Qutenza®
(capsaicin) 8% topical system

ACCESS TOOL KIT

Navigating the coverage and reimbursement process to help patients start and stay on therapy

Averitas
A Grünenthal Company

About This Guide

Averitas Pharma, Inc., the manufacturer of QUTENZA® (capsaicin) 8% topical system, is committed to supporting patients seeking medically appropriate treatment of painful diabetic peripheral neuropathy of the feet. The Access Tool Kit is designed to assist healthcare providers (HCPs) with coverage and reimbursement questions related to the use and administration of QUTENZA, including information and resources to assist with benefits investigations, prior authorizations, product ordering, claims submission, appeals, and co-payment support.

In addition, My QUTENZA Connect (MQC), a service provided by Averitas, offers customized support depending on your unique coverage and reimbursement needs.

Important Note

- This Access Tool Kit and My QUTENZA Connect are intended solely as resources to assist healthcare providers with coverage and reimbursement-related questions about QUTENZA. Health insurance coverage and reimbursement for QUTENZA may vary. Averitas makes no representations about the information provided, as applicable coverage and reimbursement requirements may change periodically and often without warning.
- Any resources provided by Averitas, including this Access Tool Kit or My QUTENZA Connect, are for educational purposes only. Any available information is not intended to be conclusive or exhaustive and should not replace the guidance of a qualified professional advisor. The healthcare provider or the appropriate personnel of a provider's office or facility, not Averitas, must determine the appropriate method for seeking reimbursement based on the medical procedure performed and any other relevant information.
- Averitas 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.
- The content in this Access Tool Kit is current as of February 2024. Information on My QUTENZA Connect is also updated from time to time.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Important Safety Information

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 full Prescribing Information at https://QUTENZAhcp.com/pdfs/QUTENZA_Prescribing_Information.pdf

Qutenza® (capsaicin) 8% topical system

Integrating QUTENZA Into Your Practice

Actor portrayal

Please see full Prescribing Information as well as Important Safety Information on page 3

Integrating QUTENZA in 4 Easy Steps

The steps provided below will enable you to implement an efficient ordering, approval, and reimbursement process.

1 Getting Started

Once you have identified patients who would benefit from using QUTENZA, ensure that the proper systems and processes are in place for providers to prescribe QUTENZA.

Establish whether your office or facility requires a formal review of QUTENZA.

Should additional information be required to support a review, please contact your QUTENZA Account Manager.

Confirm product availability.

Refer to the list of QUTENZA-contracted specialty distributors.

QUTENZAhcp.com/access-and-savings/product-access

Request product application training.

Your QUTENZA Account Manager can conduct a product in-service and demonstrate how QUTENZA should be applied. Click the link below to watch a demonstration of the application process.

QUTENZAhcp.com/dpn/about-QUTENZA/applying-QUTENZA

2 Enrolling in My QUTENZA Connect

My QUTENZA Connect (MQC) is available to conduct benefit investigations before your patients are scheduled for treatment. You can also contact your Field Access Manager to address any questions that you may have.

Determine benefits.

Enrollment in My QUTENZA Connect is simple. MQC offers access to tools and information that may aid in the reimbursement process. You can submit a benefits investigation request through the MQC portal to obtain information about coverage for a patient, including percentage of deductible met, an estimate of patient out-of-pocket costs, and payer utilization requirements.

MyQUTENZAConnect.com/enrollments/new

Set up your account with MQC.

Enroll your patients to determine benefit coverage.

Obtain payer approval, when necessary.

You may be asked to submit clinical documentation to establish the medical necessity of your patient's treatment with QUTENZA. The Patient Chart Documentation form is a tool that can support this process. MQC also provides prior authorization and certification support.

QUTENZAhcp.com/pdfs/M-QZA-US-12-21-0010_QUTENZA-Patient-Chart-Documentation-Form.pdf

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Integrating QUTENZA in 4 Easy Steps (cont'd)

The steps provided below will enable you to implement an efficient ordering, approval, and reimbursement process.

3 Treating Patients

Completion of steps 1 and 2 will help you implement an efficient workflow for prescribing QUTENZA. Next is the treatment phase.

Order the product.

Order QUTENZA so you have it on hand for your patient's treatment.

QUTENZAhcp.com/access-and-savings/product-access

Schedule your patient and conduct the in-office procedure.

To help manage expectations, educate your patients on what to expect during treatment. Your QUTENZA Account Manager can provide you with a step-by-step QUTENZA application guide as well as various resources, such as:

- **Patient brochures**
- **Patient treatment tips sheet**

Establish ongoing treatment as appropriate.

Ensure your patients are scheduled for ongoing treatment as clinically appropriate. Treatment may be repeated no more frequently than every 3 months.

MyQUTENZAConnect.com

4 Submitting Claims

Obtaining appropriate reimbursement for QUTENZA can be simple.

Bill for QUTENZA and/or the administration.

The Reimbursement Guide includes helpful tips for submitting a claim. You can also contact your Field Access Manager for additional support with your questions.

QUTENZAhcp.com/pdfs/QZA-02-22-0023_v12_August-2023-Reimbursement-Guide_AFD_082223.pdf

Explore cost savings support options for your commercially insured patients.

The My QUTENZA Connect Cost Savings Program can help cover costs related to QUTENZA treatment. Your patients may be eligible for cost savings if they:

- **Are taking QUTENZA for an FDA-approved use**
- **Are 18 years of age or older**
- **Use commercial (private) insurance for QUTENZA coverage**
- **Live and receive treatment in the United States**
- **Do not use a state or federal healthcare plan to pay for their medication, including Medicare, Medicaid, and TRICARE**
- **See full terms and conditions at:**

QUTENZAhcp.com/access-and-savings/patient-savings

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

MQC

My Qutenza Connect

Please see full Prescribing Information as well as Important Safety Information on page 3

Introducing My QUTENZA Connect

My QUTENZA Connect was created to offer healthcare professionals a suite of educational tools and support programs tailored to the different phases of the patient's treatment journey.

REIMBURSEMENT SUPPORT

Plan-specific requirements for reimbursement:

- Benefits investigation
- Prior authorization support

BILLING AND CODING SUPPORT

Helpful tips when submitting a claim:

- Patient chart documentation template
- QUTENZA topical system product codes
- Information on claims submission and appeals

PRODUCT ORDERING

Product ordering guidelines and resources:

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

ONGOING SUPPORT

Resources to help once your patients are undergoing treatment:

- Resources and tools to support patient education
- Field Access Managers
- Cost Savings Program for commercially insured patients; see page 30 for more information

