MQC
My Qutenza Connect

Qutenza®
(capsaicin) 8% topical system

Actor portrayal

REIMBURSEMENT GUIDE

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

Averitas
A Grünenthal Company

TAP INTO ALL MQC HAS TO OFFER

MQC provides tools and resources for your QUTENZA patients and your practice.

REIMBURSEMENT SUPPORT

Plan-specific requirements for reimbursement:

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

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

My QUTENZA Connect Cost Savings Program can help cover costs related to treatment with QUTENZA.

Register your practice with MQC at MyQUTENZAConnect.com

Help your patients save on their QUTENZA® (capsaicin) 8% topical system treatment.

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.

*See full Terms and Conditions at www.QUTENZAHCP.com/access-and-savings/patient-savings/.

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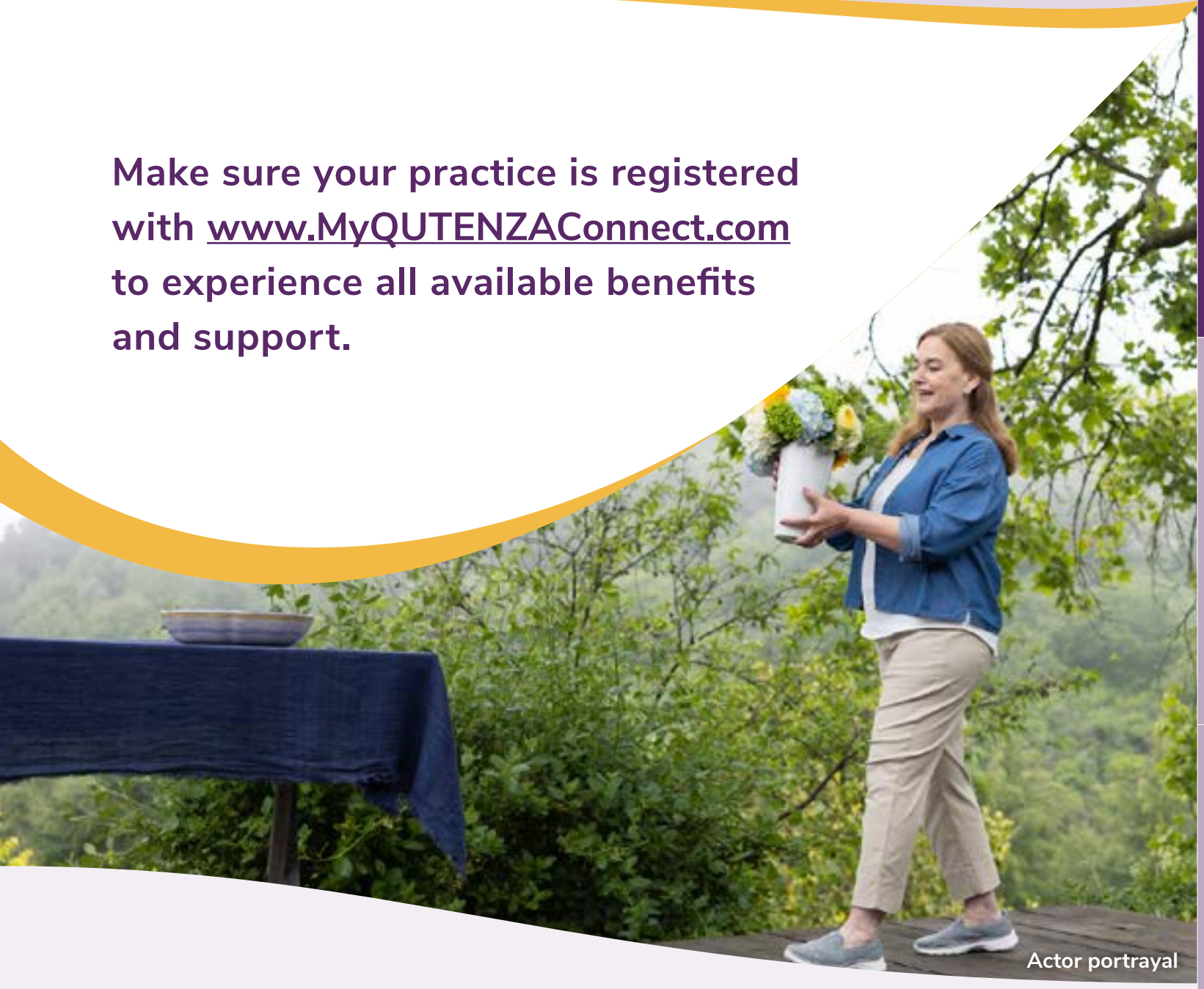
Make sure your practice is registered with www.MyQUTENZAConnect.com to experience all available benefits and support.


