

Qutenza[®]
(capsaicin) 8% topical system

MyQutenzaCoverage Reimbursement Guide



MyQutenzaCoverage is available
throughout the reimbursement process

Not Actual Patients

Visit: MyQutenzaCoverage.com
Call: 855-802-8746
Fax: 855-454-8746

**AveritasPharma**[™]

Introduction

Averitas Pharma has developed this resource to support healthcare professionals (HCPs) navigate coverage, coding, and reimbursement for QUTENZA (capsaicin) 8% topical system.

Understanding coverage, coding, and reimbursement is critical for ensuring patient access and successful claims adjudication.

The information in this Reimbursement Guide is intended solely as a resource to assist the staff in physicians' offices and hospitals with certain reimbursement-related questions for QUTENZA. Averitas Pharma makes no representation about the information provided, as reimbursement information, including applicable policies and laws, are subject to change without notice for QUTENZA. This Reimbursement Guide is not conclusive or exhaustive and is not intended to replace the guidance of a qualified, professional advisor. The appropriate staff member of a physician's office or hospital, not Averitas Pharma, determines the appropriate method of seeking reimbursement based on the medical procedure performed and any other relevant information. Averitas Pharma does not recommend or endorse the use of any particular diagnosis or procedure code(s), and makes no determination regarding if or how reimbursement may be available. The use of this information does not guarantee payment or that any payment received will equal a certain amount.

Information about Healthcare Common Procedure Coding System (HCPCS) codes is based on guidance issued by the Centers for Medicare & Medicaid Services (CMS) applicable to Medicare Part B and may not apply to other public or private payers. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of a particular code and for information on additional codes. Please refer to payer policies for specific guidance.

MyQutenzaCoverage Reimbursement Guide




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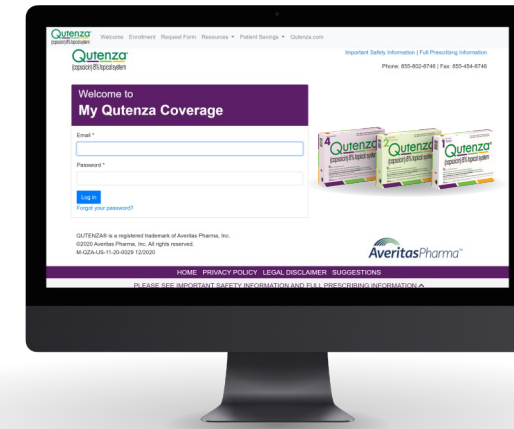
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Product Information

QUTENZA® (capsaicin) 8% topical system is indicated in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and for neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

A single, in-office procedure, may provide up to 3 months of relief from neuropathic pain associated with PHN or from neuropathic pain associated with DPN of the feet. QUTENZA is the first and only prescription-strength capsaicin product targeted to the TRPV1-expressing nociceptive nerve fibers in the skin.

Qutenza	NDC #72512-928-01 (10-digit format)	NDC #72512-929-01 (10-digit format)	NDC #72512-930-01 (10-digit format)												
Packaging	Kit (carton) contains one (1) single-use topical system and one (1) 50 g tube of Cleansing Gel	Kit (carton) contains two (2) single-use topical systems and one (1) 50 g tube of Cleansing Gel	Kit (carton) contains four (4) topical systems and three (3) 50 g tubes of Cleansing Gel												
															
Strength	Contains 8% capsaicin (640 mcg per cm ²). Each QUTENZA topical system contains a total of 179 mg of capsaicin.														
Ordering information	QUTENZA is available through select specialty distributors or through specialty pharmacy ordering.														
	Specialty Distributors: <table border="0"> <tr> <td>ASD Healthcare®</td> <td>800-746-6273</td> <td>CuraScript SD®</td> <td>877-599-7748</td> </tr> <tr> <td>Besse® Medical</td> <td>800-543-2111</td> <td>McKesson Specialty Health</td> <td>855-477-9800</td> </tr> <tr> <td>Cardinal Health™</td> <td>877-453-3972</td> <td>McKesson Medical-Surgical</td> <td>855-571-2100</td> </tr> </table>			ASD Healthcare®	800-746-6273	CuraScript SD®	877-599-7748	Besse® Medical	800-543-2111	McKesson Specialty Health	855-477-9800	Cardinal Health™	877-453-3972	McKesson Medical-Surgical	855-571-2100
ASD Healthcare®	800-746-6273	CuraScript SD®	877-599-7748												
Besse® Medical	800-543-2111	McKesson Specialty Health	855-477-9800												
Cardinal Health™	877-453-3972	McKesson Medical-Surgical	855-571-2100												
	Specialty Pharmacy: MyQutenzaCoverage will recommend a specialty pharmacy partner														
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 topical system in the sealed pouch until immediately before use.														
Reimbursement questions and support	Health insurance coverage for QUTENZA may vary from plan to plan. For more information about reimbursement support, call MyQutenzaCoverage at 855-802-8746 or email Field Access Support at US-FieldAccessSupport@grunenthal.com .														



