Access Toolkit

Your guide to navigating coverage, reimbursement, and patient affordability—every step of the way.

Averitas
A Grünenthal Company

MQC
My Qutenza Connect

Through My QUTENZA Connect (MQC), Averitas offers resources for your practice to support your patients.

Some MQC resources require practice enrollment and are noted throughout.

MQC Benefit Investigation (BI) Portal

Enrollment required: Obtain information about patient coverage to efficiently track next steps for your patients.

Patient Support Services

Enrollment required:

- Patient Care Coordinators help navigate access and Cost Savings Program eligibility.
- QUTENZA Nurse Specialists support adherence through education and treatment reminders.

Patient Cost Savings Program

Eligible patients who are commercially insured may pay as little as $0 for QUTENZA medication and in-office application.*

Resources

Materials to help you efficiently manage every step of the process—from BI submission forms and results to communicating with patients.

*Up to $5,000 in annual savings for medication and $1,500 in annual savings for administration. Savings are available only for eligible patients with commercial insurance. Patients cannot be reimbursed or receive coverage through federal or state healthcare programs. See full terms and conditions at QUTENZAhcp.com.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Your Access Roadmap

MQC
My Qutenza Connect

For support, contact MQC
Phone: 855-802-8746 Fax: 855-454-8746
Your Averitas Field Access Manager can also assist with patient-specific case review.

Benefit Investigation (BI) Portal

Leverage the expertise of MQC by enrolling in the BI Portal.

REQUEST A BI, INCLUDING:

- Payer coverage requirements
- Claims and submission guidance
- Acquisition pathways (eg, Buy & Bill, specialty pharmacy)
- Cost savings options

GET CURRENT STATUS:

- Monitor patient case information and receive status updates through the portal
- Live chat with your MQC Case Manager
- Connect with your Averitas Field Access Manager

GET THE ANSWERS YOU NEED:

- Does the payer have a maximum number of applications?
- Does the payer have a specific medical policy pertaining to QUTENZA, and if so, can they provide a link to the publicly available policy?
- Does the patient have any coverage limitations or policy exclusions that apply to QUTENZA?
- Is further documentation required?

Remember to always verify benefits prior to initiating treatment.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Benefit Investigation (BI) Portal (cont'd)

MQC delivers **rapid and reliable BI results**

~90%

of BIs indicated QUTENZA coverage in 2025

—with results in 1 to 2 business days.[1]
Subject to change.

ONE-ON-ONE SUPPORT FOR YOUR PATIENTS

When your practice enrolls patients via the BI Portal, they are eligible to receive support from our:

- **Patient Care Coordinators (PCC)**
  A PCC will reach out after coverage verification to discuss coverage and eligibility for the Patient Cost Savings Program.
- **QUTENZA Nurse Specialists (QNS)**
  A QNS will contact the patient directly to introduce QUTENZA, answer treatment-related questions, confirm scheduling, and provide follow-up reminders.

Reference: 1. Averitas Pharma, Inc. Data on file. My QUTENZA Connect (MQC), 2025.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Interpreting BI Results

An MQC Reimbursement Case Manager will provide a **BI Summary of Benefits**. Important sections of the form are highlighted below. For more information about each section, download the Quick Guide.

- Summarizes patient's insurance coverage
- Details Patient Cost Savings Program eligibility

Indication | 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

Cost savings program details and eligibility requirements are available at QUTENZAhcp.com.

- Provides details about the patient's:
  - Primary medical plan
  - Prior authorization
  - Referral requirements
  - In-network status
  - Copay/deductible
- Provides direction for next steps

PRIMARY MEDICAL BENEFITS (BUY & BILL)						
Insurance Company		**Member ID**		**Group Number**		Effective Date
Plan Type		Payer Contact		Payer Phone		Provider in Network ⊙ Is in Network ⊙ Is **Not** in Network
J7336 Coverage % of allowable amount	%	J7336 Copay	$	Deductible	$	Prior Auth Needed for J7336 ⊙ Yes ⊙ No
Administration Coverage % of allowable amount	%	Administration Copay	$	Deductible Met	$	Prior Auth Needed For Administration ⊙ Yes ⊙ No
Office Coverage % of allowable amount	%	Office Copay	$	Deductible Remaining	$	PCP Referral Required ⊙ Yes ⊙ No
Additional instructions:						