MQC
My Qutenza Connect

Phone: 855-802-8746
Fax: 855-454-8746

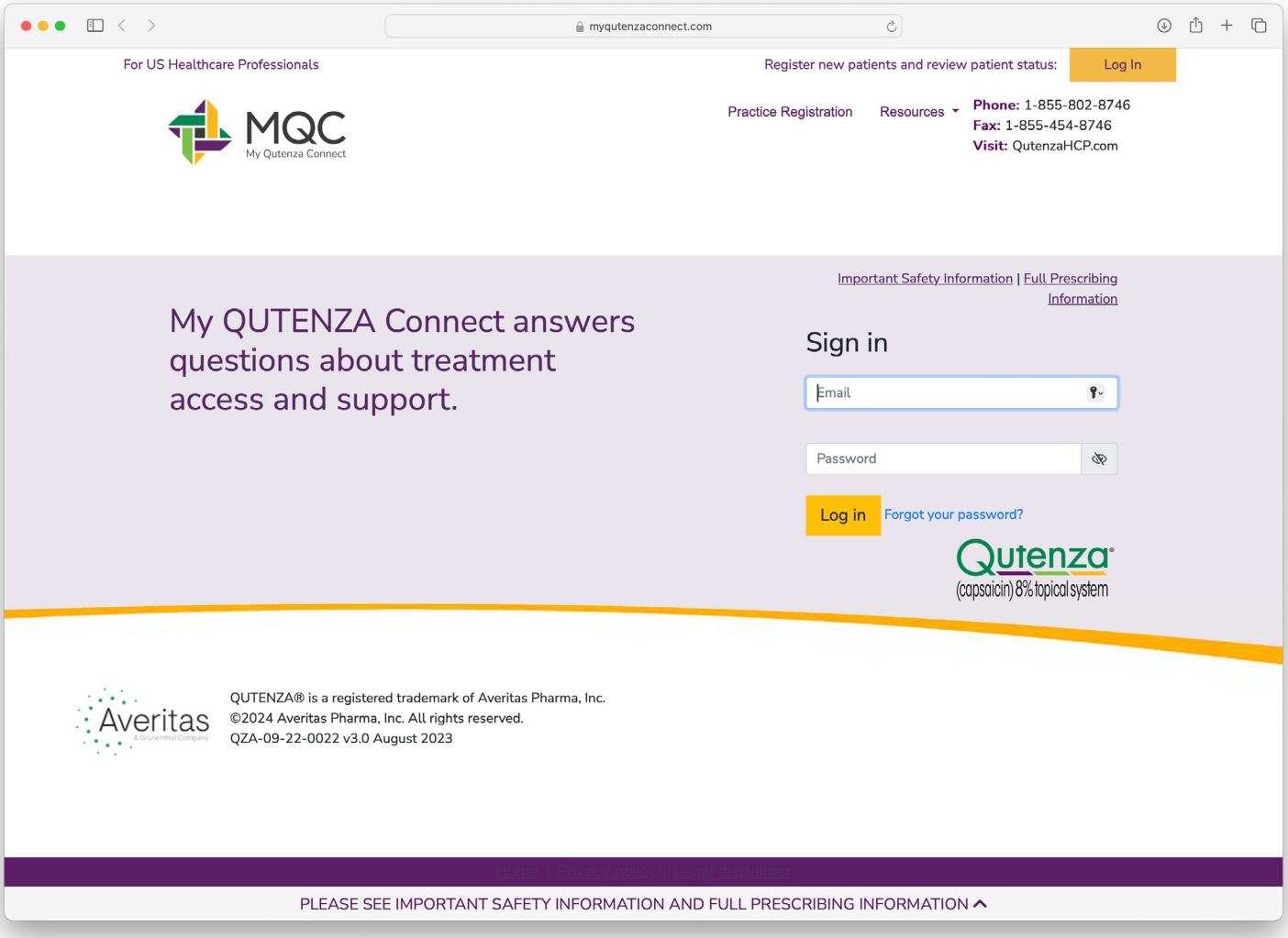
Monday – Friday
9AM – 7PM ET

MyQUTENZAConnect.com

Please see full Prescribing Information as well as Important Safety Information on page 3

Enrolling in My QUTENZA Connect

My QUTENZA Connect offers customized support depending on your unique access and reimbursement needs, a provider support hotline to help with questions, and the opportunity for more hands-on assistance with reimbursement specialists who can conduct a benefits investigation and help with your questions on prior authorizations and appeals.



MQC
My Qutenza Connect

Once you enroll in MQC, you can:

- Monitor patient case information
- Receive case status updates
- Upload clinical information
- Live chat with your MQC Case Manager
- Connect with your Averitas Field Access Manager

Benefits Investigation

Please see full Prescribing Information as well as Important Safety Information on page 3

Conducting a Benefits Investigation

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

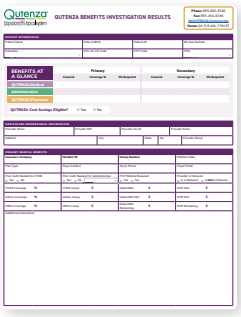
Payer Coverage Requirements | **Coding and Billing Requirements** | **Patient Cost-Share Considerations**

RECOMMENDED BEST PRACTICES

- ✓ Obtain the patient's information, the patient's insurance information, and your facility/office's tax ID number 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 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 the appropriate HCPCS and CPT codes and how much the patient will be required to pay out of pocket.

MQC My Qutenza Connect

Need Assistance Conducting a Benefits Investigation?



My QUTENZA Connect can help. A Reimbursement Case Manager will research the patient's insurance benefits and send a patient-specific Summary of Benefits and Benefits Results to your office. The results can also be viewed on the My QUTENZA Connect HCP Portal. Visit MyQUTENZAConnect.com or ask your Averitas Field Access Manager for more information.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Supporting Your Benefits Investigation

MQC
My Qutenza Connect

After My QUTENZA Connect receives the Benefits Investigation Request and Prescription Form, the team will provide your practice with the patient's QUTENZA Benefits Investigation Results.

Patient Information

Included in this section are the patient's name, DOB, and ID as well as the BI Case Number. The BI Case Number is assigned by MQC and is specific to the benefits investigation outlined on the form. A new BI Case Number is generated each time a benefits investigation is performed on behalf of your patient.

Benefits at a Glance

Provides a summary of key components of your patient's insurance coverage and indicates whether your patient may be eligible for the QUTENZA Cost Savings program.

Healthcare Professional Information

Overview of the provider's information.

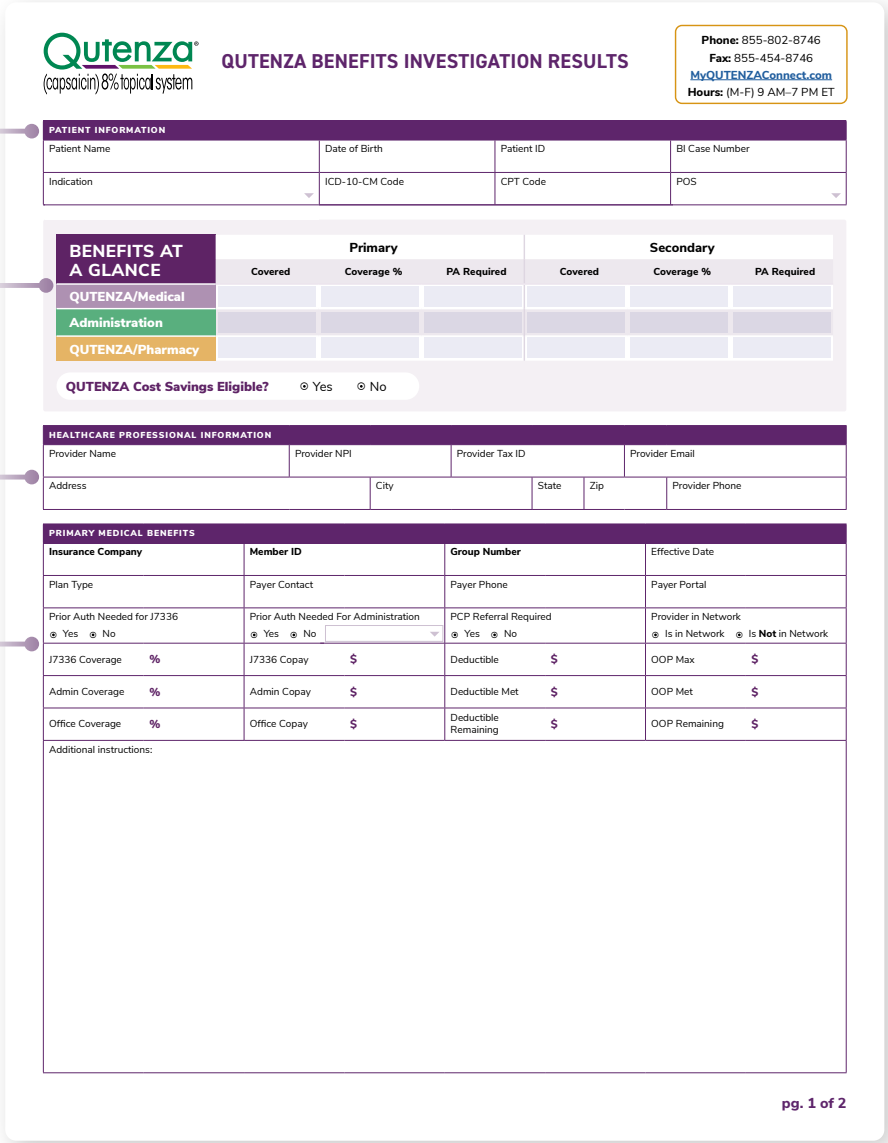
Primary Medical Benefits

Shows your patient's primary medical plan details.

Shows the plan's prior authorization and referral requirements as well as the provider's in-network status.

Lists information on your patient's medical coverage. It also outlines the patient's copay, deductible, and out-of-pocket (OOP) responsibility.

The Additional instructions field includes a narrative of key points and any pertinent details related to the research of your patient's coverage.



Qutenza® (capsaicin) 8% topical system

QUTENZA BENEFITS INVESTIGATION RESULTS

Phone: 855-802-8746
Fax: 855-454-8746
MyQUTENZAConnect.com
Hours: (M-F) 9 AM–7 PM ET

PATIENT INFORMATION

Patient Name	Date of Birth	Patient ID	BI Case Number
Indication	ICD-10-CM Code	CPT Code	POS

BENEFITS AT A GLANCE	Primary			Secondary		
	Covered	Coverage %	PA Required	Covered	Coverage %	PA Required
QUTENZA/Medical						
Administration						
QUTENZA/Pharmacy						

QUTENZA Cost Savings Eligible? ○ Yes ○ No

HEALTHCARE PROFESSIONAL INFORMATION

Provider Name	Provider NPI	Provider Tax ID	Provider Email	
Address	City	State	Zip	Provider Phone

PRIMARY MEDICAL BENEFITS

Insurance Company	Member ID	Group Number	Effective Date
Plan Type	Payer Contact	Payer Phone	Payer Portal
Prior Auth Needed for J7336 ○ Yes ○ No	Prior Auth Needed For Administration ○ Yes ○ No	PCP Referral Required ○ Yes ○ No	Provider in Network ○ Is in Network ○ Is **Not** in Network
J7336 Coverage %	J7336 Copay $	Deductible $	OOP Max $
Admin Coverage %	Admin Copay $	Deductible Met $	OOP Met $
Office Coverage %	Office Copay $	Deductible Remaining $	OOP Remaining $
Additional instructions:			

pg. 1 of 2

The Benefits Investigation Summary or Results is not a guarantee of coverage or payment. It is the responsibility of the practice to confirm eligibility and that coverage requirements are met prior to each QUTENZA administration.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Supporting Your Benefits Investigation (cont'd)

MQC
My Qutenza Connect

The comprehensive results allow you to make the most appropriate choice for your patient and your practice on how to access QUTENZA.

