

Product Overview



QUTENZA is indicated for the management of neuropathic pain associated with postherpetic neuralgia (PHN). A single, 1-hour, localized treatment may provide up to 3 months of relief from pain associated with postherpetic neuralgia (PHN). QUTENZA is the first and only prescription-strength capsaicin product targeted to the nerves in the skin.

QUTENZA	NDC #72512-928-01	NDC #72512-929-01
Packaging:	Kit (carton) contains one (1) single-use patch and one (1) 50 g tube of Cleansing Gel	Kit (carton) contains two (2) single-use patches and one (1) 50 g tube of Cleansing Gel
Strength:	179 mg per patch, 8% capsaicin	179 mg per patch, 8% capsaicin
Ordering Information:	QUTENZA is available through select specialty distributors. For more information about these distributors, call 1-877-900-6479 and select option 3.	
Reimbursement Questions and Support:	Health insurance coverage of QUTENZA may vary from plan to plan. For more information about reimbursement support, call 1-877-900-6479 and select option 3.	
Storage Guidelines:	Store between 20° and 25°C (68° and 77°F). Excursions between 15° and 30°C (59° and 86°F) are allowed. Keep the patch in the sealed pouch until immediately before use.	

IMPORTANT SAFETY INFORMATION:

Only physicians or healthcare professionals under the close supervision of a physician are to administer QUTENZA. In clinical trials, serious adverse reactions included application associated pain and increase in blood pressure. The most common adverse reactions (≥ 5% and greater than control) were application-site erythema, application-site pain, application-site pruritus, or application-site papules, and nausea.

Please see additional Important Safety Information on last page.

Coding and Billing Guide



Diagnosis Codes

These codes are provided for educational purposes only. It is the healthcare provider’s responsibility to use the diagnosis code(s) that accurately and fully reflect the patient’s condition. Use of these codes is not a guarantee of reimbursement. The manufacturer does not recommend use of QUTENZA in a manner inconsistent with its label. Physicians must consult the QUTENZA full Prescribing Information, including the limitations applicable to approved use of QUTENZA.

Postherpetic Neuralgia (PHN)	
ICD-10-CM	Descriptor
B02.23	Postherpetic polyneuropathy
B02.29	Other postherpetic nervous system involvement

QUTENZA has only been approved by the FDA for the management of neuropathic pain associated with postherpetic neuralgia (PHN).

IMPORTANT SAFETY INFORMATION:
Do not apply QUTENZA to the face or scalp to avoid risk of exposure to the eyes or mucous membranes.

Please see additional Important Safety Information on last page.

Contact the patient’s health plan or **QUTENZA Reimbursement Support** at 1-877-900-6479 (option 3) if you have questions about billing or coding.

For more information or assistance, call **QUTENZA Reimbursement Support:** 1-877-900-6479, option 3, Monday–Friday, 8AM–7PM ET.

The information presented on this page is of a general nature and for informational purposes only. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the ultimate responsibility of the provider. The information provided in the Fact Sheet is not a guarantee of coverage or reimbursement.

ICD-10-CM: International Classification of Diseases, Tenth Edition, Clinical Modification.

Coding and billing change effective January 1, 2015

Product Codes

Physician Office Information	
QUTENZA	
HCPCS II	Descriptor
J7336	Capsaicin 8% patch, 1 cm ²
J7336JW	Drug amount discarded/not administered to any patient

Hospital Information	
QUTENZA	
HCPCS II	Descriptor
J7336	Capsaicin 8% patch, 1 cm ²
J7336JW	Drug amount discarded/not administered to any patient

One QUTENZA patch constitutes 280 cm². As of January 1, 2015, one billing unit of QUTENZA indicates usage of 1 cm² of a QUTENZA patch. One QUTENZA patch is equivalent to 280 billing units. The provider should submit claims accurately reflecting the amount of QUTENZA used to treat a patient.

Some Medicare administrative contractors require that providers submit claims that reflect both the actual amount of QUTENZA administered to a patient as well as the amount that was discarded (if any). Other administrative contractors permit, but do not require, that claims reflect the amount that was discarded. When indicating the amount of QUTENZA discarded, the JW modifier should be used on a separate line on the claim form. The patient's medical record should accurately and concisely reflect the amount administered and the amount discarded, along with the date, time, and reason for discarding a portion of a patch.

For further information, providers may contact the administrative contractor retained by the Medicare program for the region in which the provider is located. Contact information is available on the Centers for Medicare and Medicaid Services website.

Procedure Codes

QUTENZA requires administration by a physician or healthcare professional under the close supervision of a physician. The list of codes below is not comprehensive. Reimbursement for services associated with the administration of QUTENZA may require the submission of an unlisted procedure code or an Evaluation and Management (E&M) code, if appropriate. The provider shall select the code(s) that accurately and fully reflect the patient's treatment and shall appropriately document the patient's treatment in the patient's medical records, and shall not select codes in a manner only to ensure and/or maximize coverage and reimbursement. The provider shall rely on his/her own authoritative coding sources and medical judgment, and shall not rely on this Fact Sheet. Contact the patient's health plan for plan-specific coverage limitations and coding policies.

Ultimate responsibility for submission of the appropriate billing code lies with the provider, and the provider therefore must always exercise independent judgment concerning the selection of appropriate codes.

Physician Office Information	
CPT Code	Descriptor
99201–99205*	Office or other outpatient visit, new patient
99211–99215*	Office or other outpatient visit, established patient

Hospital Information	
CPT Code	Descriptor
99201–99205*	Office or other outpatient visit, new patient
99211–99215*	Office or other outpatient visit, established patient

*Other E&M codes may apply or may be more appropriate for a given visit.

Note: Some health plans may require the use of code 64999 (unlisted procedure, nervous system) instead of E&M codes.

Indication:

QUTENZA® (capsaicin) 8% Patch is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

IMPORTANT SAFETY INFORMATION:

Only physicians or healthcare professionals under the close supervision of a physician are to administer QUTENZA.

Contraindications:

None

Warnings and Precautions:

- Do not apply QUTENZA to the face or scalp to avoid risk of exposure to the eyes or mucous membranes.
- Aerosolization of capsaicin can occur and inhalation may result in coughing or sneezing.
- If skin not intended to be treated comes into contact with QUTENZA, clean area using Cleansing Gel.
- Patients may experience substantial procedural pain. Prepare to treat pain with local cooling (such as a cold pack) and/or appropriate analgesic medication.
- Transient increases in blood pressure may occur during and shortly after the QUTENZA treatment. Blood pressure changes were associated with treatment-related increases in pain. Monitor blood pressure and provide adequate support for treatment-related pain. Patients with unstable or poorly controlled hypertension or a recent history of cardiovascular or cerebrovascular events may be at an increased risk of adverse cardiovascular effects. Consider these factors prior to initiating QUTENZA treatment.
- If opioids are used to treat pain associated with the application procedure, please note that opioid treatment may affect the patient's ability to perform potentially hazardous activities such as driving or operating heavy machinery.

Adverse Reactions:

In clinical trials, serious adverse reactions included application associated pain and increase in blood pressure. The most common adverse reactions ($\geq 5\%$ and greater than control) were application-site erythema, application-site pain, application-site pruritus, or application-site papules, and nausea.

To report an adverse event, you can visit www.fda.gov/medwatch or call 1-800-FDA-1088; or you can call Averitas Pharma, Inc. at 1-877-900-6479.

Please see full Prescribing Information.

www.QUTENZA.com 1-877-900-6479



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