BI results are 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.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Interpreting BI Results (cont'd)

- Provides details about patients on secondary insurance, when applicable

SECONDARY OR SUPPLEMENTAL MEDICAL BENEFITS							
Insurance Company		**Member ID**		**Group Number**		Effective Date	
Plan Type		Payer Contact		Payer Phone		Provider in Network ◉ Is in Network ◉ Is **Not** in Network	
J7336 Coverage % of allowable amount	%	J7336 Copay	$	Deductible	$	Prior Auth Needed for J7336 ◉ Yes ◉ No	
Administration Coverage % of allowable amount	%	Administration Copay	$	Deductible Met	$	Prior Auth Needed For Administration ◉ Yes ◉ No	
Office Coverage % of allowable amount	%	Office Copay	$	Deductible Remaining	$	PCP Referral Required ◉ Yes ◉ No	
Additional instructions:							

Identifies:

- Pharmacy Benefit Manager
- Prior authorization requirements
- Copay/deductible

PHARMACY BENEFITS (SPECIALTY PHARMACY)			
Insurance Company	**Member ID**	Group Number	
Pharmacy Benefit Manager	Prior Authorization Needed For National Drug Code ◉ Yes ◉ No	Prior Authorization Needed For Administration ◉ Yes ◉ No	Medication Copay
Additional instructions:			

- Provides information regarding mandated or in-network pharmacies

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

Quick Guide: Understanding Your BI Results bit.ly/QTZBIQuickGuide

BI results are 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.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Prior Authorization

The benefit investigation will alert your practice if prior authorization is needed.

You may request prior authorization for up to 4 applications or a year of treatment, rather than submitting a new request in advance of each treatment.

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

Customizable resources to streamline the prior authorization process:

PATIENT CHART DOCUMENTATION

Captures important information that may be required, such as diagnosis code, numerical pain rating scale score, and A1C level.

Patient Chart Documentation bit.ly/QTZPatientChartDoc

SAMPLE LETTERS OF MEDICAL NECESSITY

Customizable templates for patients new to QUTENZA or those continuing with treatment.

Letters of Medical Necessity bit.ly/QTZLOMN

Template Letters of Medical Necessity are for informational purposes only and serve as a guide for the HCP. The HCP must customize the letter according to their clinical judgment 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.

Step Edits

The benefit investigation confirms whether the patient's health plan requires a step edit.

Payers may require documentation of the patient's treatment history, including trial of prior oral agents, inadequate response, or intolerance to other treatments.

Some plans may consider exception requests based on patient-specific factors, such as contraindications, safety concerns, insufficient pain relief, fall risks, or inability to tolerate prior therapies.

MQC can provide information regarding payer-required documentation.

Coverage requirements, including step edits, vary by payer and may change. Refer to the BI Results Form for patient-specific details. Averitas Pharma does not determine or influence payer coverage policies.

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Acquiring & Prescribing QUTENZA

There are 2 ways to order—through a specialty distributor (Buy & Bill) or via a specialty pharmacy.

The BI Results Form will clarify the best way to acquire QUTENZA based on the patient's coverage.

1 THROUGH A SPECIALTY DISTRIBUTOR (BUY & BILL)

Choose from a participating specialty distributor below. If you do not have an account with the distributor, you can visit their website to create one before placing an order.

Authorized Specialty Distributor	Contact Information	Website
ASD Medical (Cencora)	**Phone:** 800-746-6273 **Fax:** 800-547-9413	asdhealthcare.com
Besse Medical (Cencora)	**Phone:** 888-767-7123 **Fax:** 800-543-8695	besse.com/home
Cardinal Health Specialty Distribution	**Phone:** 877-453-3972 **Fax:** 888-345-4916	cardinalhealth.com
Curascript Specialty Distribution	**Phone:** 877-599-7748 **Fax:** 800-862-6208	curascriptsd.com
McKesson Medical-Surgical	**Phone:** 855-571-2100 **Fax:** 800-311-3408	mms.mckesson.com
McKesson Plasma & Biologics	**Phone:** 877-625-2566 **Fax:** 888-752-7626	connect.mckesson.com
McKesson Specialty Health	**Phone:** 855-477-9800 **Fax:** 800-800-5673	mscs.mckesson.com

Please see full Prescribing Information as well as Important Safety Information on page 25.