Actor portrayal

Eligibility

The program may apply toward any copay, coinsurance, and deductible for QUTENZA.†

Your patients may be eligible for the 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

Visit the website to learn more

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

Qutenza® (capsaicin) 8% topical system

PRODUCT INFORMATION

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

Ongoing treatment can help deliver ongoing relief. Keep QUTENZA treatments scheduled **once every 3 months** for patients with painful DPN.

QUTENZA is the first and only prescription-strength capsaicin product targeted at the TRPV1-expressing nociceptive nerve fibers in the skin.

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information on page 15.

Qutenza®
(capsaicin) 8% topical system

Packaging	**NDC #72512-928-01** Kit (carton) contains one (1) single-use topical system and one (1) 50 g tube of Cleansing Gel	**NDC #72512-929-01** Kit (carton) contains two (2) single-use topical systems and one (1) 50 g tube of Cleansing Gel	**NDC #72512-930-01** Kit (carton) contains four (4) single-use topical systems and three (3) 50 g tubes of Cleansing Gel
Strength	Contains 8% capsaicin (640 mcg per cm^2). Each QUTENZA topical system contains a total of 179 mg of capsaicin.		
Ordering information	QUTENZA is available through select specialty distributors or through specialty pharmacy ordering. **Specialty Distributors:** ASD Healthcare® 1-800-746-6273 Besse® Medical 1-800-543-2111 Cardinal Health™ 1-877-453-3972 CuraScript SD® 1-877-599-7748 McKesson Specialty Health 1-855-477-9800 McKesson Medical-Surgical 1-855-571-2100 **Specialty Pharmacy:** My QUTENZA Connect will recommend a specialty pharmacy partner.		
Storage guidelines	Store between 20°C and 25°C (68°F and 77°F). Excursions between 15°C and 30°C (59°F and 86°F) are allowed. Keep the topical system in the sealed pouch until immediately before use.		

IMPORTANT NOTE

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

For more information about reimbursement support, call My QUTENZA Connect at 855-802-8746 or please visit https://www.qutenza.com/hcp/request-a-rep/. The information in this Reimbursement Guide is intended solely as a resource to assist the staff in physicians' offices and hospitals with certain reimbursement-related questions about QUTENZA. Averitas Pharma makes no representation about the information provided, as reimbursement information for QUTENZA, including applicable policies and laws, is subject to change without notice. This Reimbursement Guide is not conclusive or exhaustive and is not intended to replace the guidance of a qualified, professional advisor. The appropriate staff member of a physician's office or hospital, not Averitas Pharma, determines the appropriate method of seeking reimbursement based on the medical procedure performed and any other relevant information. **Averitas Pharma does not recommend or endorse the use of any particular diagnosis or procedure code(s), and makes no determination regarding if or how reimbursement may be available. The use of this information does not guarantee payment or that any payment received will equal a certain amount.**