Secondary or Supplemental Medical Benefits

This section includes the same information as the Primary Medical Benefits section and will be completed if your patient has applicable secondary or supplemental medical benefits.

Pharmacy Benefits

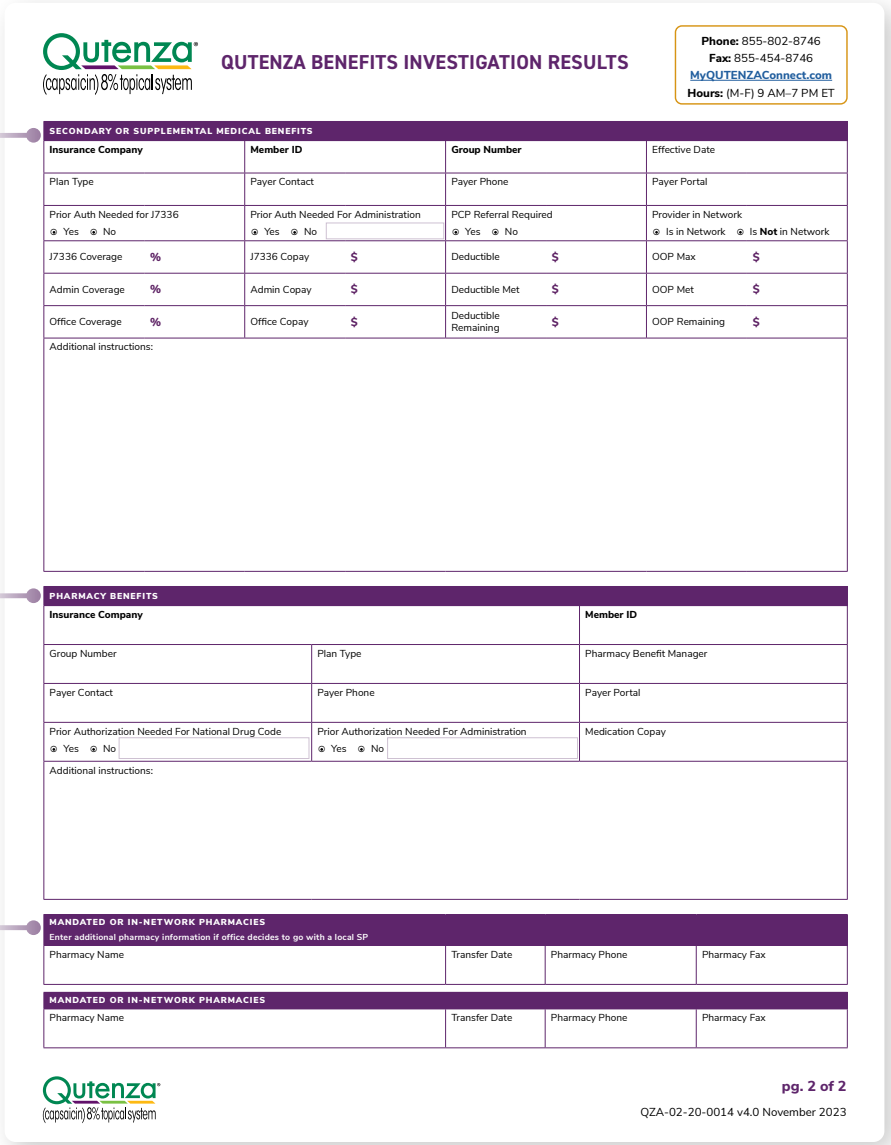
Outlines your patient's pharmacy plan details, including the pharmacy benefit manager.

Lists the plan's prior authorization requirements and your patient's medication OOP responsibilities.

The Additional instructions field includes a narrative of key points and any pertinent details related to the research of your patient's coverage.

Mandated or In-Network Pharmacies

Identifies pharmacies mandated or preferred by the patient's insurance plan details related to the research of your patient's coverage.



Qutenza (capsaicin) 8% topical system

QUTENZA BENEFITS INVESTIGATION RESULTS

Phone: 855-802-8746
Fax: 855-454-8746
MyQUTENZAConnect.com
Hours: (M-F) 9 AM–7 PM ET

SECONDARY OR SUPPLEMENTAL MEDICAL BENEFITS

Insurance Company	Member ID	Group Number	Effective Date
Plan Type	Payer Contact	Payer Phone	Payer Portal
Prior Auth Needed for J7336 ◉ Yes ◉ No	Prior Auth Needed For Administration ◉ Yes ◉ No	PCP Referral Required ◉ Yes ◉ No	Provider in Network ◉ Is in Network ◉ Is **Not** in Network
J7336 Coverage %	J7336 Copay $	Deductible $	OOP Max $
Admin Coverage %	Admin Copay $	Deductible Met $	OOP Met $
Office Coverage %	Office Copay $	Deductible Remaining $	OOP Remaining $
Additional instructions:			

PHARMACY BENEFITS

Insurance Company		Member ID
Group Number	Plan Type	Pharmacy Benefit Manager
Payer Contact	Payer Phone	Payer Portal
Prior Authorization Needed For National Drug Code ◉ Yes ◉ No	Prior Authorization Needed For Administration ◉ Yes ◉ No	Medication Copay
Additional instructions:		

MANDATED OR IN-NETWORK PHARMACIES
Enter additional pharmacy information if office decides to go with a local SP

Pharmacy Name	Transfer Date	Pharmacy Phone	Pharmacy Fax

MANDATED OR IN-NETWORK PHARMACIES

Pharmacy Name	Transfer Date	Pharmacy Phone	Pharmacy Fax

Qutenza (capsaicin) 8% topical system

pg. 2 of 2

QZA-02-20-0014 v4.0 November 2023

The Benefits Investigation Summary or Results is not a guarantee of coverage or payment. It is the responsibility of the practice to confirm eligibility and that coverage requirements are met prior to each QUTENZA administration.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Prior Authorization

Please see full Prescribing Information as well as Important Safety Information on page 3

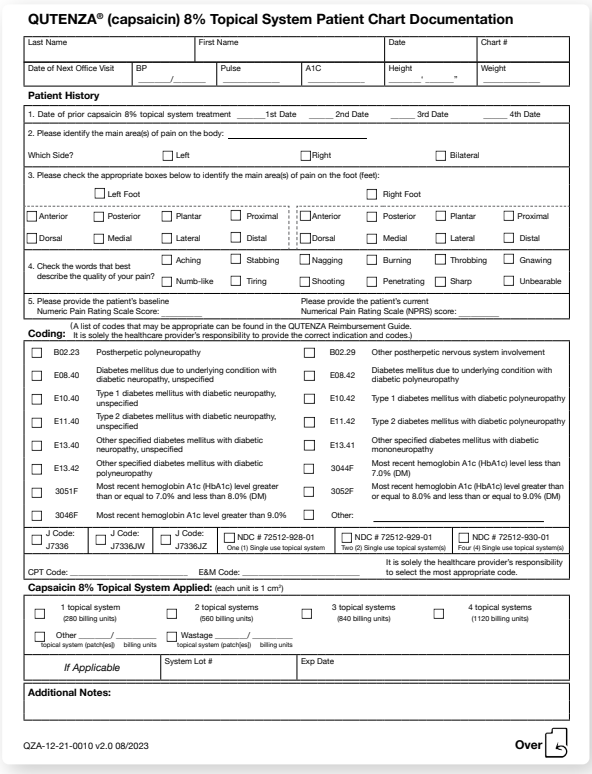
Establishing Medical Necessity for a Prior Authorization

Health insurers use prior authorizations to evaluate the medical necessity of planned medical services.

If a patient's health plan requires prior authorization, you likely will be asked to submit specific information and send a letter or statement to support the medical necessity for the use of QUTENZA for your patient. Otherwise, QUTENZA treatment and its administration may not be covered by the patient's insurance. An approved prior authorization request confirms coverage, but it does not guarantee reimbursement.

While the format and requested information for a prior authorization may differ from health plan to health plan, examples of the type of information generally required is below.

- Diagnosis summary, including the ICD-10-CM code and date of diagnosis
- Diagnostic tests
- Summary of patient's medical history
- Severity of patient's condition, including comorbidities
- Previously administered treatments/procedures including dates, and any response to those interventions which may include:
  - Gabapentin, pregabalin, SSRIs, tricyclic, OTCs, topical capsaicin, lidocaine
- Relevant procedure and HCPCS codes
- Product prescribing information and NDC number
- Identifying information for the referring provider and servicing provider
- Number of treatments required



QUTENZA® (capsaicin) 8% Topical System Patient Chart Documentation

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	☐ Anterior	☐ Posterior	☐ Plantar	☐ Proximal
☐ Dorsal	☐ Medial	☐ Lateral	☐ Distal	☐ 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		

5. Please provide the patient's baseline Numeric Pain Rating Scale Score: _____ Please provide the patient's current Numerical Pain Rating Scale (NPRS) score: _____

Coding: (A list of codes that may be appropriate can be found in the QUTENZA Reimbursement Guide. It is solely the healthcare provider's responsibility to provide the correct indication and codes.)