Acquiring & Prescribing QUTENZA (cont'd)

2 THROUGH A SPECIALTY PHARMACY

Prescribers may use a specialty pharmacy of their choosing—however, some payers may require a specific specialty pharmacy.

When applicable, prescriptions may be transferred from MQC to CenterWell, our contracted specialty pharmacy for dispensing.

Contact CenterWell with general questions or to transfer a prescription:
Phone: 800-486-2668
Monday–Friday: 8 AM to 11 PM ET | Saturday: 8 AM to 6:30 PM ET
centerwellpharmacy.com/support

Prescribing QUTENZA

Be sure to include the following information:

- **Diagnosis:** Painful DPN of the feet or PHN
- **Quantity:** Up to 4 topical systems per treatment
  - Most patients with bilateral foot involvement require 2 topical systems **per foot**.
- **Refill:** Up to 3 refills per year, a total of 4 treatments over 12 months

Packaging	• One topical system • One 50-g tube of post-application Cleansing Gel	• Two topical systems • One 50-g tube of post-application Cleansing Gel	• Four topical systems • Three 50-g tubes of post-application Cleansing Gel
NDC	**NDC #72512-928-01**	**NDC #72512-929-01**	**NDC #72512-930-01**
Strength	Contains 8% capsaicin (640 mcg per cm^2). Each topical system contains a total of 179 mg of capsaicin.		

Please refer to the full Prescribing Information for storage and handling instructions.

NDC: National Drug Code.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Billing and Coding

After administering QUTENZA, claims may be submitted for the product and/or administration based on payer requirements. The information in this section reviews some of the codes commonly associated with QUTENZA and its administration.

QUTENZA TOPICAL SYSTEM CODING

HCPCS codes (J7336)	
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.[1]

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)

Each topical system is billed in units (cm^2)

1 topical system = 280 units	2 topical systems = 560 units
3 topical systems = 840 units	4 topical systems = 1120 units

DIAGNOSIS CODING

ICD-10-CM codes | Postherpetic neuralgia – PHN

The following primary diagnosis codes may be appropriate to describe patients with postherpetic neuralgia (PHN):

B02.23	Postherpetic polyneuropathy
B02.29	Other postherpetic nervous system involvement

The content in this section is for informational purposes only and does not guarantee coverage/reimbursement. Coverage, coding, and reimbursement requirements vary by payer. The provider must exercise their independent professional judgment in selecting the appropriate codes; it is always the provider's responsibility to determine the appropriate codes, modifiers, and billing pathways for each patient and to ensure that submissions accurately reflect the services performed and documentation captured in the medical record.

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

Reference: 1. 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.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Billing and Coding (cont'd)

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

PROCEDURE AND EVALUATION & MANAGEMENT CODING

CPT codes*	
17999	Other procedures on the integumentary system
64632	Destruction by neurolytic agent; plantar common digital nerve
64640	Destruction by neurolytic agent; other peripheral nerve or branch
64999	Other procedures on the nervous system

Evaluation and management coding*	
99213	Patient office visit, 20-29 minutes
99214	Established patient office visit, 30-39 minutes
99215	High complexity office visit, 40-54 minutes
G0463	Hospital outpatient clinic visit for patient assessment