MyQutenzaCoverage is here to help support patient access.

MyQutenzaCoverage was created to offer healthcare professionals a suite of educational tools tailored to the different phases of the patient's treatment journey, including:

Patient Access

Obtain payer-specific requirements for reimbursement:

- Benefits investigation
- Prior authorization support
- Formulary information
- Cost savings program for commercially-insured patients

Billing and Coding

Provide resources and support for coding, reimbursement, and claims:

- Procedure Notes Template
- QUTENZA Topical System coding information (HCPCS/J-Codes and NDCs)
- Diagnosis codes (ICD-10-CM codes)
- Administration and services codes (CPT, E&M, and G-codes)

Product Information and Ordering

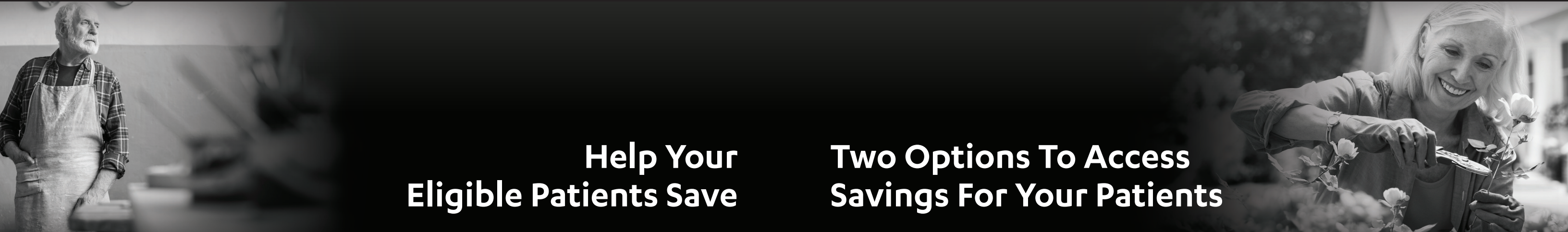
Product ordering guidelines and resources:

- Product codes and packaging
- Specialty distributor ordering availability
- Specialty pharmacy ordering information available through MyQutenzaCoverage

Ongoing Support

Resources to help once your patients are on treatment:

- Treatment reminders
- Ongoing tips and tools to help your patients through treatment



Help Your Eligible Patients Save

Two Options To Access Savings For Your Patients

Patient Cost Savings Program Overview

For your patients with painful diabetic peripheral neuropathy (DPN) of the feet or postherpetic neuralgia (PHN), help them get 3 months of relief and save on their QUTENZA treatments.

ELIGIBLE, COMMERCIALLY INSURED PATIENTS MAY

PAY AS LITTLE AS \$25*

FOR THEIR PRESCRIPTION

*Terms and conditions apply.

The program may apply towards copay, coinsurance, and deductible **for QUTENZA only†**

Patients may be eligible if they:

- Have commercial insurance
- Are 18 years of age or older
- Have a valid prescription for QUTENZA

Patients are not eligible if they:

- Have Medicare, Medicaid, TRICARE, or any other state or federal health insurance
- Pay for their prescription with cash
- Are uninsured
- Are insured, but QUTENZA is not covered

*See full Terms and Conditions at [QUTENZA.com/savings](https://www.QUTENZA.com/savings).

†The program does not cover procedural codes (ie, ICD-10, E&M, or CPT codes). The application to deductibles may vary across pharmacy and medical benefits.

Patient Cost Savings Program Enrollment

Option 1 Electronic claim submission

- Register your practice through the Patient Cost Savings Portal
- Complete account activation following practice verification
- Begin submitting claims

Option 2 Mail or fax claim submission

- Download and complete the enrollment form
- Bill using a standard HCFA 1500 CMS form
- Obtain patient's Explanation of Benefits
- Mail or fax completed forms

Get your patients on the road to relief with QUTENZA



Scan the code to access the Patient Cost Savings Portal or to download the pre-populated physician reimbursement form.