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

Qutenza® (capsaicin) 8% topical system

These codes are provided for educational purposes only and do not guarantee payment. This is not an exhaustive list of available codes. Coding and coverage policies change periodically and often without warning. Consult with your local payer or Medicare Administrative Contractor (MAC) for appropriate coding of QUTENZA treatment. Payers may have differing or additional guidance and requirements. **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) (Box 24D)	**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 (Box 19)	FDA lists NDCs in a 10-digit format, but payers often require an 11-digit NDC format for electronic claim forms. Review payer-specific requirements prior to submitting a claim.	
	72512-0928-01	(1 topical system and Cleansing Gel)
	72512-0929-01	(2 topical systems and Cleansing Gel)
	72512-0930-01	(4 topical systems and Cleansing Gel)
Additional claim information (Box 19)	Please consult with a patient's plan to determine what information, if any, should be provided.	
Number of units (Box 24G)	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 (Box 21)**	The following primary diagnosis codes may be appropriate to describe patients with diabetic postherpetic neuralgia (PHN):	
	B02.23	Postherpetic polyneuropathy
	B02.29	Other postherpetic nervous system involvement
ICD-10-CM codes **Diabetic peripheral neuropathy – DPN of the feet (Box 21)**	The following primary diagnosis codes may be appropriate to describe patients with diabetic peripheral neuropathy (DPN) of the feet:	
	E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
	E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
	E09.42	Drug- or chemical-induced diabetes mellitus with neurological complications with diabetic polyneuropathy
	E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
	E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
	E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
	E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
	E13.40	Other specific diabetes mellitus with diabetic neuropathy, unspecified
	E13.42	Other specific diabetes mellitus with diabetic polyneuropathy

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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.

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

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SAMPLE FORMS BY TREATMENT SETTING

To receive reimbursement for QUTENZA® (capsaicin) 8% topical system administered by a physician's office, providers must submit a CMS-1500 claim form for the drug and associated services. The use of QUTENZA is covered by specific codes and may be considered medically necessary, depending on the payer.