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

☐ J Code: J7336	☐ J Code: J7336JW	☐ J Code: J7336JZ	☐ NDC # 72512-928-01 One (1) Single use topical system	☐ NDC # 72512-929-01 Two (2) Single use topical system(s)	☐ NDC # 72512-930-01 Four (4) Single use topical system(s)

CPT Code: _____ E&M Code: _____ It is solely the healthcare provider's responsibility to select the most appropriate code.

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

☐ 1 topical system (280 billing units)	☐ 2 topical systems (560 billing units)	☐ 3 topical systems (840 billing units)	☐ 4 topical systems (1120 billing units)
☐ Other ____/____ topical system (patch/es) billing units	☐ Wastage ____/____ topical system (patch/es) billing units		

If Applicable	System Lot #	Exp Date

Additional Notes:

QZA-12-21-0010 v2.0 08/2023 Over

Averitas offers helpful resources that you can use when documenting medical necessity for QUTENZA. The Patient Chart Documentation form allows you to capture important information in a patient's chart that may be required for the prior authorization, such as diagnosis code, patient's Numeric Pain Rating Scale Score, and A1C level. To download the form, visit QUTENZAhcp.com or ask your Averitas Field Access Manager for more information.

Download Patient Chart Documentation Form

ICD-10-CM, International Classification of Diseases, 10th edition, Clinical Modification; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code

Qutenza® (capsaicin) 8% topical system

Drafting a Letter of Medical Necessity

Additional support for medical necessity may be required. This form letter can be used to help you draft a letter to support the need for QUTENZA for a patient. Always check to see if the patient's health insurance has their own template for you to follow when submitting a letter of 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]
Diagnosis: [Code and Description]
Date of Diagnosis: [Date]

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. [Patient Name] was first diagnosed with [The patient's diagnosis (ICD-10-CM code)] on [date of diagnosis]. Therapies prescribed to treat the condition include [list the names of current or past treatments].

At this time, I plan to start [Patient Name] on a course of treatment with QUTENZA.

[Patient Name] will be treated with [two/three/four] systems on [specify treatment area(s)] for [number of treatment cycles] treatment cycles.

[Insert a statement describing how the patient's disease is impacting the patient's health.]

In my professional opinion, QUTENZA is medically necessary and is an appropriate drug for [Patient Name] at this time. I have enclosed the prescribing information for QUTENZA along with [Patient Name]'s [list pertinent enclosures such as prior medication flow sheets and chart notes]. Please feel free to contact me if you require any additional information.

Sincerely,

[Physician Name]
[Physician Signature]
[Provider Identification Number]

Enclosures: [List and attach as appropriate]

QZA-04-21-0002 v2.0 June 2023

Download the Sample Letter of Medical Necessity at QUTENZAhcp.com.

Checklist for a Letter of Medical Necessity

- **Indicate whether the patient is newly initiating therapy or continuing ongoing therapy.** Requirements may differ, depending on where the patient is in the ongoing treatment being received.
- **Specify the likely date of service.** This will help confirm that coverage will be active at the time of QUTENZA administration.
- **Identify the need for multiple procedure codes, if necessary.** If a family of CPT codes is relevant, be proactive and request preauthorization for those codes. Many payers will not allow for a CPT code they did not authorize.
- **State the specific site of service.** Payers may have differing coverage and reimbursement policies that are based on the geographic location of the site of care.
- **Identify the prescribing specialist.** Plan managers may want to verify that QUTENZA was prescribed by, or in consultation with, a specialist.
- **Be clear and detailed regarding the rationale for prescribing QUTENZA.** Ensure that all supporting documentation is complete before submitting the form(s).
- **Append supporting documentation.** Types of relevant documentation may include peer-reviewed, nationally recognized guidelines (e.g., ADA Clinical Compendia, AACE Clinical Practice Guideline) or the prescribing information.

This Letter of Medical Necessity form is for educational purposes only and serves as a guide for the HCP. The HCP must modify the format of the letter and include the appropriate detail to reflect the patient's specific facts and circumstances, or to include specific information that may be required by individual payers.

CPT, Current Procedural Terminology; ADA, American Diabetes Association; AACE, American Association of Clinical Endocrinology

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Requesting the Prior Authorization

For safety and cost reasons, plans may set quantity limits on the amount of therapy they cover over a certain period of time. When submitting a prior authorization request, you may ask to obtain preauthorization for the full number of treatments of Qutenza for your patient rather than to submit a new request in advance of each treatment. Treatments may be repeated no more frequently than every 3 months, which equals up to 4 treatments a year.

TREATMENT 1

Assess patient progress over multiple treatments

PAIN RELIEF
Is patient starting to experience pain relief?

IMPACT ON DAY-TO-DAY ACTIVITIES
With less pain, has patient seen any progress on their day-to-day activities (time with family, socializing with friends, sleep, cooking, or household chores)?

TREATMENT 2
(Month 3*)

TREATMENT 3
(Month 6*)

ONGOING TREATMENTS 4 TIMES EACH YEAR

Evaluate patient response to treatment and schedule ongoing treatments.

*Treatment may be repeated no more frequently than every 3 months.

Some payers may have established quantity limits for QUTENZA. My QUTENZA Connect can help your office understand the coverage policies for most payers, when available. If you need further assistance, contact My QUTENZA Connect at 855-802-8746, Monday through Friday, 9 am to 7 pm ET.

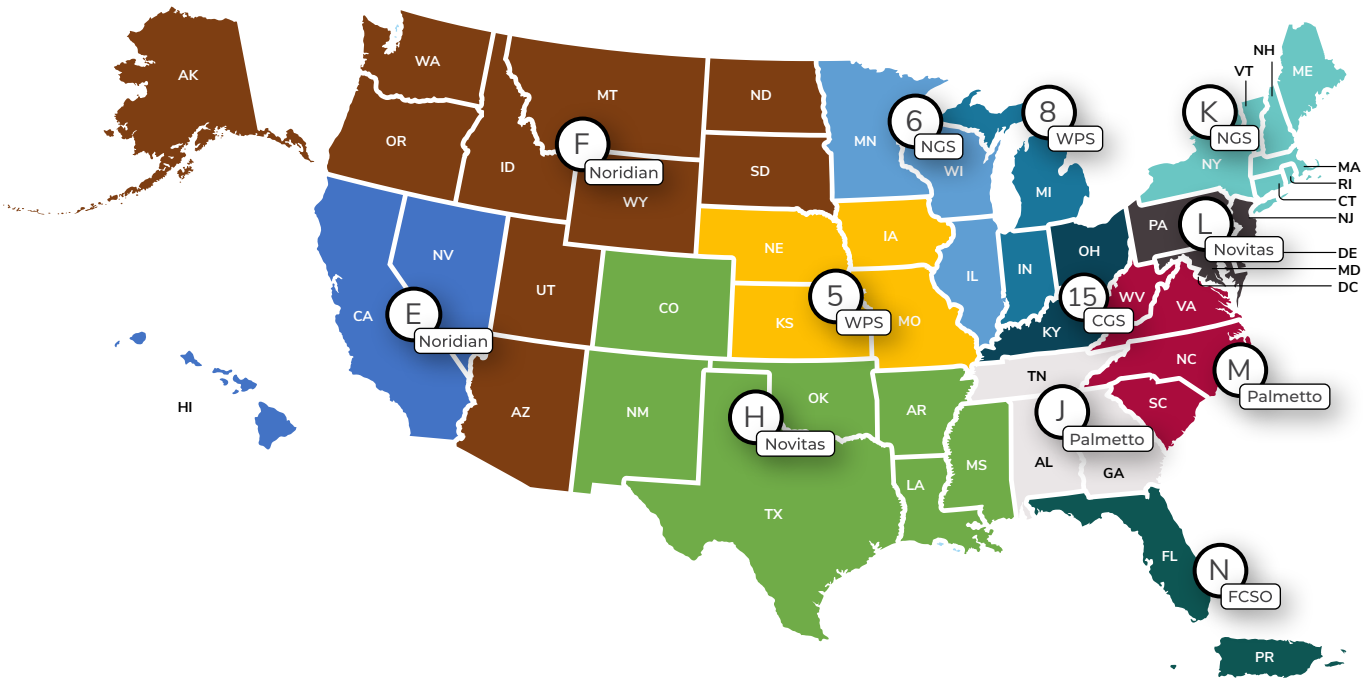
Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Contacting a Payer

Contact a payer via their dedicated provider services phone number or through their online portal. When calling, have the patient's insurance details, the provider's information, and the specifics of the service or procedure you are inquiring about ready to ensure a smooth and efficient discussion.

Medicare Part B Jurisdictions[1]



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	866-518-3285
6	877-908-9499
8	866-234-7331
15	866-276-9558

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

Jurisdiction	IVR
K	877-869-6504
L	877-235-8073
M	855-696-0705
N	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.
www.QUTENZAhcp.com/request-a-rep/

Qutenza® (capsaicin) 8% topical system

Acquiring QUTENZA

Actor portrayal

Please see full Prescribing Information as well as Important Safety Information on page 3

Qutenza®
(capsaicin) 8% topical system

QUTENZA is a single-use topical system stored in a foil pouch. Each QUTENZA is 14 cm x 20 cm (280 cm^2). QUTENZA is supplied with Cleansing Gel that is used to remove residual capsaicin from the skin after treatment.