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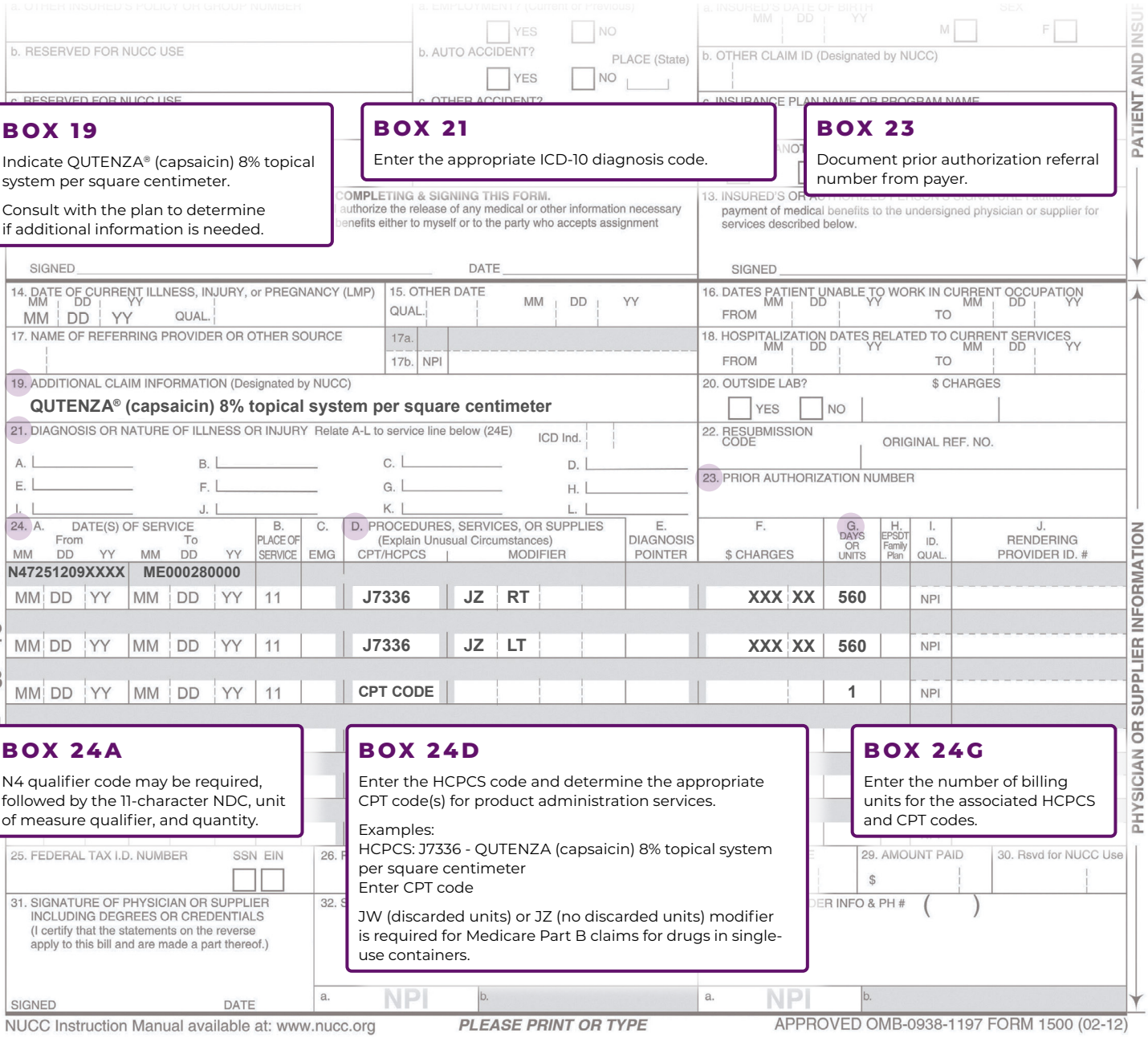
CPT: current procedural terminology

*Please note that the use of modifiers may be appropriate. There is no CPT or other code specific to the administration of QUTENZA. This list was derived from external sources and does not reflect an exhaustive list of codes that may be associated with the administration of QUTENZA.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Sample Reimbursement Forms

Completing the CMS-1500 for QUTENZA Administration in Physician Offices



BOX 19

Indicate QUTENZA® (capsaicin) 8% topical system per square centimeter.

Consult with the plan to determine if additional information is needed.