CMS-1500: PHYSICIAN OFFICE

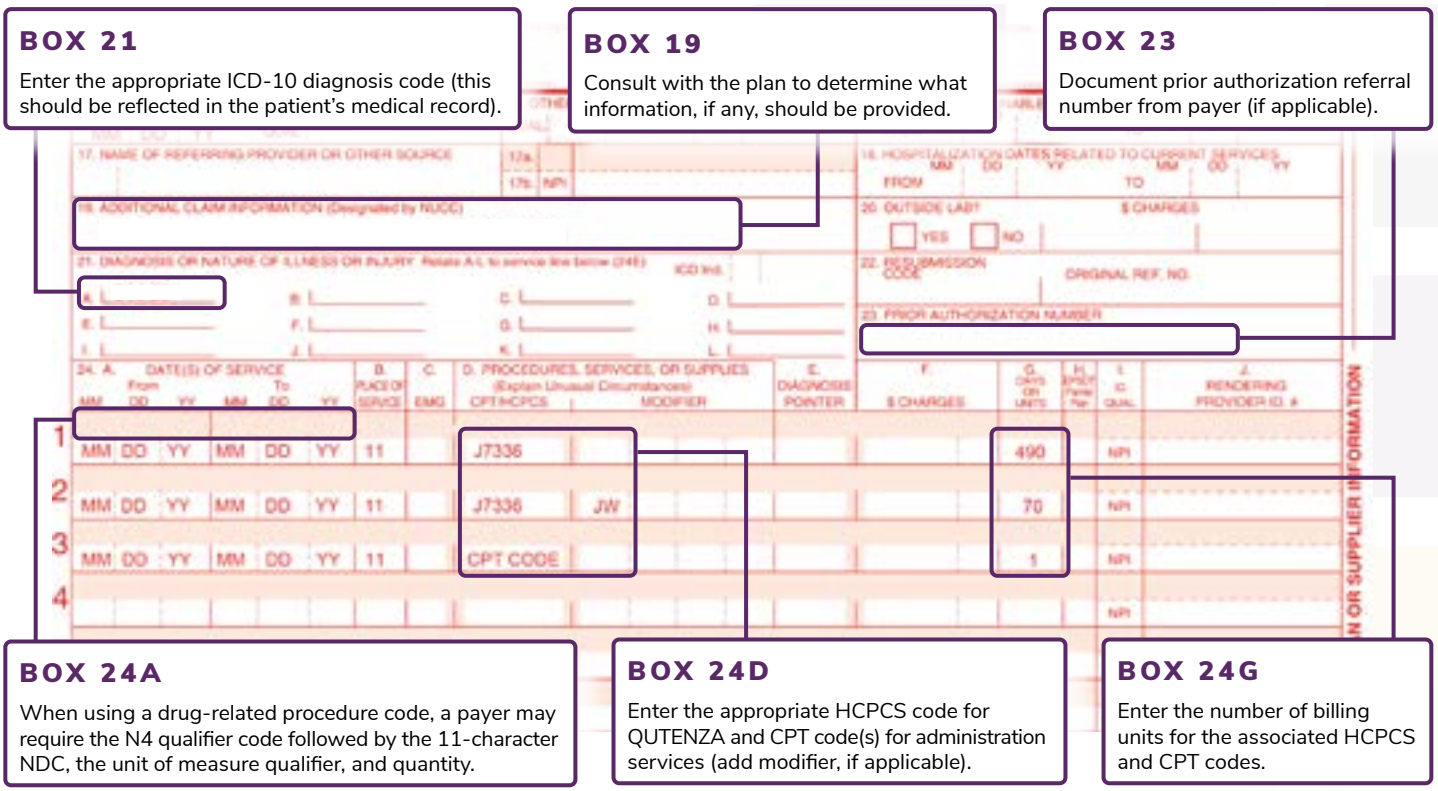
Example 1: JW Modifier

- A provider requires two 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.

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

BOX 19
Consult with the plan to determine what information, if any, should be provided.

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



BOX 24A
When using a drug-related procedure code, a payer may require the N4 qualifier code followed by the 11-character NDC, the unit of measure qualifier, and quantity.

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

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

Example 2: JZ Modifier

- A provider requires two 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.

Example 3: JZ, RT, and LT Modifier

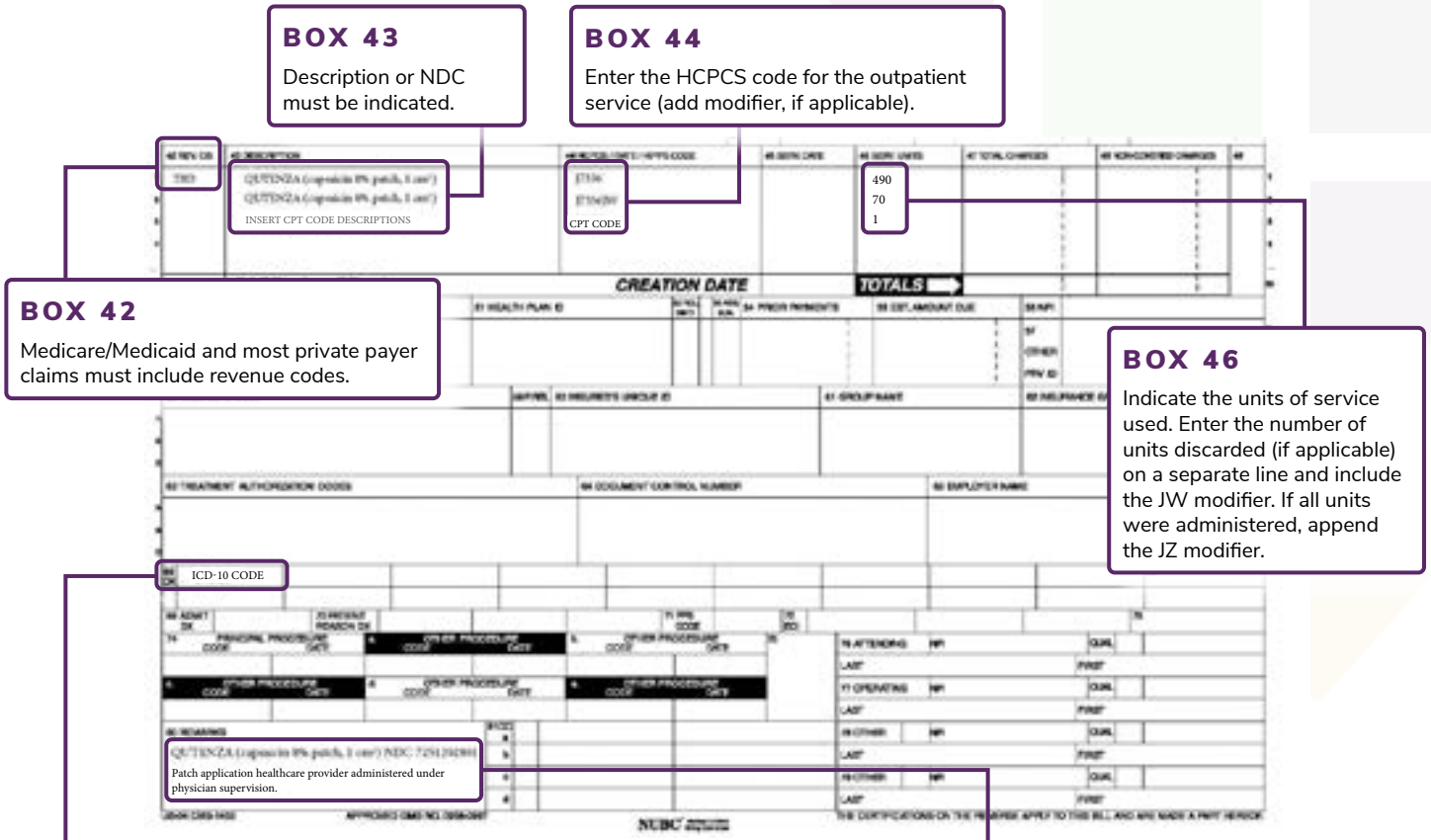
- A provider requires two topical systems per foot to cover a treatment area of 560 cm^2 (560 units).
- No topical system was discarded.
- The provider must include the JZ modifier to demonstrate that the entire product was administered to the patient.

