 patches every 90 days

Duration 3 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Qutenza (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. The safety and effectiveness of Qutenza in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Qutenza while maintaining optimal therapeutic outcomes.

References

1. Qutenza patch [package insert]. Morristown, NJ: Averitas Pharma, Inc.; February 2023.

Policy History

Date	Action
June 2020	Addition to PA
August 2020	Addition of indication: neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
September 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.