QUTENZA Topical System Coding Information

HCPCS code (J-code) (Box 24D)	J7336 J7336JW	QUTENZA (capsaicin) 8% topical system per square centimeter Drug amount discarded/not administered to any patient
NDC numbers, 11-digit format (Box 19)	FDA lists NDCs in a 10-digit format, but payers often require an 11-digit NDC format for electronic claim forms. Review payer-specific requirements prior to submitting a claim	
	72512-0928-01	(1 topical system and Cleansing Gel)
	72512-0929-01	(2 topical systems and Cleansing Gel)
	72512-0930-01	(4 topical systems and Cleansing Gel)
Additional claim information (Box 19)	QUTENZA (capsaicin) 8% topical system, 1 cm ²	
Number of units (Box 24G)	1 topical system = 280 cm ² units 2 topical systems = 560 cm ² units 3 topical systems = 840 cm ² units 4 topical systems = 1120 cm ² units	

Diagnosis Coding Information

ICD-10-CM codes Postherpetic Neuralgia (PHN) (Box 21)	The following primary diagnosis codes may be appropriate to describe patients with postherpetic neuralgia (PHN):
	B02.23 Postherpetic polyneuropathy B02.29 Other postherpetic nervous system involvement
ICD-10-CM codes Diabetic Peripheral Neuropathy (DPN) of the feet (Box 21)	The following primary diagnosis codes may be appropriate to describe patients with diabetic peripheral neuropathy (DPN) of the feet:
	E08.40 Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified E08.42 Diabetes mellitus due to underlying condition with diabetic polyneuropathy E09.42 Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy E10.40 Type 1 diabetes mellitus with diabetic neuropathy, unspecified E10.42 Type 1 diabetes mellitus with diabetic polyneuropathy E11.40 Type 2 diabetes mellitus with diabetic neuropathy, unspecified E11.42 Type 2 diabetes mellitus with diabetic polyneuropathy E13.40 Other specific diabetes mellitus with diabetic neuropathy, unspecified E13.42 Other specific diabetes mellitus with diabetic polyneuropathy

PLEASE NOTE

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 patient and/or procedure, is always the ultimate responsibility of the provider.

Administration and Professional Service Coding Information

These codes are provided for educational purposes only and do not guarantee payment. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a patient and/or procedure, is always the ultimate responsibility of the provider.

No existing CPT code is specific to the QUTENZA application. HCPCS coding requirements will vary by payer, setting of care, and date of service. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a patient and/or procedure, is always the ultimate responsibility of the provider. Consult with your local payer or Medicare Administrative Contractor (MAC) for appropriate coding coverage of QUTENZA treatment. Please note that payers may have additional requirements.

CPT codes	64620	Destruction by neurolytic agent, intercostal nerve
	64632	Destruction by neurolytic agent, plantar common digital nerve
	64640	Destruction by neurolytic agent; other peripheral nerve or branch
	64999	Unlisted procedure, nervous system
	96999	Unlisted special dermatological service or procedure

If the QUTENZA application is performed during an Evaluation and Management (E&M) service, it may be appropriate to report an E&M code if payer-specific report requirements have been met. If providing a separate E&M service at the same time as the application, it may be appropriate to report the E&M code with a modifier. A complete list of available codes and instructions governing their use can be found in the CPT code book. Please note that payers may have additional requirements.

E&M codes	99202	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15-29 minutes of total time is spent on the date of the encounter
	99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30-44 minutes of total time is spent on the date of the encounter
	99204	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45-59 minutes of total time is spent on the date of the encounter
	99205	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60-74 minutes of total time is spent on the date of the encounter
	99211	Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional
	99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter
	99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter
	99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter
	99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter

Claims Filing Checklist

A clean claim is defined as a claim free of errors. In order to facilitate prompt and accurate payment, it is important to ensure that the information on the claim is accurate and error-free. Consider the following:



Always verify the patient's insurance eligibility and coverage before treatment. Working with MyQutenzaCoverage will also provide support



Check payer policies for covered diagnoses and treatment frequency limits. Double check claims for simple/clerical errors



Check for codes that are billed but not supported by documentation, have incorrect dates of services, or have missing provider or patient data



Verify the codes entered on the claim form; a simple transposition error can delay processing or cause the claim to be processed incorrectly