	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	

SUPPLIER INFORMATION

CMS-1450: OUTPATIENT HOSPITAL

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



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.

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CONSIDERATIONS FOR VERIFYING INSURANCE BENEFITS

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

Payer Coverage Requirements

Coding and Billing Requirements

Patient Cost-share Considerations

RECOMMENDED BEST PRACTICES:

- ✓ Obtain the patient's information, the patient's insurance information, and your facility/office's tax ID and national provider identifier (NPI), then call the payer's provider services line.
- ✓ Ask about the coverage criteria specifically for the use of QUTENZA.
- ✓ Verify that HCPCS and CPT codes for use are covered for the patient's diagnosis. Provide applicable ICD-10-CM code(s).
- ✓ Ask whether the payer has set a maximum number of applications or treatment options and, if so, how many.
- ✓ Ask whether any documentation should be submitted with the claim. If so, ask 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.

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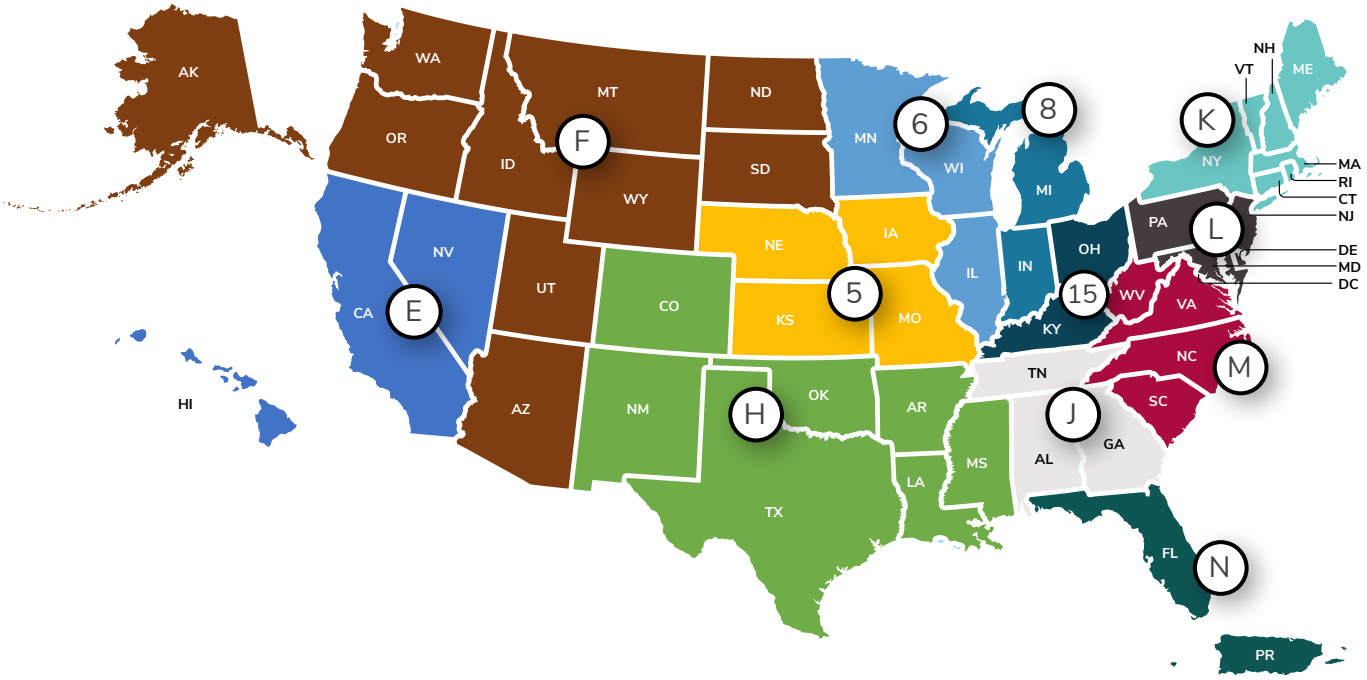
MEDICARE CONTRACTOR PROVIDER CONTACT NUMBERS[3]