Each topical system contains a total of 179 mg of capsaicin.

Packaging	**NDC #72512-928-01** Kit (carton) contains one single-use topical system and one 50 g tube of Cleansing Gel	**NDC #72512-929-01** Kit (carton) contains two single-use topical systems and one 50 g tube of Cleansing Gel	**NDC #72512-930-01** Kit (carton) contains four single-use topical systems and three 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.		

QUTENZA STORAGE AND HANDLING

- 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.
- Shelf life is 4 years for an unopened kit.
- Recommended to keep the package stored horizontally until use.

NDC, national drug code

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Ordering QUTENZA

Via Specialty Distributors

- You may order from one of the specialty distributors included in the QUTENZA network. If you don't have an account, one should be created before ordering QUTENZA.

Authorized Specialty Distributor	Contact Information	Website
AmerisourceBergen / ASD Healthcare	**Phone:** 800-746-6273 **Fax:** 800-547-9413	**asdhealthcare.com**
Besse Medical Supply	**Phone:** 800-543-8695 **Fax:** 800-543-8695	**besse.com**
Cardinal Health	**Community Practice** **Phone:** 877-453-3972 **Institutions** **Phone:** 866-677-4844 **Fax:** 888-345-4916	**specialtyonline.cardinalhealth.com**
Curascript	**Phone:** 877-599-7748 **Fax:** 800-862-6208	**curascriptsd.com**
McKesson Medical-Surgical	**Phone:** 855-571-2100 **Fax:** 866-906-5688	**mms.mckesson.com**
McKesson Plasma & Biologics	**Phone:** 877-625-2566 **Fax:** 888-752-7626	**connect.mckesson.com**
McKesson Specialty Care	**Phone:** 855-477-9800 **Fax:** 800-800-5673	**mscs.mckesson.com**

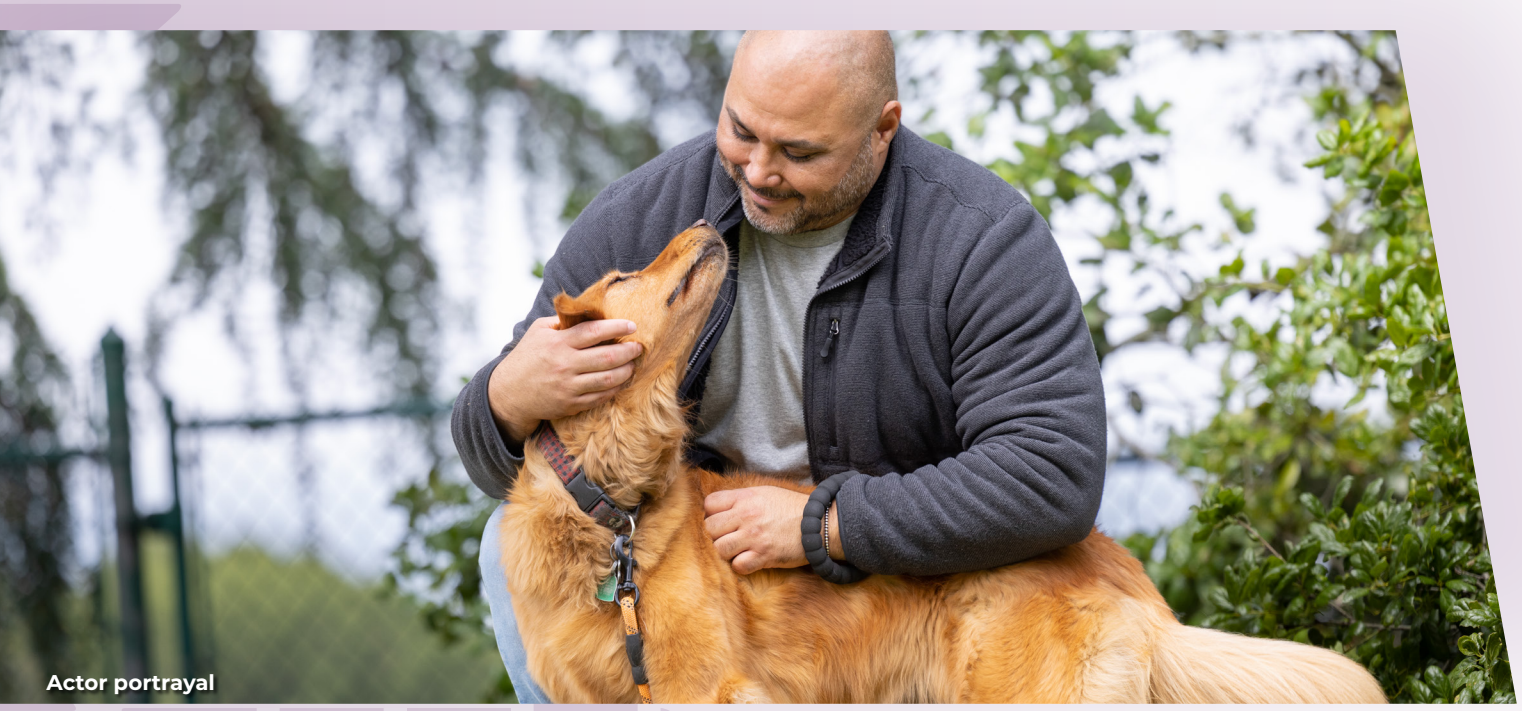
Via Specialty Pharmacy

- Some payers may require use of a specific acquisition method. If you request a benefits investigation from My QUTENZA Connect, the office will be notified if the patient's payer requires QUTENZA to be purchased from a specific specialty pharmacy.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Billing and Coding



Actor portrayal

Please see full Prescribing Information as well as Important Safety Information on page 3

Coding Claims

When the patient has received QUTENZA, your office may submit a claim to the patient's insurance plan. Depending on the patient's benefits, your office may submit a claim for the drug, for the administration services, or for both. The information within this section reviews some of the codes commonly associated with the administration of QUTENZA. **Determining coverage and reimbursement parameters and appropriate coding for a patient and/or procedure is always solely the responsibility of the provider.**

QUTENZA Topical System Coding

HCPCS code (J-code)	**J7336**	QUTENZA (capsaicin) 8% topical system per square centimeter
	J7336 JW	Drug amount discarded
	J7336 JZ	Zero drug amount discarded
	CMS requires providers to report either the JW or JZ modifier on Medicare Part B claims for outpatient settings of care.[2]	
NDC numbers, 11-digit format	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	Please consult with a patient's plan to determine what information, if any, should be provided.	
Number of units	1 topical system = 280 units	2 topical systems = 560 units
	3 topical systems = 840 units	4 topical systems = 1,120 units

Diagnosis Coding

ICD-10-CM codes **Postherpetic neuralgia – PHN**	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**	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

ICD-10-CM, International Classification of Diseases, 10th edition, Clinical Modification; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code

Coding Claims (cont'd)

HCPs may need to consider several factors to ensure accurate billing and coding for services provided. How a procedure is performed, and how complex that procedure is, may determine the appropriate code to select. Also, please note that there may be different codes associated with where exactly on the body the procedure is performed. Finally, the use of modifiers may be appropriate, as explained below.

Administration Coding

No existing CPT code is specific to the application of QUTENZA. CPT coding requirements will vary by payer, setting of care, and date of service.

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
	17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
	64999	Unlisted procedure, nervous system
	96999	Unlisted special dermatological service or procedure

Evaluation and Management Coding

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 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.

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.

CPT, current procedural terminology; E&M, evaluation and management

*Please note that the use of modifiers may be appropriate.