Ensure each service is linked to the appropriate diagnosis code and the frequency (eg, units) is within appropriate limits



Most electronic claims processing software and/or clearinghouses have the capability to perform simple proofreading functions



Check with your payers to ensure you have the most up-to-date fee schedule

Considerations for Verifying Insurance Benefits

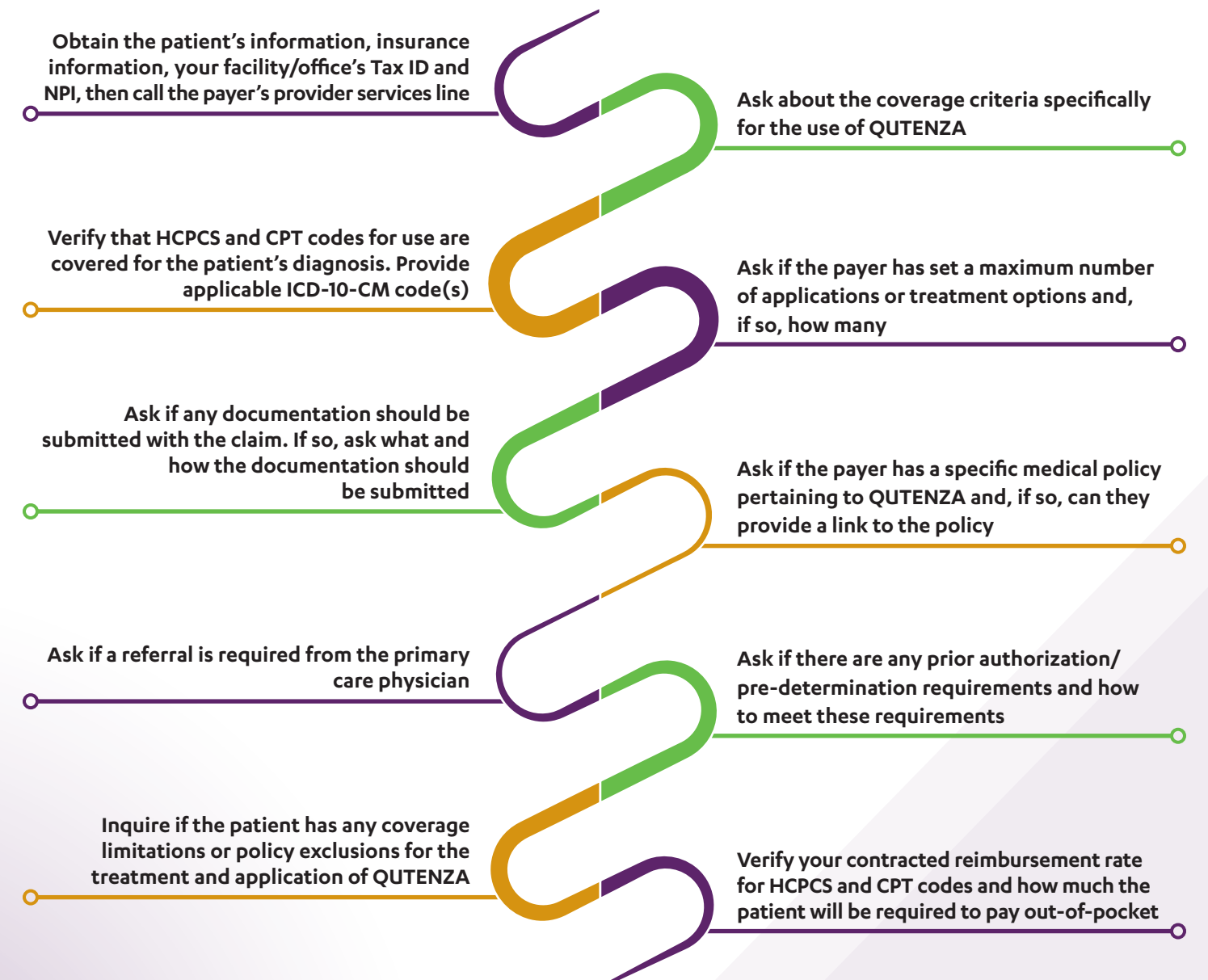
It is important to understand and verify patient insurance benefits prior to initiating treatment. Conducting a benefit verification can provide the HCP office with the following:

Payer coverage requirements

Coding and billing requirements

Patient cost-share considerations

Recommended Best Practices:



CMS-1500 Claim Form Sample

For reimbursement of QUTENZA administered by a physician's office, providers must submit a CMS-1500 claim form for the drug and associated services.

