



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Topical Pain Patches

Policy # 00365

Original Effective Date: 10/16/2013

Current Effective Date: 10/16/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand or generic topical lidocaine patches (Lidoderm[®])[‡] or capsaicin patches (Qutenza[®])[‡] to be **eligible for coverage** when the drug's respective patient selection criteria are met.

Qutenza

Patient Selection Criteria

Coverage eligibility will be considered for brand or generic capsaicin patches (Qutenza) when the following patient selection criterion is met:

- Patient has post-herpetic neuralgia

Lidoderm Patch

Patient Selection Criteria

Coverage eligibility will be considered for brand or generic topical lidocaine patches (Lidoderm) when one of the following patient selection criteria is met:

- Patient has post-herpetic neuralgia; OR
- Patient has neuropathic pain; OR
- Patient has musculoskeletal pain/myofascial pain; AND
 - Lidoderm Patch is used in combination with a standard myofascial trigger point (MTP) treatment modality; OR
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has low back pain; AND
 - Patient has tried and failed at least three other pharmacologic therapies commonly used to treat low back pain (e.g. acetaminophen, non-steroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, opioids, cyclooxygenase-2 [COX-2] inhibitors, tramadol, gabapentin, tricyclic antidepressants); OR
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has carpal tunnel syndrome; AND
 - Patient has tried and failed one other pharmacologic therapy for carpal tunnel syndrome (e.g. steroids [oral or injectable], non-steroidal anti-inflammatory drugs [NSAIDs]); OR
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*



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- Patient has osteoarthritis; AND
 - Patient has tried and failed three other pharmacologic therapies commonly used for the treatment of osteoarthritis of the hand, hip, and knee (e.g. acetaminophen, COX-2 inhibitors, NSAIDs, salicylates, tramadol, opioids, intraarticular glucocorticoids, intraarticular hyaluronan, topical capsaicin, and topical methylsalicylate)
(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of brand or generic topical lidocaine patches (Lidoderm) or capsaicin patches (Qutenza) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as **not medically necessary****).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand or generic topical lidocaine patches (Lidoderm) or capsaicin patches (Qutenza) when ANY of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary****:

- Musculoskeletal pain/myofascial pain
 - Lidoderm Patch is used in combination with a standard myofascial trigger point (MTP) treatment modality
- Low back pain
 - Patient has tried and failed at least three other pharmacologic therapies commonly used to treat low back pain (e.g. acetaminophen, non-steroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, opioids, cyclooxygenase-2 [COX-2] inhibitors, tramadol, gabapentin, tricyclic antidepressants)
- Carpal tunnel syndrome
 - Patient has tried and failed one other pharmacologic therapy for carpal tunnel syndrome (e.g. steroids [oral or injectable], non-steroidal anti-inflammatory drugs [NSAIDs])
- Osteoarthritis
 - Patient has tried and failed three other pharmacologic therapies commonly used for the treatment of osteoarthritis of the hand, hip, and knee (e.g. acetaminophen, COX-2 inhibitors, NSAIDs, salicylates, tramadol, opioids, intraarticular glucocorticoids, intraarticular hyaluronan, topical capsaicin, and topical methylsalicylate)

Background/Overview

Lidoderm and Qutenza are both indicated for the relief of pain associated with post-herpetic neuralgia. There are other uses for Lidoderm that are supported by literature, however there are some uses that don't have sufficient data. A few of the unsupported indications include use in rheumatoid arthritis and fibromyalgia. Qutenza also has some unsupported indications, such as HIV neuropathy.



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Rationale/Source

Lidoderm and Qutenza have the potential to be used off label for certain conditions that do not have sufficient evidence to support usage. There is very little clinical evidence to support the use of Lidoderm or Qutenza in conditions not listed in the above patient selection criteria. The purpose of this policy is to limit the use of Lidoderm and Qutenza to those uses mentioned in the patient selection criteria. Patient selection criteria are based on information collected in a review of the available data.

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No code
HCPCS	J7335
ICD-9 Diagnosis	All diagnoses
ICD-9 Procedure	No code



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10/03/2013 Medical Policy Committee review

10/16/2013 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 10/2014

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.