BOX 21

Enter the appropriate ICD-10 diagnosis code.

BOX 23

Document prior authorization referral number from payer.

BOX 24A

N4 qualifier code may be required, followed by the 11-character NDC, unit of measure qualifier, and quantity.

BOX 24D

Enter the HCPCS code and determine the appropriate CPT code(s) for product administration services.

Examples:
HCPCS: J7336 - QUTENZA (capsaicin) 8% topical system per square centimeter
Enter CPT code

JW (discarded units) or JZ (no discarded units) modifier is required for Medicare Part B claims for drugs in single-use containers.

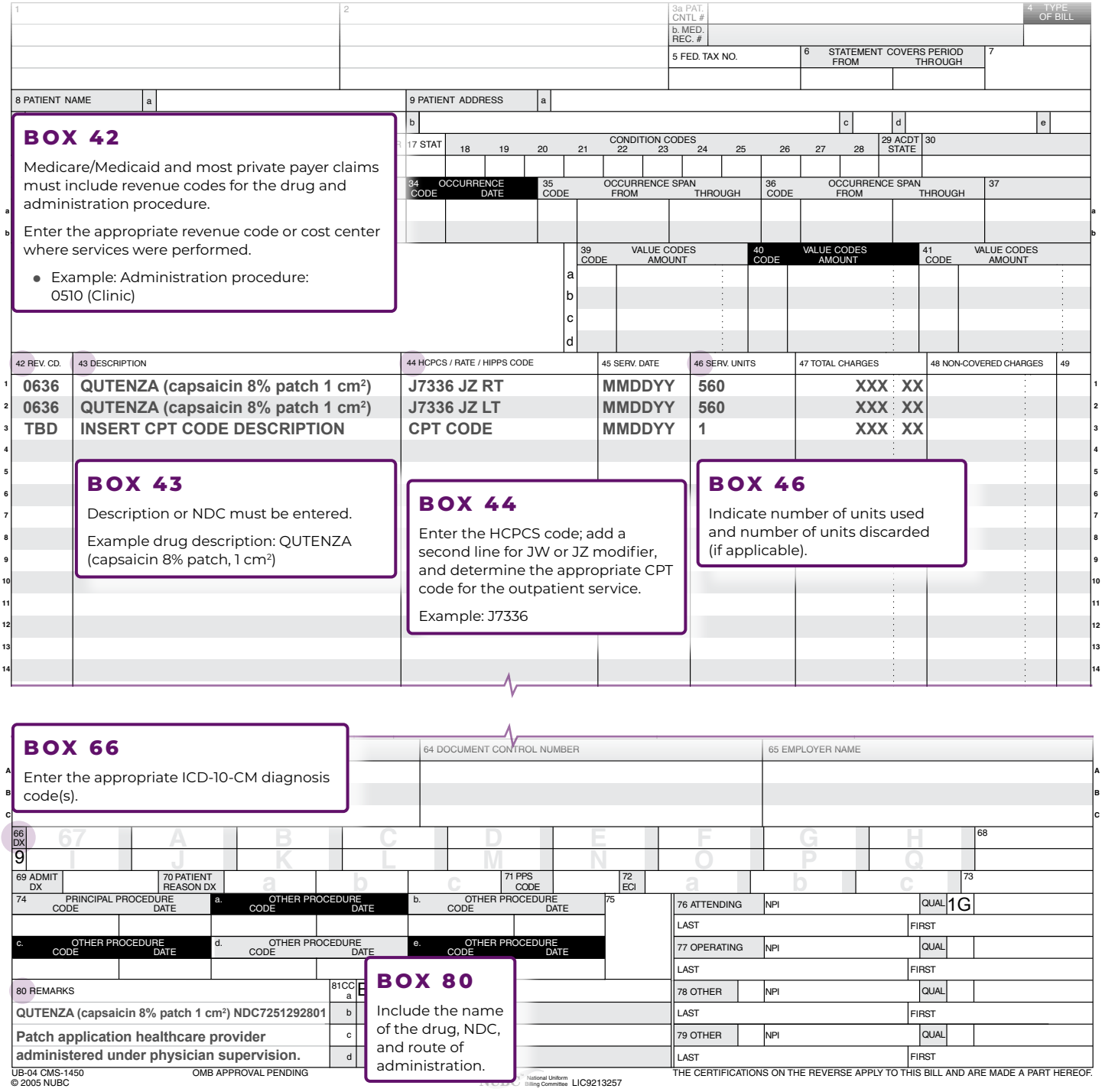
BOX 24G

Enter the number of billing units for the associated HCPCS and CPT codes.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Sample Reimbursement Forms (cont'd)