The use of QUTENZA is covered by specific codes and may be considered medically necessary depending on the payer:

- Diagnosis of postherpetic neuralgia (PHN) AND/OR neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
- A CPT code that indicates how the physician administered the drug in addition to coding specifics. Some payers may require additional information, such as documentation of medical necessity

Example 1: Bilateral applications

Box 21
Enter the appropriate ICD-10 diagnosis code (this should be reflected in the patient's medical record)

Box 19
Indicate drug name, NDC, strength, and route of administration (physician administered)

Box 23
Document prior authorization referral number from payer (if applicable)

Box 24D
Enter the appropriate HCPCS code for QUTENZA and CPT code(s) for administration services (add modifier if applicable)

Box 24G
Enter the number of billing units for the associated HCPCS and CPT codes

Example 2: Unilateral applications

	24. A. DATE(S) OF SERVICE		B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES		E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSONI Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
	From	To			CPT/HCPCS	MODIFIER						
1	MM	DD YY	MM	DD YY	11	J7336	RT		560			
2	MM	DD YY	MM	DD YY	11		CPT CODE		1			
3	MM	DD YY	MM	DD YY								
4	MM	DD YY	MM	DD YY								

CMS-1450 Hospital Outpatient Department Claim Form Sample

UB-04 is used for reimbursement administered in an outpatient institutional setting, such as an outpatient hospital, a clinic, or an ambulatory surgical center.

- Providers must submit a UB-04 claim form documenting the drug administered and associated services
- Coding specifics for the UB-04 claim form (based on payer specifications) should be used

Box 42
Medicare/Medicaid and most private payer claims must include revenue codes

Box 43
Description or NDC must be indicated

Box 44
Enter the HCPCS code for the outpatient service (add modifier, if applicable)

Box 46
Indicate the units of service used. Enter the number of units discarded (if applicable) on a separate line and include the JW modifier

Box 66
Enter the appropriate ICD-10 diagnosis code (this should be reflected in the patient's medical record)

Box 80
Indicate the name of the drug, NDC, and route of administration

Strategies for Appealing Denied Claims

In some cases, a denied claim can be resolved over the phone, but in other cases, an HCP may need to complete and submit an appeal letter in order to overturn a denied claim. Here are some strategies for working through this process:

What is the limit for timely filing an appeal?

Limits for timely filing vary by level of appeal and by payer. For example, the first level of appeal (redetermination) for Medicare requires appeal submission within 120 days of receipt of denial.



Tip

File the claim appeal as soon as possible and within timely filing limits.

What is the method for submission (eg, electronic, fax or mail)?

HCPs may submit written requests via mail, fax, or secure Internet portal/application depending on the payer.



Tip

Verify that faxing or submission through a portal/application is an option to submit an appeal, as the payer has discretion in what format they use.

How long does the appeal process usually take?

Decision times vary by level of appeal and payer.



Tip

Timelines for reprocessing the claim can be delayed due to incomplete requests.

How will the payer communicate the appeal decision to the HCP?

Payers generally will respond via the method used in the request, followed by a letter received by mail.



Tip

Timelines for actual payment after a favorable decision can vary by payer. Check with the payer so you know when to follow up if you do not receive payment.

Is there a particular form that must be completed?

Check with the payer to confirm if they have a specific form or guidelines for submitting an appeal.



Tip

Payers will often post template forms for download on their website. If you cannot locate the form online, contact the payer for additional guidance.

Common Denial Reasons

Understanding the reason for a denial will determine next steps for resolving the denial. Here are some common reasons a claim may be denied and actions one may take to overturn the denial.

Error: Technical

Incorrect patient ID, missing signatures:
Missing or incorrect code (eg, transposed numbers)

- Incorrect units

Required Action

- Call to correct
- Prepare and submit a corrected claim
- Contact Field Access Support for assistance

Error: Billing

Non-covered or non-allowed service:

- Service was unbundled
- Incorrect placement of service code
- Duplicate claim
- Invalid code
- Incorrect units

Required Action

- Prepare and submit a corrected claim
- Prepare and submit an appeal
- Contact Field Access Support for assistance

Error: Medical Necessity

The diagnosis code is not covered for the services performed:

- Medical record documentation does not support the services performed as medically necessary and in accordance with the respective medical policy in place

Required Action

- Prepare and submit an appeal
- Contact Field Access Support for assistance

Error: Payer Denial

Insurance payer doesn't pay for product

- Step Edit, Not on Formulary
- Investigative Product

Required Action

- Prepare and submit an appeal
- Contact Field Access Support for assistance

Sample Letter of Appeal

These sample letters are intended to provide an example of how to structure a letter of appeal and letter of medical necessity for QUTENZA. The HCP should modify the format of these letters as appropriate. (e.g, to reflect the patient's specific facts and circumstances, or to include specific information that may be required by individual payers).

