Actor portrayal

REIMBURSEMENT GUIDE

Visit: MyQUTENZAConnect.com
Call: 1-855-802-8746
Fax: 1-855-454-8746

GETTING STARTED WITH MQC

Make sure your practice is registered so you can experience all available benefits and support.

GETTING STARTED IS SIMPLE

Get your office READY

Register your office

Register your office to activate your QUTENZA Connector, a reimbursement specialist, and gain access to the MQC portal, where you can find essential tools and training materials.

Get your patients SET

Enroll your patients

Once your registration is confirmed, you can begin enrolling patients to receive support for their QUTENZA® (capsaicin) 8% topical system treatment.

Everything is ready to GO

Tap into all MQC has to offer

Once your office and your patients are enrolled in the program, utilize the tools provided.

My QUTENZA Connect Cost Savings Program Overview

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

*Terms and condition may apply. See full Terms and Conditions at QUTENZA.com/savings.

MQC offers tools and training for your patients and your practice.

PATIENT SUPPORT

Plan-specific requirements for reimbursement:

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

BILLING AND CODING

Information needed to submit a claim:

- Procedure notes template
- QUTENZA topical system product codes
- Diagnosis codes
- Procedure codes
- Appeal support

PRODUCT ORDERING

Product ordering guidelines and resources:

- Buy-and-bill and specialty pharmacy options
- Packaging information
- Specialty distributor and specialty pharmacy contact information

ONGOING SUPPORT

Resources to help once your patients are undergoing treatment:

- Treatment reminders
- Field Access Managers

Make sure your practice is registered with My QUTENZA Connect to experience all available benefits and support.

Eligibility

The program may apply toward any copay, coinsurance, and deductible for QUTENZA. Copay and coinsurance for the administration of QUTENZA may be supported also.†

Patients may be eligible if they:

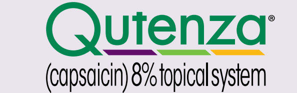
- ✓ Have commercial insurance
- ✓ Are 18 years of age or older
- ✓ Have a valid prescription for QUTENZA

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
- ✗ Are insured, but procedure code is not covered

Learn more and enroll now

†The program does cover procedural codes (e.g., Current Procedural Terminology codes). The application to deductibles may vary across pharmacy and medical benefits.



PRODUCT INFORMATION

QUTENZA® (capsaicin) 8% topical system is indicated in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) or associated with diabetic peripheral neuropathy (DPN) of the feet.[1]

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 at the TRPV1-expressing nociceptive nerve fibers in the skin.

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Use only on dry, unbroken skin. Only physicians or healthcare professionals are to administer and handle QUTENZA, following the procedures in the label.

Please see additional Important Safety Information on page 15.

Packaging	**NDC #72512-928-01** Kit (carton) contains one (1) single-use topical system and one (1) 50 g tube of Cleansing Gel	**NDC #72512-929-01** Kit (carton) contains two (2) single-use topical systems and one (1) 50 g tube of Cleansing Gel	**NDC #72512-930-01** Kit (carton) contains four (4) topical systems and three (3) 50 g tubes of Cleansing Gel
Strength	Contains 8% capsaicin (640 mcg per cm²). 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:** ASD Healthcare® 1-800-746-6273 Besse® Medical 1-800-543-2111 Cardinal Health™ 1-877-453-3972 CuraScript SD® 1-877-599-7748 McKesson Specialty Health 1-855-477-9800 McKesson Medical-Surgical 1-855-571-2100 **Specialty Pharmacy:** My QUTENZA Connect will recommend a specialty pharmacy partner.		
Storage guidelines	Store between 20°C and 25°C (68°F and 77°F). Excursions between 15°C and 30°C (59°F and 86°F) are allowed. Keep the topical system in the sealed pouch until immediately before use.		

HEALTH INSURANCE COVERAGE

Health insurance coverage for QUTENZA may vary from plan to plan.

For more information about reimbursement support, call My QUTENZA Connect at 855-802-8746 or email Field Access Support at US-FieldAccessSupport@grunenthal.com. 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 about QUTENZA. Averitas Pharma makes no representation about the information provided, as reimbursement information for QUTENZA, including applicable policies and laws, is subject to change without notice. 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.