Completing the CMS-1450 (UB-04) for QUTENZA Administration in the Outpatient Hospital



Electronic Medical Record Systems Best Practices

When using an Electronic Medical Record (EMR) system, providers should follow applicable guidelines to help ensure the integrity and accuracy of the medical records.

✓ CHECKLIST FOR DOCUMENTATION OF BILLING AND REIMBURSEMENT

Confirm the following before claim submission:

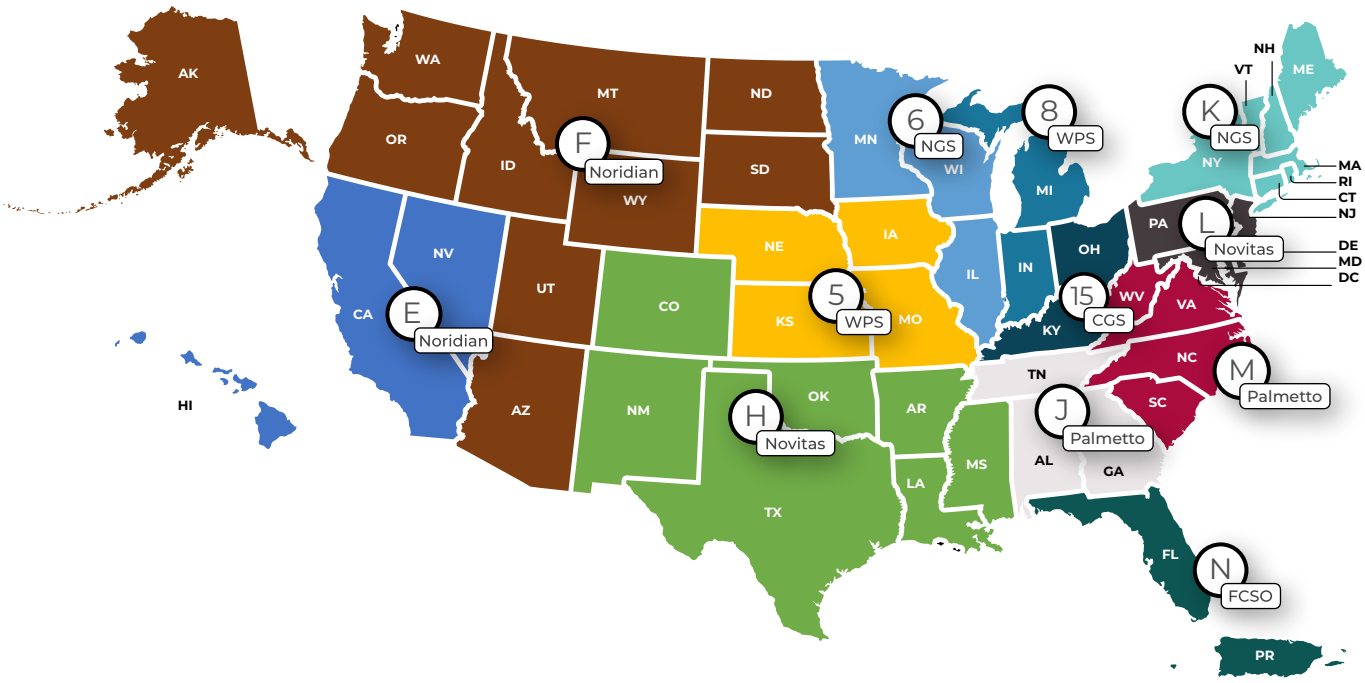
- ☐ Diagnosis on claim matches clinical documentation
- ☐ CPT/procedure code is correct
- ☐ HCPCS/J-code or NDC included (if required)
- ☐ Each topical system is billed in units (cm^2)
  - 1 topical system = 280
  - 2 topical systems = 560
  - 3 topical systems = 840
  - 4 topical systems = 1120
- ☐ POS correct for site of care
- ☐ Authorization on file (if required)
- ☐ Documentation supports medical necessity