LETTER OF APPEAL [To be completed by prescriber and printed on letterhead]

[Date]

[Name of Health Insurance Company]

[Attn:]

[Address]

[City, State, ZIP]

Re: Letter of Appeal for QUTENZA (capsaicin) 8% topical system

Patient: [Patient Name]

Group/Policy Number: [Number]

Date(s) of service: [Dates]

Diagnosis: [Code & Description]

Dear [Insert contact name or department]:

I am writing to request a review of a denied claim for **[PATIENT NAME]**. The claim was denied for the following reason(s), listed on the attached Explanation of Benefits (EOB).

[Fill in reason(s) from EOB.]

The Centers for Medicare and Medicaid Services (CMS) has established a permanent Healthcare Common Procedure Coding System (HCPCS) code for QUTENZA® (capsaicin) 8% topical system, which was effective in 2015. The code for QUTENZA is J7336 and J7336 JW (Drug amount discarded/not administered to any patient). These codes should replace any previous J-Codes or miscellaneous codes that have been previously used, such as J7335, as they are no longer valid.

QUTENZA (capsaicin) 8% topical system has received approval for the treatment of the following two indications in adults:

- Neuropathic pain associated with Postherpetic Neuralgia (PHN)
- Neuropathic pain associated with Diabetic Peripheral Neuropathy (DPN) of the feet

QUTENZA (capsaicin) 8% topical system, non-opioid, non-systemic, non-steroidal medical benefit product that can be used with or without any adjunct procedure and treatment, 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 [see USPI section Clinical Pharmacology (12.2)]. 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.

- The recommended dose of QUTENZA for neuropathic pain associated with postherpetic neuralgia is a single, 60-minute application of up to four topical system.
- The recommended dose of QUTENZA for neuropathic pain associated with diabetic peripheral neuropathy of the feet is a single, 30-minute application on the feet of up to four topical system.

This letter serves to document that **[PATIENT NAME]** has a diagnosis of **[DIAGNOSIS]** and needs treatment with QUTENZA, and that QUTENZA is necessary therapy for [him/her] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatment.

Download at MyQutenzaCoverage.com

Sample Letter of Medical Necessity

These sample letters are intended to provide an example of how to structure a letter of appeal and letter of medical necessity for QUTENZA. The HCP should modify the format of these letters as appropriate. (e.g, to reflect the patient's specific facts and circumstances, or to include specific information that may be required by individual payers).

LETTER OF MEDICAL NECESSITY [To be completed by prescriber and printed on letterhead]

[Date]

[Name of Health Insurance Company]

[Attn:]

[Address]

[City, State, Zip]

Re: Letter of Medical Necessity for QUTENZA (capsaicin) 8% Topical System

Patient: [Patient Name]

Group/policy Number: [Number]

Date(s) of service: [Dates]

Diagnosis: [Code & Description]

Dear [Insert contact name or department]:

I am writing on behalf of my patient, **[PATIENT NAME]**, to document medical necessity for treatment with QUTENZA (capsaicin) 8% Topical System.

The Centers for Medicare and Medicaid Services (CMS) has established a permanent Healthcare Common Procedure Coding System (HCPCS) code for QUTENZA® (capsaicin) 8% topical system, which was effective in 2015. The code for QUTENZA is J7336 and J7336 JW (Drug amount discarded/not administered to any patient). These codes should replace any previous J-Codes or miscellaneous codes that have been previously used, such as J7335, as they are no longer valid.

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This letter serves to document that **[PATIENT NAME]** has a diagnosis of **[DIAGNOSIS]** and needs treatment with QUTENZA, and that QUTENZA is medically necessary for [him/her] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatment.