PHONE NUMBERS FOR EACH MEDICARE PART B JURISDICTION

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

Jurisdiction	IVR
5	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/

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CLAIM FILING BEST PRACTICES

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

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

COMMON DENIAL REASONS

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

ERROR TYPE		REQUIRED ACTION
Technical	Incorrect patient ID, missing signatures: • Missing or incorrect code (e.g., transposed numbers) • Incorrect units	• Call to correct • Prepare and submit a corrected claim • Contact Field Access Manager or MQC for assistance
Billing	Non-covered or non-allowed service: • Service was unbundled • Incorrect placement of service code • Duplicate claim • Invalid code • Incorrect units	• Prepare and submit a corrected claim • Prepare and submit an appeal • Contact Field Access Manager or MQC for assistance
Medical Necessity	The diagnosis code is not covered for the services performed: • Medical record documentation does not support the services performed as medically necessary and in accordance with the respective medical policy in place	• Prepare and submit an appeal • Contact Field Access Manager or MQC for assistance
Payer Denial	The insurance payer will not pay for the product: • Step edit, not on formulary • Investigative product	• Prepare and submit an appeal • Contact Field Access Manager or MQC for assistance

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STRATEGIES FOR APPEALING DENIED CLAIMS

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

What is the limit for timely filing an appeal?

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

TIP

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

What is the method for submission (e.g., electronic, fax, or mail)?

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

TIP

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

How long does the appeal process usually take?

Decision times vary by level of appeal and payer.

TIP

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

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

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

TIP

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

Is there a particular form that must be completed?

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

TIP

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

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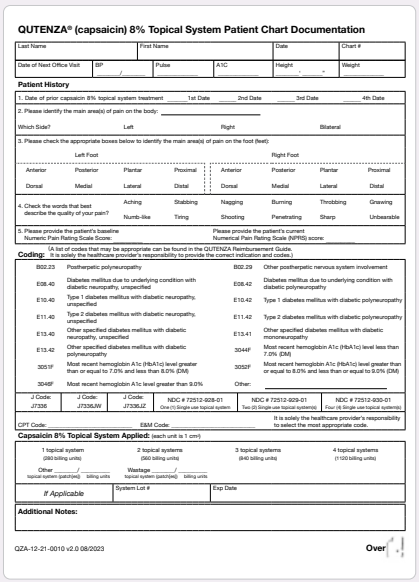
FIND ALL IMPORTANT RESOURCE DOCUMENTS IN ONE PLACE

PATIENT CHART DOCUMENTATION



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)