Best Practice Reminder: Consistent documentation across notes, orders, and charges is the most effective way to reduce denials and payment delays.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Questions on Medicare Part B Claims Submission?

Medicare has established provider contact centers to address questions about any product or service prior to submitting a claim.



MAC Provider Services Phone Numbers by Jurisdiction

Jurisdiction	IVR
5	866-518-3285
6	877-309-4290
8	866-234-7331
15	866-290-4036

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

Jurisdiction	IVR
K	877-567-7205
L	877-235-8073
M	855-696-0705
N	877-847-4992

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Claim Denials

MQC can guide your practice through a claim denial.

COMMON REASONS FOR DENIAL	HOW TO FIX
Technical • Incorrect patient ID or signatures • Transposed numbers or incorrect units	**Correct and resubmit within filing window**
Billing • Incorrect service codes, duplicate claim, invalid code • Incorrect units or unbundled services	**Verify ICD-10, CPT/HCPCS, modifiers; confirm bilateral documentation**
Medical Necessity • Documentation doesn't support diagnosis or necessity	**The Letter of Medical Necessity templates can help with documentation of chart notes (eg, medical history, symptom duration, and prior therapies)**
Payer Denial • Step edits; nonformulary status; insufficient or incomplete documentation	**Check the BI Portal and appeal with supporting data and chart notes. The Letter of Appeal template is available and can be customized to help complete your documentation**

Please see full Prescribing Information as well as Important Safety Information on page 25.

Claim Denials (cont'd)

Use the **Letter of Appeal** template to tailor specific patient or payer information.

Letter of Appeal bit.ly/QTZLoA

This Letter of Appeal template is for informational 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.

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Patient Cost Savings Program

Averitas is committed to helping appropriate patients start and stay on therapy.

The Patient Cost Savings Program provides your practice with information and tools to help support prescription access, whether your practice purchases QUTENZA (Buy & Bill) or a specialty pharmacy is utilized.

IF YOUR PRACTICE USES BUY & BILL

- **Enroll in the Patient Cost Savings Program*** to apply eligible savings for both the medication and administration directly to the patient's office bill—no additional steps for the patient.

  Visit: bit.ly/QTZCSPortal

IF YOUR PRACTICE USES A SPECIALTY PHARMACY

- **A Copay ID can be generated** by the pharmacy or your patient. The pharmacy will apply the savings to the patient's prescription and notify them of any out-of-pocket expense.†
- If your patient generates the Copay ID, advise them to share it with the specialty pharmacy when they call to confirm shipment to your office.

  Visit: bit.ly/QTZCopayID

Has Your Patient Already Paid Out-of-Pocket?
If eligible, they can get reimbursed for QUTENZA or the administration cost by submitting a Patient Reimbursement Request Form.

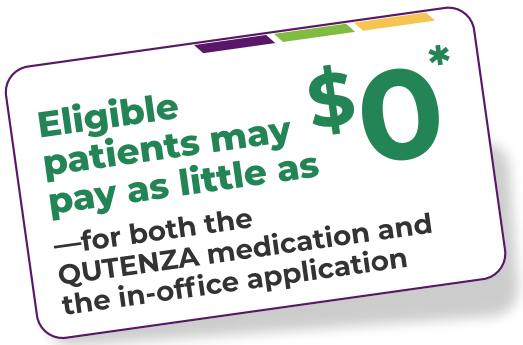
bit.ly/QTZCopayRequest

*Up to $5,000 in annual savings for medication and $1,500 in annual savings for administration. Savings are available only for eligible patients with commercial insurance. Patients cannot be reimbursed or receive coverage through federal or state healthcare programs. See full terms and conditions at QUTENZAhcp.com.
†The specialty pharmacy will submit and process the claim for the cost of the drug with the Patient Cost Savings Program listed as the patient's secondary insurance.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Patient Cost Savings Program (cont'd)