Qutenza® (capsaicin) 8% topical system

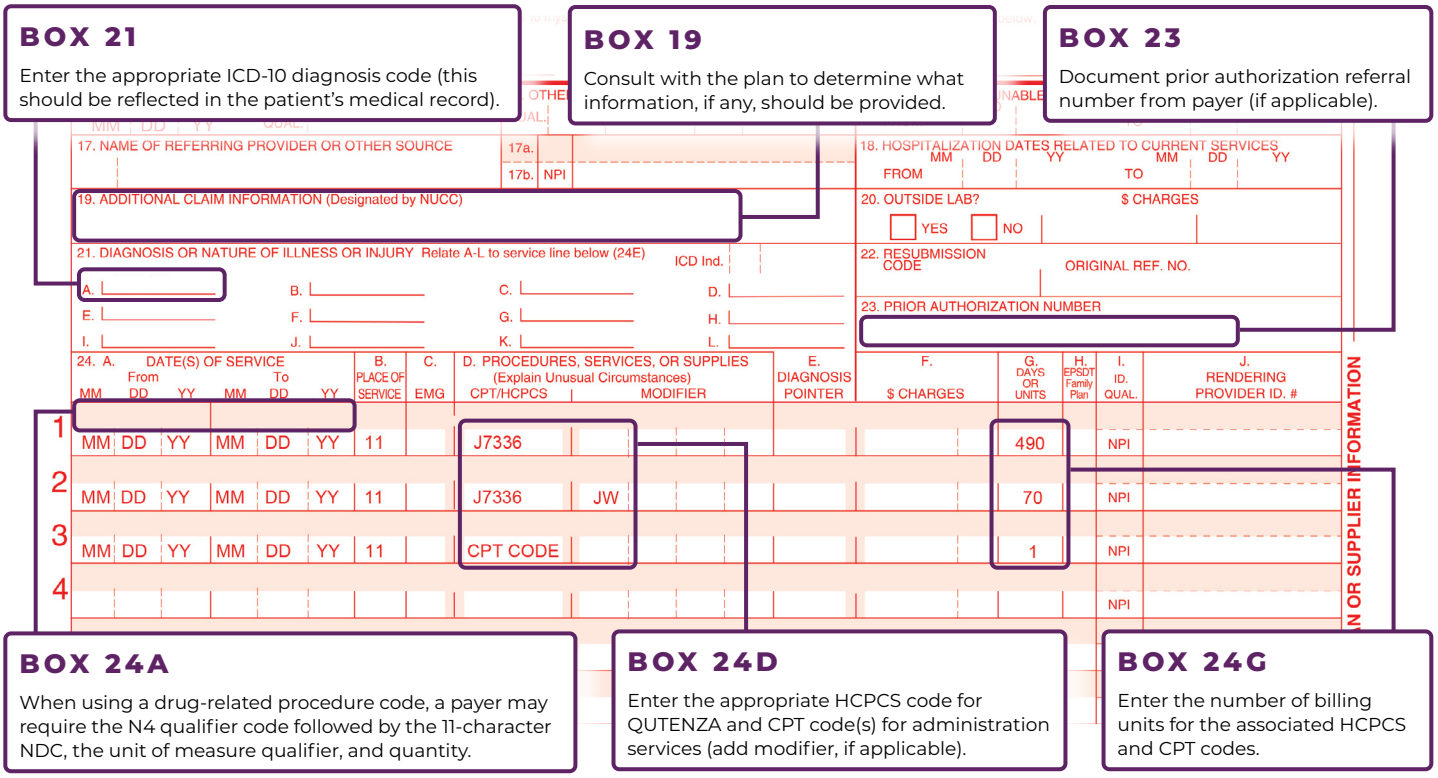
Sample Forms by Treatment Setting

CMS-1500: Physician Office Example

To receive reimbursement for QUTENZA administered in the physician office setting of care, providers must submit a CMS-1500 claim form for the drug and associated services.

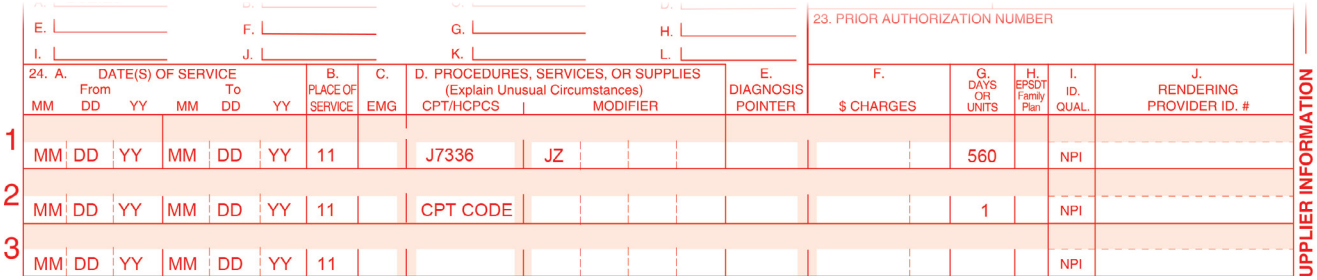
Example 1: JW Modifier

- A provider requires 2 topical systems to cover a treatment area of 560 cm^2 (560 units).
- Only 490 cm^2 (i.e., 490 units) was applied to the patient.
- The provider must bill the 490-unit dose on one line and must bill the discarded 70 units on another line using the JW modifier. Both line items will be processed for payment.



Example 2: JZ Modifier

- A provider requires 2 topical systems to cover a treatment area of 560 cm^2 (560 units).
- No topical system was discarded.
- The provider must include the JZ modifier to demonstrate that the entire product was administered to the patient.



Qutenza® (capsaicin) 8% topical system

Sample Forms by Treatment Setting (cont'd)

Example 3: JZ, RT, and LT Modifier

- A provider requires two topical systems per foot to cover a treatment area of 560 cm2 (560 units).
- No topical system was discarded.
- The provider must include the JZ modifier to demonstrate that the entire product was administered to the patient.

	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 (Explain Unusual Circumstances) 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	JZ RT			560		NPI	
2	MM	DD	YY	MM	DD	YY	11		J7336	JZ LT			560		NPI	
3	MM	DD	YY	MM	DD	YY	11		CPT CODE				1		NPI	

UPPLIER INFORMATION

CMS-1450: Outpatient Hospital Example

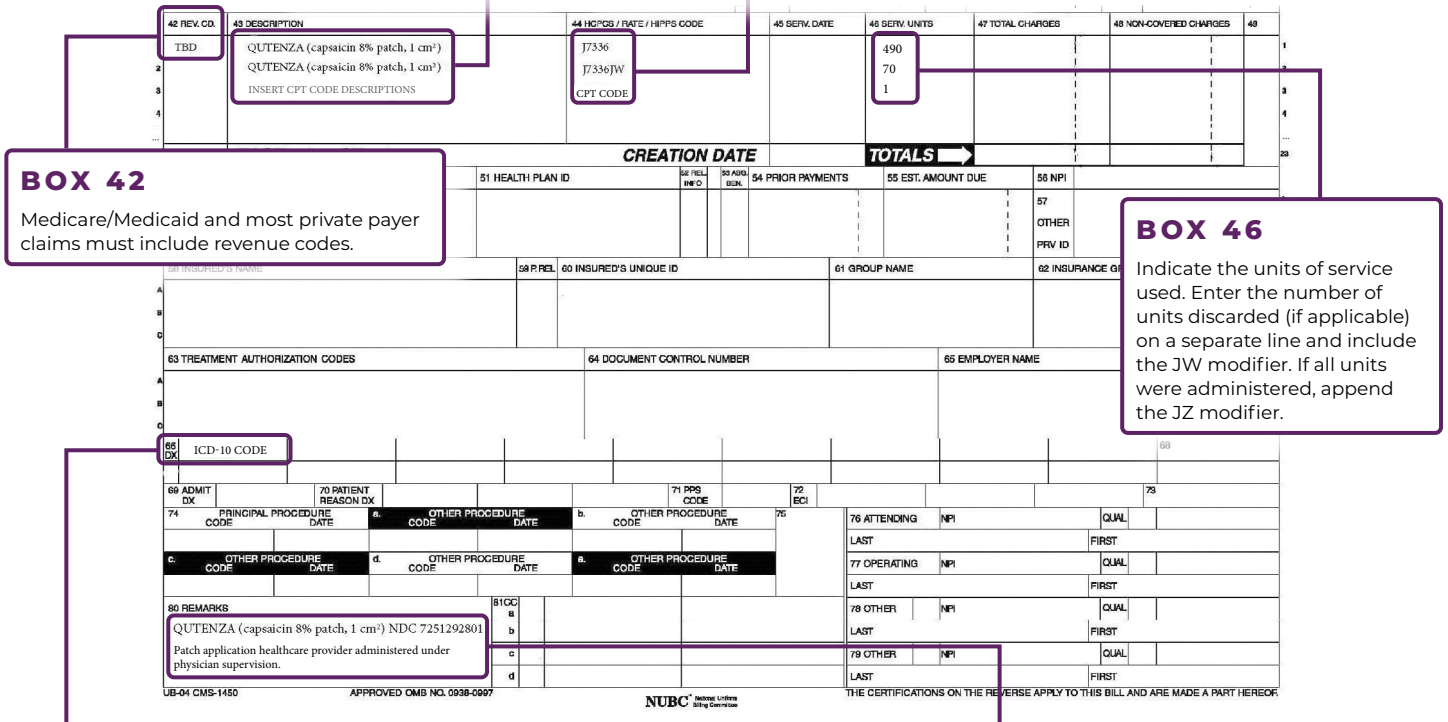
UB-04 is used for reimbursement for QUTENZA administered in an outpatient institutional setting, such as an outpatient hospital, a clinic, or an ambulatory surgical center.

BOX 43
Description or NDC must be indicated.

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

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

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. If all units were administered, append the JZ 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.

Qutenza® (capsaicin) 8% topical system

Appealing Denied Claims

Understanding the basis for a claim rejection is crucial in establishing the actions required to rectify the issue. Here are some common reasons a claim may be denied and actions one may take to overturn the decision.