QUTENZA TOPICAL SYSTEM CODING

HCPCS code (J-code) (Box 24D)	J7336 QUTENZA (capsaicin) 8% topical system per square centimeter J7336JW 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

ICD-10-CM codes Postherpetic neuralgia – PHN (Box 21)	The following primary diagnosis codes may be appropriate to describe patients with diabetic 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

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. Determining coverage and reimbursement parameters and appropriate coding for a patient and/or procedure is ultimately always the responsibility of the provider.

ADMINISTRATION AND PROFESSIONAL SERVICE CODING

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

No existing CPT code is specific to the application of QUTENZA. HCPCS coding requirements will vary by payer, setting of care, and date of service. Determining coverage and reimbursement parameters and appropriate coding for a patient and/or procedure is ultimately always the 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.‡

	Code	Description
CPT codes	64620	Destruction by neurolytic agent, intercostal nerve
	64632	Destruction by neurolytic agent, plantar common digital nerve
	64999	Unlisted procedure, nervous system
	64640	Destruction by neurolytic agent, other peripheral nerve or branch
	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 the 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.‡

	Code	Description
E&M codes	99202	Office or other outpatient visit for the evaluation and management of a new patient that 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 that 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 that 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 that 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 healthcare professional.
	99212	Office or other outpatient visit for the evaluation and management of an established patient that 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 that 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 that 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 that 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.