98% of eligible patients who enrolled in the Cost Savings Program had a $0 copay in 2025[1]



Eligibility Criteria

Your patient may be eligible for the Patient 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, Medicare Part D or Medicare Advantage, Medicaid, and TRICARE

*Up to $5,000 in annual savings for medication and $1,500 in annual savings for administration. Savings are available only for eligible patients with commercial insurance. Patients cannot be reimbursed or receive coverage through federal or state healthcare programs. See full terms and conditions at QUTENZAhcp.com.

Reference: 1. Averitas Pharma, Inc. Data on file. My QUTENZA Connect (MQC), 2025.

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“Going Live” with QUTENZA

Use this checklist to ensure your practice is ready to start treating appropriate patients with QUTENZA.

✓ BEFORE TREATMENT

- ☐ Coverage, billing, and reimbursement requirements confirmed.
  - Refer to BI results, PA status, and payer-specific coding requirements.
- ☐ Topical systems secured through specialty distributor (Buy & Bill) or delivery arranged via specialty pharmacy.
- ☐ QUTENZA EMR system built out.
- ☐ Patient scheduled and prepared.
  - Visit **QUTENZAhcp.com** for resources to help the patient understand what to expect during and after application.
  - Enter patient’s scheduled treatment date into MQC.

✓ AFTER TREATMENT

- ☐ Claim submitted within 24 to 48 hours post application.
  - Confirm documentation, codes, and modifiers reflect payer requirements.
  - Enter actual patient treatment date into MQC.

✓ FOLLOW-UP

- ☐ Monitor reimbursement timelines based on payer requirements.
  - Address any payer requests for additional information.
- ☐ Schedule Explanation of Benefits (EOB) review with Averitas Field Access Manager.

✓ CLINIC/HOSPITAL CONSIDERATIONS - ENSURE THAT:

- The QUTENZA order set meets facility requirements and is built correctly in the EMR.
- The chargemaster is built and completed.
- The system-wide or specialty-specific codes are correct.
- Relative Value Units (RVUs), if applicable, are established and in the system.
- Staff has completed training covering ordering, documentation, billing, and workflow expectations.

Please see full Prescribing Information as well as Important Safety Information on page 25.

Access resources at your fingertips

You don't have to do it on your own. Through MQC, Averitas Pharma offers information and resources to help your patients get started on QUTENZA.

Find the resources included in this kit at **bit.ly/QTZAccessMaterials**

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Important Note on Coverage and Reimbursement

This content is for informational purposes only and does not guarantee coverage/reimbursement. Coverage and reimbursement for QUTENZA may vary by plan. Averitas makes no representations about the information provided, as requirements may change without notice.

Any resources provided by Averitas, including this toolkit, are for educational purposes only and are not intended to be conclusive or exhaustive. This information should not replace the guidance of qualified reimbursement or legal professionals. The HCP or appropriate office personnel—not Averitas—must exercise their independent professional judgment to determine the correct coding, billing, and reimbursement approach for each patient.

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 Toolkit is current as of February 2026.

Please see full Prescribing Information as well as Important Safety Information on page 25.

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 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. Assess for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory loss occurs, treatment should be reconsidered.
- **Severe Application Site Burns:** Full-thickness (third-degree) and deep partial-thickness (second-degree) burns have been reported following administration of QUTENZA. Cases of full-thickness (third-degree) burns, requiring hospitalization and skin grafting have been reported in patients who received QUTENZA for an unapproved indication and/or frequency of dosing at an application site where there had been prior skin trauma. Ensure that dosage and administration recommendations are followed.

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.

Qutenza®
(capsaicin) 8% topical system

Please see full Prescribing Information as well as Important Safety Information on page 25.

Qutenza®

(capsaicin) 8% topical system

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