Patient Medical History and Diagnosis:

[PATIENT NAME] is a **[AGE]**-year-old **[MALE/FEMALE]** diagnosed with **[DIAGNOSIS]**. **[NAME OF PATIENT]** has been in my care since **[DATE]**. As a result of **[DIAGNOSIS]**, my patient **[ENTER BRIEF DESCRIPTION OF PATIENT HISTORY]**. Additionally, **[PATIENT]** has tried **[PREVIOUS THERAPIES]** and **[OUTCOMES]**. The attached medical records document **[PATIENT NAME]**'s clinical condition and medical necessity for treatment with QUTENZA.

Download at MyQutenzaCoverage.com

Procedure Notes Template

This Procedure Note Template is intended to collect additional information about the patient's condition being treated with QUTENZA. This form can be completed by the HCP and submitted with the Letter of Medical Necessity to the payer. Documents are available at MyQutenzaCoverage.com.

Capsaicin 8% Topical System Procedure Notes

Last Name	First Name	Date	Chart #
Date of Next Office Visit	BP	Pulse	A1C
Height	Weight		

Patient History

1. Date of prior capsaicin 8% topical system treatment: 1st Date _____ 2nd Date _____ 3rd Date _____ 4th Date _____

2. Please identify the main area(s) of pain on the body: _____

Which Side? Left Right Bilateral

3. Please check the appropriate boxes below to identify the main area(s) of pain on the foot (feet):

Left Foot Right Foot

Anterior Posterior Plantar Proximal Dorsal Medial Lateral Distal

4. Check the words that best describe the quality of your pain? Aching Stabbing Nagging Burning Throbbing Gnawing Numb-like Tiring Shooting Penetrating Sharp Unbearable

Coding: (Coverage Reimbursement Guide provides a list of codes. It is the physician's responsibility to provide the correct codes.)

<input type="checkbox"/> B02.23 Postherpetic polyneuropathy	<input type="checkbox"/> B02.29 Other postherpetic nervous system involvement
<input type="checkbox"/> E08.40 Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified	<input type="checkbox"/> E08.42 Diabetes mellitus due to underlying condition with diabetic polyneuropathy
<input type="checkbox"/> E10.40 Type 1 diabetes mellitus with diabetic neuropathy, unspecified	<input type="checkbox"/> E10.42 Type 1 diabetes mellitus with diabetic polyneuropathy
<input type="checkbox"/> E11.40 Type 2 diabetes mellitus with diabetic neuropathy, unspecified	<input type="checkbox"/> E11.42 Type 2 diabetes mellitus with diabetic polyneuropathy
<input type="checkbox"/> E13.40 Other specified diabetes mellitus with diabetic neuropathy, unspecified	<input type="checkbox"/> E13.41 Other specified diabetes mellitus with diabetic mononeuropathy
<input type="checkbox"/> E13.42 Other specified diabetes mellitus with diabetic polyneuropathy	<input type="checkbox"/> 3044F Most recent hemoglobin A1c (HbA1c) level less than 7.0% (DM)
<input type="checkbox"/> 3051F Most recent hemoglobin A1c (HbA1c) level greater than or equal to 7.0% and less than 8.0% (DM)	<input type="checkbox"/> 3052F Most recent hemoglobin A1c (HbA1c) level greater than or equal to 8.0% and less than or equal to 9.0% (DM)
<input type="checkbox"/> 3046F Most recent hemoglobin A1c level greater than 9.0%	<input type="checkbox"/> Other: _____

J Code: J7336 J7336JW NDC # 72512-928-01 NDC # 72512-929-01 NDC # 72512-930-01

CPT Code: _____ Please refer to billing and reimbursement guideline for additional billing information.

Capsaicin 8% Topical System Applied: (each unit is 1cm²)

1 topical system (280 cm² billing units) 2 topical systems (560 cm² billing units) 3 topical systems (840 cm² billing units) 4 topical systems (1120 cm² billing units)

Other _____ Waistage _____

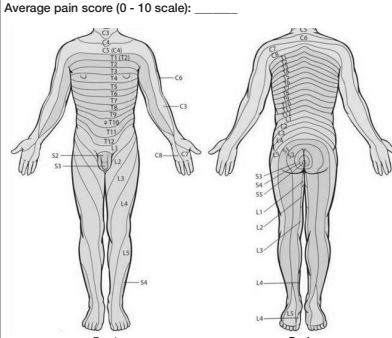
If Applicable: System Lot # _____ Exp Date _____

Additional Notes:

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Capsaicin 8% Topical System Procedure Notes

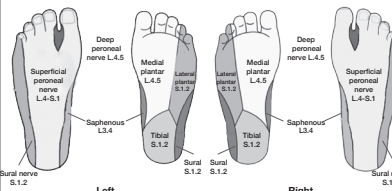
Please shade the area where the patient feels pain: Average pain score (0 - 10 scale): _____