Rejection 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**
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**
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**
Payer Denial	The insurance payer will not pay for the product: • Step edit, not on formulary • Investigative product	• **Prepare and submit an appeal**

MQC My Qutenza Connect

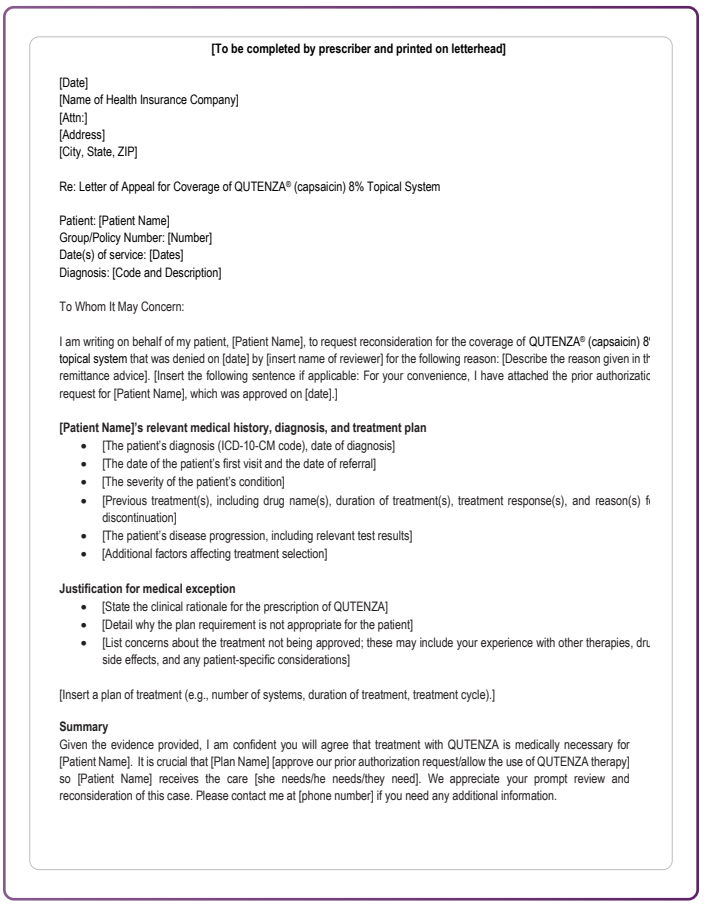
Provide your submitted claim form, the provider explanation of benefits, and the Benefits Investigation Results to your Averitas Field Access Manager or My QUTENZA Connect to help assess the nature of the denial and learn the appropriate steps to correct.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Submitting an Appeal Letter

In some cases, a denied claim can be resolved over the phone, but in other cases, the provider may need to complete and submit an appeal letter.



[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 Coverage of QUTENZA® (capsaicin) 8% Topical System

Patient: [Patient Name]
Group/Policy Number: [Number]
Date(s) of service: [Dates]
Diagnosis: [Code and Description]

To Whom It May Concern:

I am writing on behalf of my patient, [Patient Name], to request reconsideration for the coverage of QUTENZA® (capsaicin) 8
topical system that was denied on [date] by [insert name of reviewer] for the following reason: [Describe the reason given in th
remittance advice]. [Insert the following sentence if applicable: For your convenience, I have attached the prior authorizatic
request for [Patient Name], which was approved on [date].]

[Patient Name]'s relevant medical history, diagnosis, and treatment plan

- [The patient's diagnosis (ICD-10-CM code), date of diagnosis]
- [The date of the patient's first visit and the date of referral]
- [The severity of the patient's condition]
- [Previous treatment(s), including drug name(s), duration of treatment(s), treatment response(s), and reason(s) fo
  discontinuation]
- [The patient's disease progression, including relevant test results]
- [Additional factors affecting treatment selection]

Justification for medical exception

- [State the clinical rationale for the prescription of QUTENZA]
- [Detail why the plan requirement is not appropriate for the patient]
- [List concerns about the treatment not being approved; these may include your experience with other therapies, dru
  side effects, and any patient-specific considerations]

[Insert a plan of treatment (e.g., number of systems, duration of treatment, treatment cycle).]

Summary

Given the evidence provided, I am confident you will agree that treatment with QUTENZA is medically necessary for [Patient Name]. It is crucial that [Plan Name] [approve our prior authorization request/allow the use of QUTENZA therapy] so [Patient Name] receives the care [she needs/he needs/they need]. We appreciate your prompt review and reconsideration of this case. Please contact me at [phone number] if you need any additional information.

Download the Sample Letter of Appeal at QUTENZAhcp.com.

Checklist for an Appeal Letter

- **Acknowledge the reason for the denial.**
  This ensures the recipient knows that you are aware of the health plan's coverage policies.
- **Stick to the facts of the case.**
  Do not include any conjecture.
- **Know your contract.**
  To prove or support your case, refer to the relevant contract page/section/paragraph number.
- **Cite specific laws, when applicable.**
  Strengthen your points with examples of relevant regulations, such as timely filing and prompt payment laws.
- **Do the math for the plan.**
  If an underpayment was made, identify specifically what happened; some examples may include missed CPT codes, wrong payment rates, or use of modifiers indicating bilateral procedures.
- **Attach supporting documentation.**
  Types of relevant documentation include claim forms, physician notes, or records describing the rationale for any modifiers applied to the claim.
- **Write/type clearly and concisely.**
  Ensure that your arguments are reasonable, clearly articulated, and supported by the enclosed documentation; be direct and get to the point quickly without including extraneous background or other information.
- **Sign your name.**
  Include your job title.
- **Upload or e-mail documentation as directed by payer, otherwise send via USPS registered mail.**
  Copy and direct the contents of your appeal to appropriate personnel within the practice, as well as the recipient's. Save all delivery confirmation details as proof of arrival at the destination.
- **Follow up.**
  If you receive no reply, check on the status of your request after the 30-day deadline has elapsed.

This Letter of Appeal form is for educational purposes only and serves as a guide for the HCP. The HCP must modify the format of the letter and include the appropriate detail to reflect the patient's specific facts and circumstances, or to include specific information that may be required by individual payers.

CPT, Current Procedural Terminology; HCP, Healthcare Professional; USPS, United States Postal Service

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Patient Cost Savings Program

Actor portrayal

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Supporting Your Patient During Treatment

My QUTENZA Connect Cost Savings Program can help patients cover costs related to treatment with QUTENZA. Copayment assistance may be available for out-of-pocket copay or coinsurance costs related to QUTENZA prescriptions or administration costs.

MEDICATION SAVINGS

Patients pay as little as

$0 per treatment for their medication

UP TO $5,000* ANNUAL SAVINGS

*Terms and conditions may apply.

ADMINISTRATION SAVINGS

Patients pay as little as

$0 per treatment for QUTENZA administration

UP TO $1,500* ANNUAL SAVINGS

*Terms and conditions may apply.

MQC
My Qutenza Connect

Cost Savings Program

Your patient may be eligible for the QUTENZA Cost Savings Program if they:

- Are using QUTENZA for an FDA-approved use
- Are 18 years of age or older
- Have commercial (private) insurance that covers QUTENZA
- Live and receive treatment in the United States
- Do not use a state or federal healthcare plan to pay for their medication — this includes, but is not limited to, Medicare, Medicaid, and TRICARE

See full terms and conditions at QUTENZA.com/cost-savings.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Enrolling Your Office Into the Cost Savings Program

My QUTENZA Connect Cost Savings Program permits your office to enroll in the program whether you obtain QUTENZA through buy-and-bill purchase or a specialty pharmacy.

Commercially Insured Patients*

QUTENZA is obtained through **physician purchase or buy-and-bill**

May seek reimbursement from the patient's insurance for **both QUTENZA and administration costs**

QUTENZA is obtained through **specialty pharmacy**

May seek reimbursement from the patient's insurance for the drug **administration costs only†**

Obtain EOB or remittance advice

Submit claims to the portal at **PatientCostSavings.QUTENZA.com**

MQC My Qutenza Connect

To learn more about the Patient Cost Savings Program, call 833-295-3579 or register your office at PatientCostSavings.QUTENZA.com.

*Patients can self-enroll into the Cost Savings Program. Additional information on the next page.
†The specialty pharmacy will submit and process the claim for the cost of the drug with the My QUTENZA Connect Cost Savings Program listed as the patient's secondary insurance.

Qutenza® (capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 3

Patient Self-Enrolling Into the Cost Savings Program

Patients may also self-enroll in the My QUTENZA Connect Cost Savings Program by mailing a patient enrollment form. Payment may be remitted either to the patient or to the provider's office.

PATIENT COST SAVINGS ENROLLMENT FORM

Qutenza® (capsaicin) 8% topical system

MY QUTENZA CONNECT COST SAVINGS PROGRAM PATIENT ENROLLMENT FORM

Complete this form and include a copy of your EOB and Proof of Payment for QUTENZA to apply for the My QUTENZA Connect Cost Savings Program

1. Complete the information requested below and sign this form
2. Include a copy of your EOB and Proof of Payment
3. Mail your signed form, EOB and Proof of Payment to the address to the right

NOTE: Additional documentation, such as proof of billed claims or a CMS 1500 form, may be requested.

IQVIA, Inc.
Attn: Claims Processing Dept.
77 Corporate Drive
Bridgewater, NJ 08807

Assignment of benefits:

☐ If you paid your bill in full prior to the procedure and want the remittance check sent directly to you, **check this box and complete Section A only.** Proof of payment is required.