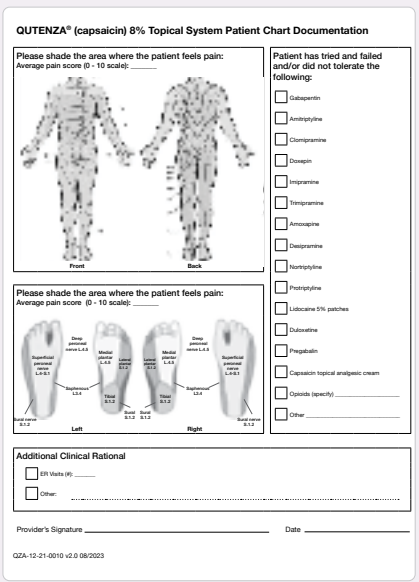
1 topical system (360 billing units)	2 topical systems (720 billing units)	3 topical systems (840 billing units)	4 topical systems (1120 billing units)

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



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

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

Front Back

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

Left Right

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

- ☐ Gabapentin
- ☐ Amitriptyline
- ☐ Clomipramine
- ☐ Doxepin
- ☐ Imipramine
- ☐ Trimipramine
- ☐ Amoxapine
- ☐ Desipramine
- ☐ Nortriptyline
- ☐ Protriptyline
- ☐ Lidocaine 5% patches
- ☐ Duloxetine
- ☐ Pregabalin
- ☐ Capsaicin topical analgesic cream
- ☐ Opioids (specify) _____
- ☐ Other _____

Additional Clinical Rational

- ☐ ER Visits (#): _____
- ☐ Other: _____

Provider's Signature _____ Date _____

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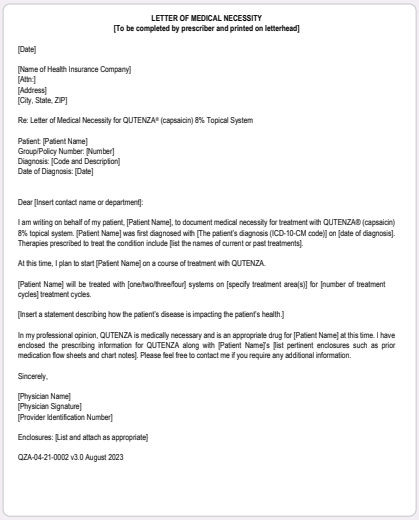
LETTERS

MEDICAL NECESSITY



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

[Date]

[Name of Health Insurance Company]
[Attn:]
[Address]
[City, State, ZIP]

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

Patient: [Patient Name]
Group/Policy Number: [Number]
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 [one/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.

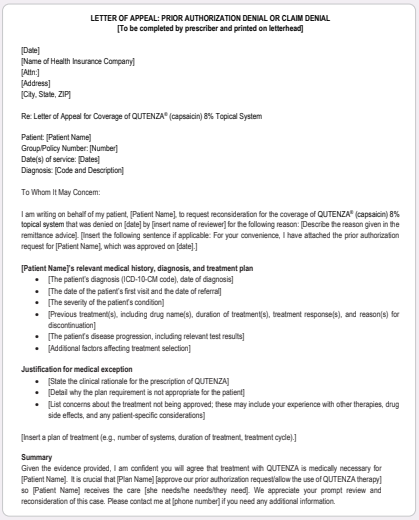
Sincerely,

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

Enclosures: [List and attach as appropriate]

QZA-04-21-0002 v3.0 August 2023

APPEAL



LETTER OF APPEAL: PRIOR AUTHORIZATION DENIAL OR CLAIM DENIAL
[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 the remittance advice]. [Insert the following sentence if applicable: For your convenience, I have attached the prior authorization 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) for 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, drug 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 NOW

www.QUTENZAHCP.com/access-and-savings/reimbursement-resources/

Qutenza® (capsaicin) 8% topical system

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

REFERENCES:

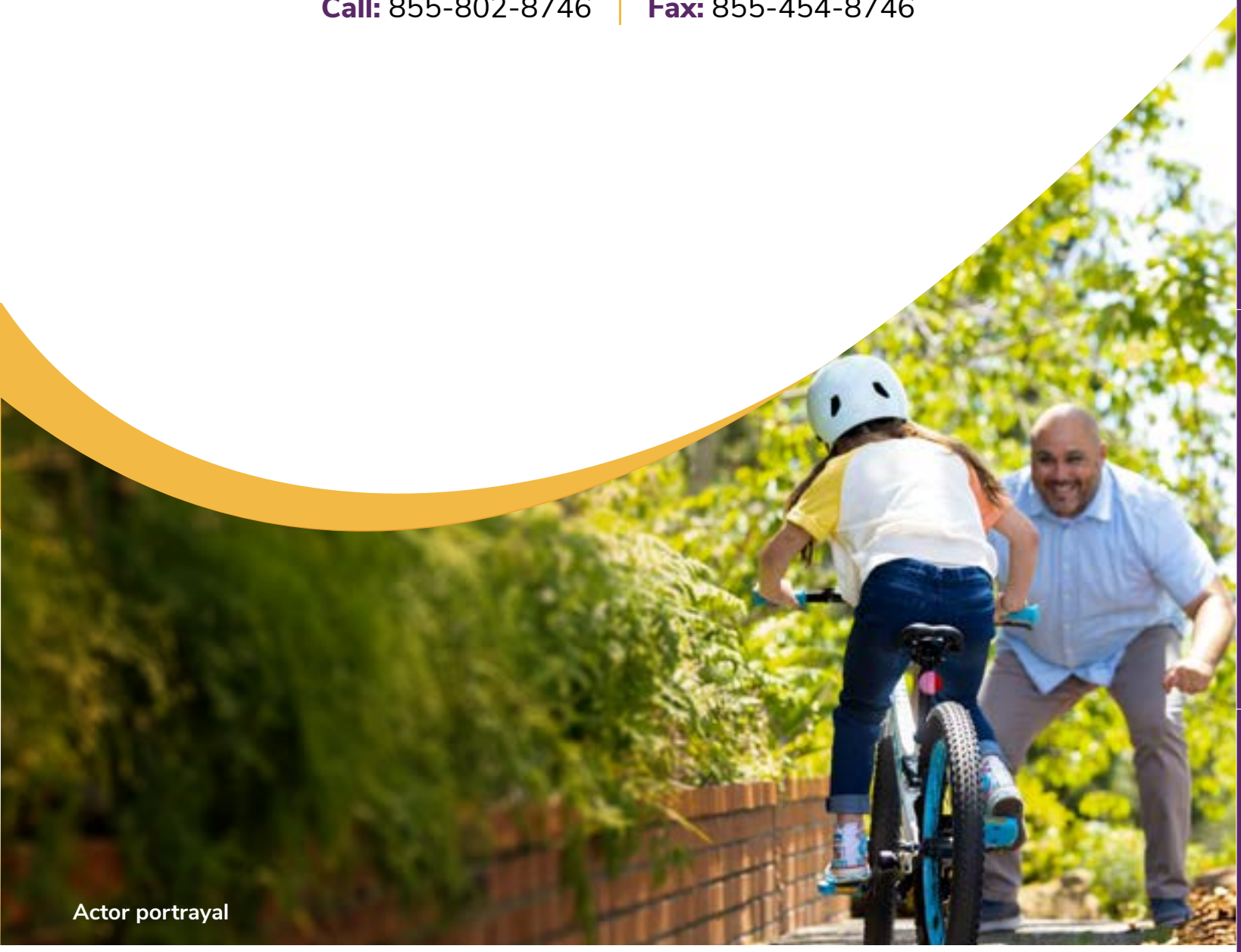
1. QUTENZA® [prescribing information]. Morristown, NJ: Averitas Pharma, Inc.
2. Centers for Medicare & Medicaid Services (CMS). New JZ Claims Modifier for Certain Medicare Part B Drugs: MLN Matters Number: MM13056. https://www.cms.gov/files/document/mm13056-new-jz-claims-modifier-certain-medicare-part-b-drugs.pdf. Published June 2, 2023. Accessed June 20, 2023.
3. 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.

Qutenza® (capsaicin) 8% topical system

MY QUTENZA CONNECT CAN HELP STREAMLINE THE REIMBURSEMENT PROCESS TODAY.

www.MyQUTENZAConnect.com

Call: 855-802-8746 | **Fax:** 855-454-8746



Actor portrayal

QZA-08-23-0040 v2.0 December 2023

Qutenza®
(capsaicin) 8% topical system