Patient has tried and failed and/or did not tolerate the following:

- Gabapentin
- Amitriptyline
- Clomipramine
- Doxepin
- Imipramine
- Trimipramine
- Amoxapine
- Desipramine
- Nortriptyline
- Protriptyline
- Lidocaine patches
- Duloxetine
- Pregabalin
- Capsaicin topical analgesic cream
- Opioids (specify) _____
- Other _____

Please shade the area where the patient feels pain: Average pain score (0 - 10 scale): _____



Additional Clinical Rational

ER Visits (#): _____

Other: _____

Provider's Signature _____ Date _____

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[Download at MyQutenzaCoverage.com](http://MyQutenzaCoverage.com)

INDICATION

QUTENZA® (capsaicin) 8% topical system is indicated in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and for neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Only physicians or healthcare professionals under the close supervision of a physician are to administer and handle QUTENZA.

When administering QUTENZA, it is important to follow the procedures in the Important Dosage and Administration Instructions in the US Prescribing Information.

In patients treated for neuropathic pain associated with diabetic peripheral neuropathy of the feet, a careful examination of the feet should be undertaken prior to each application of QUTENZA to detect skin lesions related to underlying neuropathy or vascular insufficiency.

Contraindications

None

Warnings and Precautions

- Unintended exposure to capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin in healthcare professionals, patients, and others. Healthcare professionals should ensure that the recommended procedures and protective measures are used when administering QUTENZA.
- For healthcare professionals, wear nitrile gloves when administering QUTENZA and avoid unnecessary contact with items in the room, including items that the patient may later have contact with, such as horizontal surfaces and bedsheets.
- Do not apply QUTENZA to the patient's face, eyes, mouth, nose, or scalp to avoid risk of exposure to eyes or mucous membranes. Accidental exposure to the eyes and mucous membranes can occur from touching QUTENZA, or items exposed to capsaicin, and then touching the eyes and mucous membranes. If irritation of eyes or mucous membranes occurs, flush eyes and mucous membranes with cool water. Remove the affected individual (healthcare professional or patient) from the vicinity of QUTENZA.
- Aerosolization of capsaicin can occur upon rapid removal of QUTENZA. Therefore, remove QUTENZA gently and slowly by rolling the adhesive side inward. Inhalation of airborne capsaicin can result in coughing or sneezing. Administer QUTENZA in a well-ventilated treatment area. Provide supportive medical care if shortness of breath develops. If irritation of airways occurs, remove the affected individual from the vicinity of QUTENZA. If respiratory irritation worsens or does not resolve, do not re-expose the affected healthcare professional or patient to QUTENZA.

- If skin not intended to be treated is exposed to QUTENZA, apply Cleansing Gel for one minute and wipe off with dry gauze. After the Cleansing Gel has been wiped off, wash the area with soap and water.
- Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following the application procedure with local cooling (such as a cold pack) and/or appropriate analgesic medication.
- Transient increases in blood pressure may occur during and shortly after 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.
- Reductions in sensory function have been reported following administration of QUTENZA. Decreases in sensory function are generally minor and temporary. All patients with pre-existing sensory deficits should be clinically assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory deterioration or loss is detected, or pre-existing sensory deficit worsens, continued use of QUTENZA treatment should be reconsidered.

Adverse Reactions

In all controlled clinical trials, adverse reactions occurring in ≥5% of patients in the QUTENZA group, and at an incidence at least 1% greater than in the control group, were application site erythema, application site pain, and application site pruritus.

Adverse Event Reporting

Physicians, other healthcare professionals, and patients are encouraged to voluntarily report adverse events involving drugs or medical devices. To make a report you can:

- In the US, visit www.fda.gov/medwatch or call 1-800-FDA-1088; or
- For QUTENZA, you may also call 1-877-900-6479 and select option 1, or press zero on your keypad to talk to an operator to direct your call.

Please see full [Prescribing Information](#).

REFERENCE: 1. QUTENZA® [prescribing information]. Morristown, NJ: Averitas Pharma, Inc.

A background image showing a person in a kitchen, wearing a purple long-sleeved shirt, holding a white bowl. The scene is dimly lit, with a purple overlay on the right side. The person appears to be in a kitchen setting with shelves and various items in the background.

Qutenza[®]

(capsaicin) 8% topical system