☐ If you did not pay your bill prior to the procedure and need the remittance payment sent directly to your provider's office, **check this box and complete Section A. NOTE: Section B must be completed by your provider.**

A. PATIENT TO COMPLETE **Fill out the patient information section and submit this form with a copy of your EOB and Proof of Payment.**

First name: _____ Last name: _____

Date of birth: ____/____/____ Phone: _____ Email: _____

Address: _____

City: _____ State: _____ Zip: _____

Signature: _____ Date: ____/____/____

☐ By signing above, you attest that the information provided in this claim is accurate, that expenses requested for payment here were eligible, actually incurred, and that they were not and will not be paid by your insurance, Flexible Spending Account (FSA), Health Savings Account (HSA) or any other payer. You attest that you are not covered under Medicare, Medicaid, Medigap, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD), or any other government (state or federally-funded) program, and you understand that you are liable for any misrepresentations herein to the full extent of applicable law. You attest that the use of QUTENZA is for an FDA-approved use, specifically diabetic nerve pain of the feet or post-shingles nerve pain. Please see page 2 for full Eligibility Criteria, Terms, and Conditions.

HEALTHCARE PROVIDER DIRECTIONS

Complete the treatment details in the section below, including the total amount(s) billed to insurance, in order to allow the patient to submit the form. By completing Section B below, you understand that payment will be remitted directly to you and not the patient.

B. PROVIDER TO COMPLETE **Provider to complete in order to remit payment directly to the provider, and not the patient.**

Proof of Treatment

Medication Administration ☐ **Yes** ☐ **No** Date of QUTENZA Treatment: ____/____/____

CPT code billed: _____ Total amount billed for administration $ _____

Proof of QUTENZA

☐ **QUTENZA J7336** Total amount billed to insurance for QUTENZA $ _____ ☐ **Specialty pharmacy utilized**

Authorized office staff name: _____ Signature: _____

☐ By signing above, you attest that the information provided in this claim is accurate, that expenses requested for payment here were eligible, actually incurred, and that they were not and will not be paid by the patient's insurance, Flexible Spending Account (FSA), Health Savings Account (HSA) or any other payer. You attest that the patient is not covered under Medicare, Medicaid, Medigap, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD), or any other government (state or federally-funded) program, and you understand that you are liable for any misrepresentations herein to the full extent of applicable law. You attest that the use of QUTENZA is for an FDA-approved use, specifically diabetic nerve pain of the feet or post-shingles nerve pain. Please see page 2 for full Eligibility Criteria, Terms, and Conditions.

Administering HCP name: _____ Practice NPI #: _____ Date: ____/____/____

Address: _____

City: _____ State: _____ Zip: _____ Office phone: _____

QUTENZA Savings Program is used only in conjunction with a commercial payer | Questions? Call 833-295-3579

The categories of personal information collected in this form include name, date of birth, and treatment details. The personal information collected will be used for enrollment form submission and eligibility approval for QUTENZA Savings Program and to perform research analytics on a de-identified basis. For more information about the categories of personal information collected by Averitas and the purposes for which Averitas uses personal information visit: https://www.averitaspharma.com/privacy-statement/.

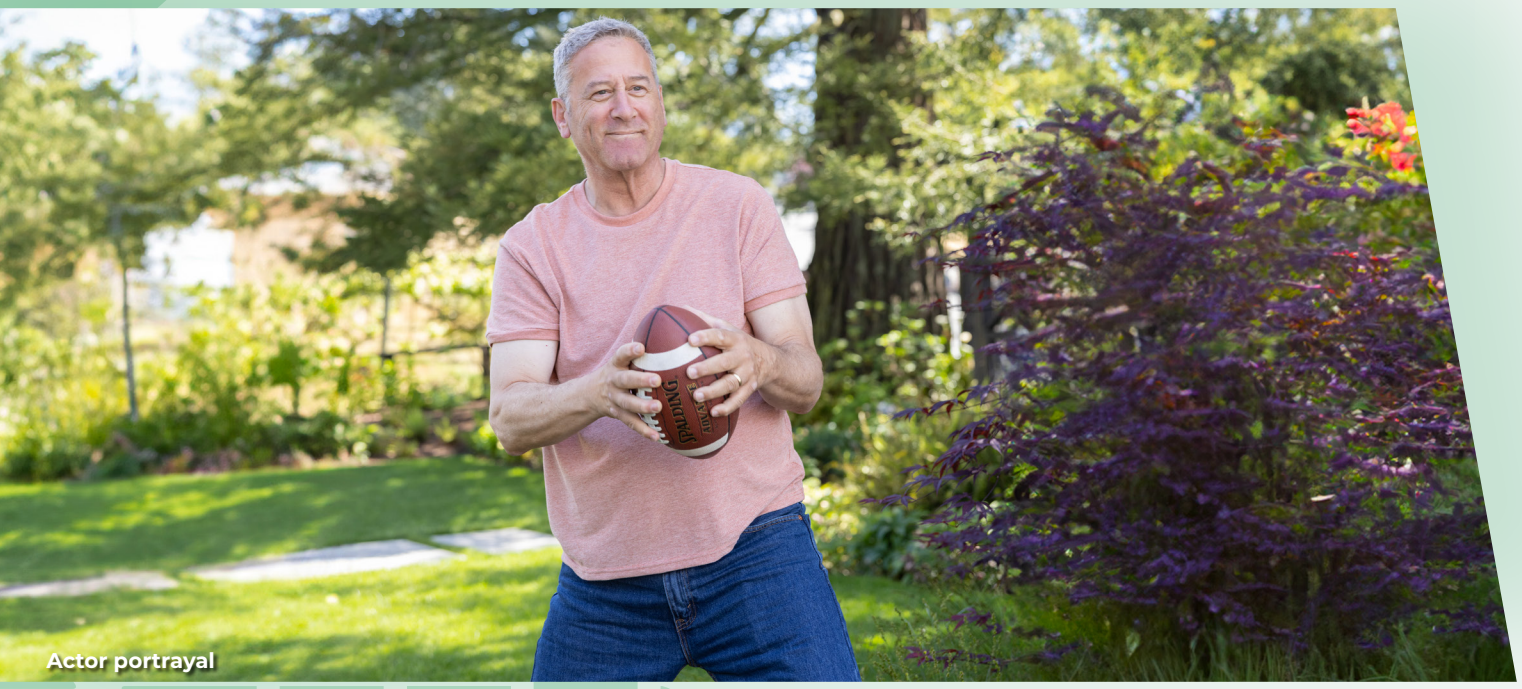
pg. 1 of 2

QZA-11-23-0016 v1.0 January 2024

Download the Patient Enrollment Form at QUTENZAhcp.com

Qutenza® (capsaicin) 8% topical system

Frequently Asked Questions



Actor portrayal

Please see full Prescribing Information as well as Important Safety Information on page 3

Frequently Asked Questions

Why doesn't QUTENZA have a specific procedure code?

CPT codes, or Current Procedural Terminology codes, are a set of medical codes used by healthcare providers to document and bill for procedures and services. They are part of a standardized system developed by the American Medical Association to ensure uniformity in the reporting and billing of medical, surgical, and diagnostic services across the healthcare industry. CPT codes are designed primarily to cover procedures, services, and tests rather than the specific products (such as drugs) used within those procedures. Claims processing systems are capable of linking the CPT code to product-specific codes (e.g., Healthcare Common Procedure Coding System codes), as needed.

What procedure code should I use?

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

HCPs may need to consider several factors to ensure accurate billing and coding for services provided. How a procedure is performed, and how complex that procedure is, may determine the appropriate code to select. Also, please note that there may be different codes associated with where exactly on the body the procedure is performed. Finally, the use of modifiers may be appropriate as explained above. Adhering to these guidelines will assist in achieving precise billing and securing appropriate reimbursement for healthcare services.

What documentation should I submit when seeking reimbursement using an unlisted CPT code?

Unlisted codes do not correspond to a specific procedure or service. In instances where an unlisted code is utilized, your office may be required, depending on the insurer, to furnish detailed information about the procedure. This may include a comprehensive description of the procedure itself, the amount of time it took, the level of effort expended, and the equipment necessary to perform the service. Additionally, you might be asked to identify a comparable procedure with an existing CPT code. Some insurers may specify which existing code to use for comparison, while others will leave it to your discretion to choose the most analogous listed code. The insurer will then assess the similarities and differences between your provided description and the comparable listed procedure to determine the appropriate reimbursement for the unlisted code.

May I obtain QUTENZA from a local specialty pharmacy?

QUTENZA is available via an authorized specialty pharmacy network. Please contact My QUTENZA Connect or the specialty pharmacy directly to determine if QUTENZA is available.

How long will it take for claims from the My QUTENZA Connect Cost Savings Program to be processed?

It may take up to 4 weeks for the claim to be processed.

I received a denial because we administered the drug when the prior authorization was "pending." Now what do we do?

For more information on appealing claims, contact your Averitas Field Access Manager or My QUTENZA Connect.

REFERENCES:

1. Centers for Medicare & Medicaid Services (CMS). Who Are the MACs. https://www.cms.gov/files/document/ ab-jurisdiction-map03282023pdf.pdf. Published March 28, 2023. Accessed August 11, 2023.

2. Centers for Medicare & Medicaid Services (CMS). New JZ Claims Modifier for Certain Medicare Part B Drugs: MLN Matters Number: MM13056. https:// www.cms.gov/files/document/mm13056-new-jz-claims-modifier-certain-medicare-part-b-drugs.pdf. Published June 2, 2023. Accessed June 20, 2023.

Qutenza® (capsaicin) 8% topical system

Qutenza®

(capsaicin) 8% topical system

QZA-02-24-0005 v1.0 February 2024

Averitas
A Grünenthal Company