‡Please note that the use of modifiers may be appropriate

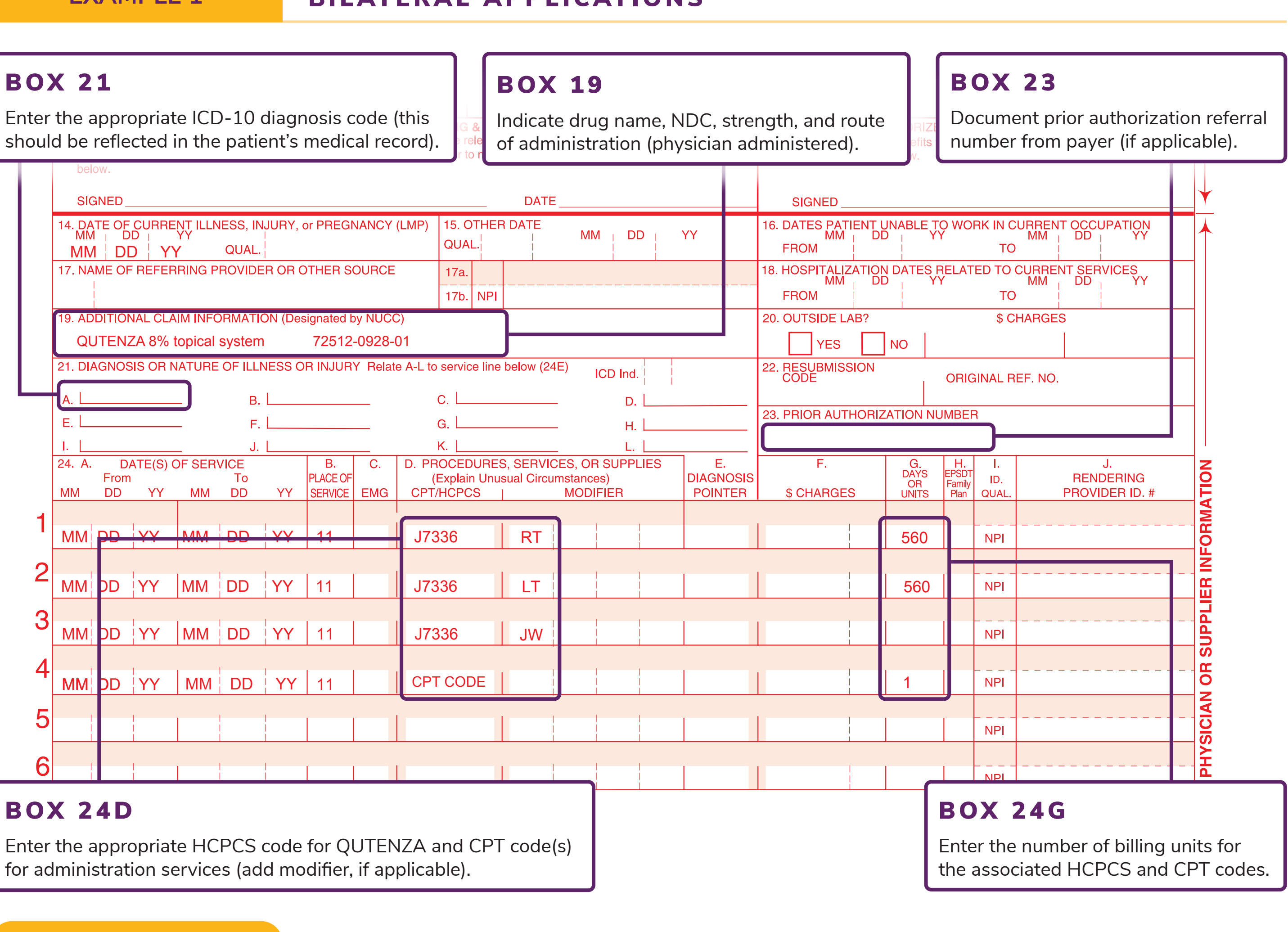
SAMPLE FORMS BY TREATMENT SETTING

CMS-1500: Physician office

To receive reimbursement for QUTENZA® (capsaicin) 8% topical system 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 AND/OR neuropathic pain associated with diabetic peripheral neuropathy 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



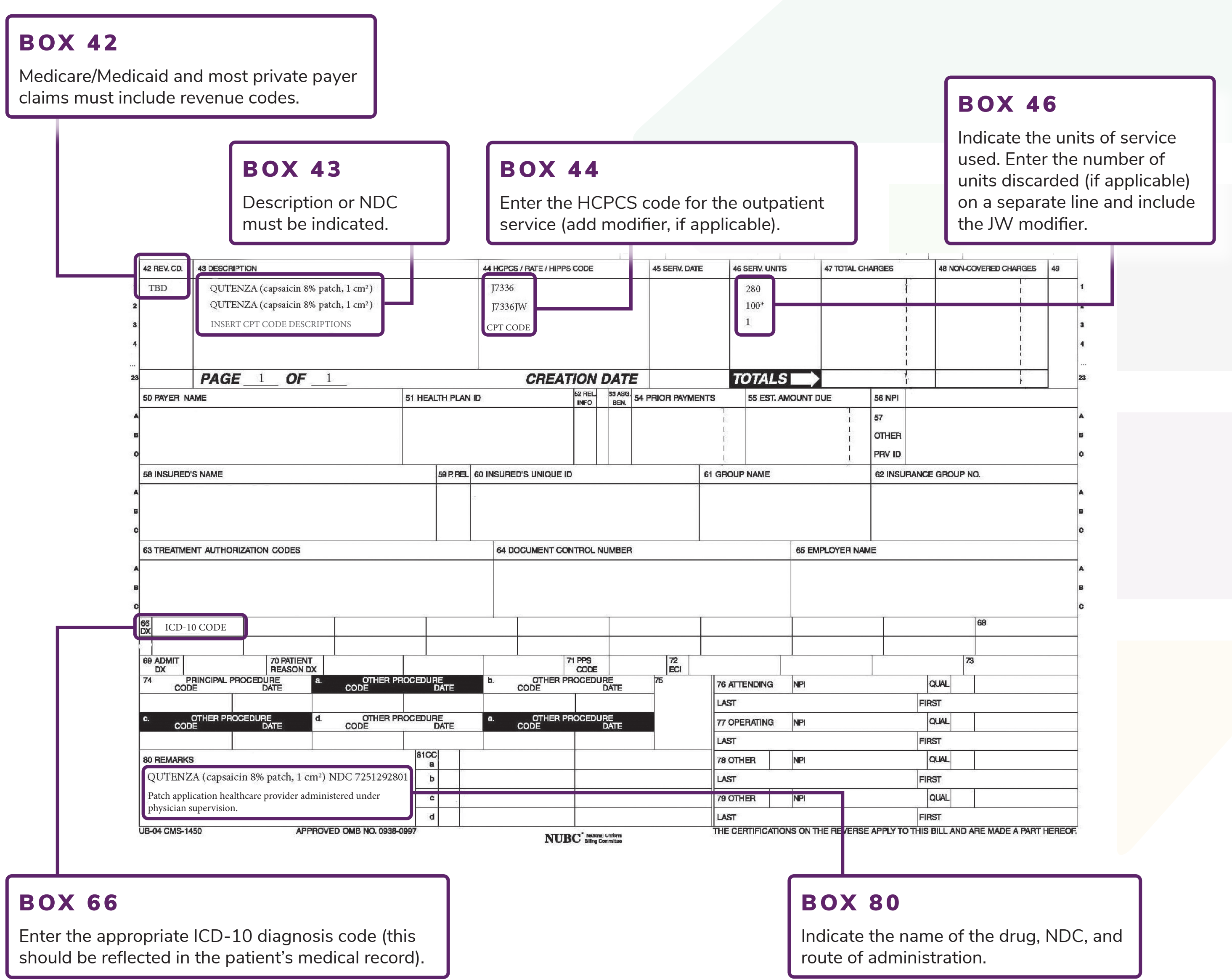
EXAMPLE 2 UNILATERAL APPLICATIONS

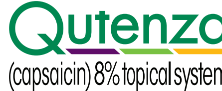
	24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	MM DD YY	MM DD YY	11		J7336	RT			560		NPI	
2	MM DD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

CMS-1450: Outpatient hospital

UB-04 is used for reimbursement for QUTENZA 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.





CONSIDERATIONS FOR VERIFYING INSURANCE BENEFITS

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

Payer Coverage Requirements

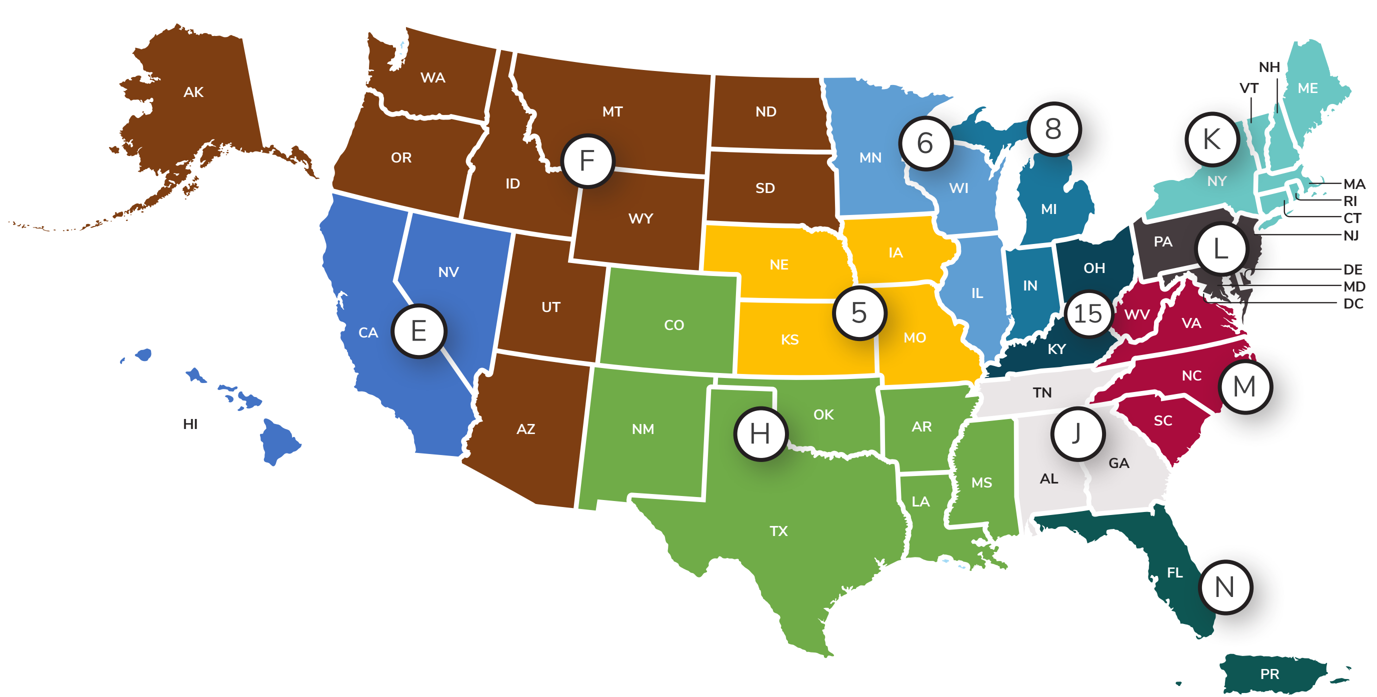
Coding and Billing Requirements

Patient Cost-share Considerations

RECOMMENDED BEST PRACTICES:

- ✓ Obtain the patient's information, the patient's insurance information, and your facility/office's tax ID and national provider identifier (NPI), then call the payer's provider services line.
- ✓ Ask about the coverage criteria specifically for the use of QUTENZA.
- ✓ Verify that HCPCS and CPT codes for use are covered for the patient's diagnosis. Provide applicable ICD-10-CM code(s).
- ✓ Ask whether the payer has set a maximum number of applications or treatment options and, if so, how many.
- ✓ Ask whether any documentation should be submitted with the claim. If so, ask what and how the documentation should be submitted.
- ✓ Ask if the payer has a specific medical policy pertaining to QUTENZA and, if so, whether they can provide a link to the policy.
- ✓ Ask whether a referral is required from the primary care physician.
- ✓ Inquire whether the patient has any coverage limitations or policy exclusions for the treatment and application of QUTENZA.
- ✓ Verify your contracted reimbursement rate for HCPCS and CPT codes and how much the patient will be required to pay out of pocket.

MEDICARE CONTRACTOR PROVIDER CONTACT NUMBERS[2]



PHONE NUMBERS FOR EACH MEDICARE PART B JURISDICTION

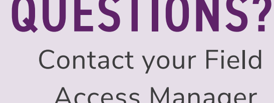
Medicare has established provider contact centers for those who may have questions about any product or service prior to submitting any claim.

Jurisdiction	IVR
5	1-866-518-3285
6	1-877-908-9499
8	1-866-234-7331
15	1-866-276-9558

Jurisdiction	IVR
E	1-855-609-9960
F	1-877-908-8431
H	1-855-252-8782
J	1-877-567-7271

Jurisdiction	IVR
K	1-877-869-6504
L	1-877-235-8073
M	1-855-696-0705
N	1-877-847-4992

All commercial claims should be addressed by calling the number on the back of the member's ID card



QUESTIONS?

Contact your Field Access Manager.

CLAIM FILING BEST PRACTICES

Confirm all information provided is correct before submitting to ensure prompt and accurate payment. This includes:

- Basic spelling and grammar
- Clerical information such as dates, codes, and code documentation
- Current fee schedules

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 TYPE		REQUIRED ACTION
Technical	Incorrect patient ID, missing signatures: • Missing or incorrect code (e.g., transposed numbers) • Incorrect units	• Call to correct • Prepare and submit a corrected claim • Contact Field Access Manager or MQC for assistance
Billing	Non-covered or non-allowed service: • Service was unbundled • Incorrect placement of service code • Duplicate claim • Invalid code • Incorrect units	• Prepare and submit a corrected claim • Prepare and submit an appeal • Contact Field Access Manager or MQC for assistance
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	• Prepare and submit an appeal • Contact Field Access Manager or MQC for assistance
Payer Denial	The insurance payer will not pay for the product: • Step edit, not on formulary • Investigative product	• Prepare and submit an appeal • Contact Field Access Manager or MQC for assistance

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 (e.g., 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 regarding what format it uses.

How long does the appeal process usually take?

Decision times vary by level of appeal and payer.

TIP

Timelines for reprocessing a 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 sent 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 it has a specific form or guidelines for submitting an appeal.

TIP

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

FIND ALL IMPORTANT RESOURCE DOCUMENTS IN ONE PLACE

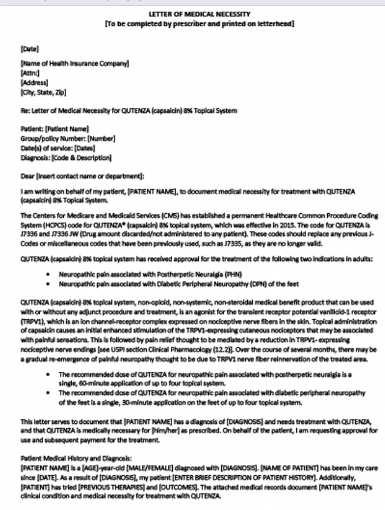
PROCEDURE NOTES

Capsaicin 8% Topical System Procedure Notes

Capsaicin 8% Topical System Procedure Notes

LETTERS

MEDICAL NECESSITY



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.

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

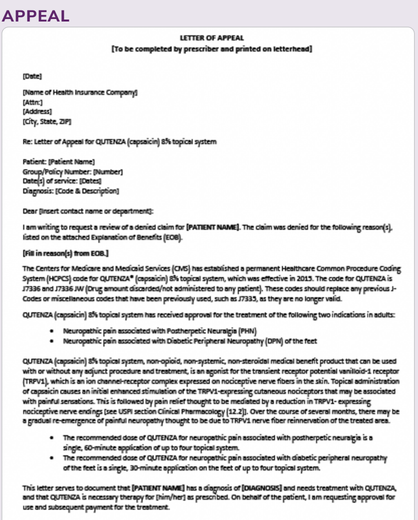
QUTENZA (capsaicin) 8% topical system, non-opioid, non-systemic, non-steroidal medical benefit product that can be used with or without any adjunct procedure and treatment, is an agonist for the transient receptor potential vanilloid-1 receptor (TRPV1), which is an ion channel-receptor complex expressed 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 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.

APPEAL



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.

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- 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 NOW

Scan the QR code to access these documents and more.

INDICATION

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

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Use only on dry, unbroken skin. Only physicians or healthcare professionals are to administer and handle QUTENZA, following the procedures in the label.

Warnings and Precautions

- **Severe Irritation:** Whether applied directly or transferred accidentally from other surfaces, capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin to the healthcare professional, patients, and others. Do not use near eyes or mucous membranes, including face and scalp. Take protective measures, including wearing nitrile gloves and not touching items or surfaces that the patient may also touch. Flush irritated mucous membranes or eyes with water and provide supportive medical care for shortness of breath. Remove affected individuals from the vicinity of QUTENZA. Do not re-expose affected individuals to QUTENZA if respiratory irritation worsens or does not resolve. If skin not intended to be treated comes into contact with QUTENZA, apply Cleansing Gel and then wipe off with dry gauze. Thoroughly clean all areas and items exposed to QUTENZA and dispose of properly. Because aerosolization of capsaicin can occur with rapid removal, administer QUTENZA in a well-ventilated area, and remove gently and slowly, rolling the adhesive side inward.
- **Application-Associated Pain:** Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following application with local cooling (e.g., ice pack) and/or appropriate analgesic medication.
- **Increase in Blood Pressure:** Transient increases in blood pressure may occur with QUTENZA treatment. Monitor blood pressure during and following treatment procedure and provide 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.
- **Sensory Function:** Reductions in sensory function (generally minor and temporary) have been reported following administration of QUTENZA. All patients with sensory deficits should be assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory loss occurs, treatment should be reconsidered.

Adverse Reactions

The most common adverse reactions (≥5% and > control group) in all controlled clinical trials are application site erythema, application site pain, and application site pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Averitas Pharma, Inc. at 1-877-900-6479 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see [accompanying] full Prescribing Information.

REFERENCES:

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