



Louisiana

Topical Pain Patches

Policy # 00365

Original Effective Date: 10/16/2013

Current Effective Date: 10/11/2021

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 capsaicin patches (Qutenza[®])[‡] or brand or generic topical lidocaine patches (Lidoderm[®], Ztlido[™])[‡] 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 capsaicin patches (Qutenza) when one of the following patient selection criteria are met:

- Patient has a diagnosis of post-herpetic neuralgia; OR
- Patient has a diagnosis of diabetic peripheral neuropathy of the feet.

Lidoderm Patch

Patient Selection Criteria

Coverage eligibility will be considered for brand or generic topical lidocaine 5% patches (Lidoderm) when the patient selection criteria are met:

- Patient has a diagnosis of post-herpetic neuralgia; OR
- Patient has a diagnosis of neuropathic pain; OR
- Patient has a diagnosis of musculoskeletal pain/myofascial pain; AND
 - Lidoderm Patch (or its generic) 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).*

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- Patient has a diagnosis of low back pain; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) 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) unless there is clinical evidence or patient history that suggests these alternatives will be ineffective or cause an adverse reaction to the patient; 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 a diagnosis of carpal tunnel syndrome; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) one other pharmacologic therapy for carpal tunnel syndrome (e.g., steroids [oral or injectable], NSAIDs) unless there is clinical evidence or patient history that suggests these alternatives will be ineffective or cause an adverse reaction to the patient; 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 a diagnosis of osteoarthritis; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) 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) unless there is clinical evidence or patient history that suggests these alternatives will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- If the request is for branded Lidoderm Patch: Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC lidocaine 5% patch unless there is clinical evidence or patient history that suggests the use of GENERIC lidocaine 5% patch will be ineffective or cause an adverse reaction to the patient.
*(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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Ztlido

Patient Selection Criteria

Coverage eligibility will be considered for lidocaine 1.8% patches (Ztlido) when the following patient selection criterion is met:

- Patient has a diagnosis of post-herpetic neuralgia.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand or generic topical lidocaine 5% patches (Lidoderm) when ANY of the following criteria for the 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 (or its generic) is used in combination with a standard 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, NSAIDs, muscle relaxants, opioids, 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], 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)

Based on review of available data, the Company considers the use of branded Lidoderm requests when the patient has NOT tried and failed GENERIC lidocaine 5% patches to be **not medically necessary.****

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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 capsaicin patches (Qutenza) or brand or generic topical lidocaine patches (Lidoderm, Ztlido) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as **not medically necessary****).

Background/Overview

Lidoderm, Qutenza, and Ztlido are indicated for the relief of pain associated with post-herpetic neuralgia. Qutenza has an additional indication for the treatment of neuropathic pain associated with diabetic peripheral neuropathy of the feet. There are other uses for Lidoderm that are supported by literature, however there are some uses that don't have sufficient data. Lidoderm does have a generic equivalent available. A few of the unsupported indications include use in rheumatoid arthritis and fibromyalgia. Qutenza also has some unsupported indications, such as human immunodeficiency virus (HIV) neuropathy. Ztlido is available in a 1.8% strength, however crossover studies have shown that Ztlido demonstrated similar area under the curve (AUC) and peak concentration (C_{max}) of lidocaine to Lidoderm 5% patch.

Rationale/Source

Lidoderm, Qutenza, and Ztlido 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, Qutenza, or Ztlido in conditions not listed in the above patient selection criteria (for the respective drug).

The purpose of this policy is to limit the use of Lidoderm (and its generic), Qutenza, and Ztlido 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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Policy History

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|------------|-----------------------------------------------------------------------------------------|
| 10/03/2013 | Medical Policy Committee review |
| 10/16/2013 | Medical Policy Implementation Committee approval. New policy. |
| 10/02/2014 | Medical Policy Committee review |
| 10/15/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2015 | Coding Update |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 10/08/2015 | Medical Policy Committee review |
| 10/21/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/06/2016 | Medical Policy Committee review |
| 10/19/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |

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02/23/2017	Coding Update
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Updated to reflect usage of generic equivalent lidocaine 5% patch prior to the brand.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2019	Medical Policy Committee review
02/20/2019	Medical Policy Implementation Committee approval. Added a new FDA approved drug (Ztlido) to the policy. Updated relevant background information.
02/06/2020	Medical Policy Committee review
03/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Removed language from Ztlido requiring a trial and failure of generic lidocaine patches. Added a new indication (diabetic peripheral neuropathy) for Qutenza.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2022

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 2020 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 codes
HCPCS	J7336
ICD-10 Diagnosis	All related diagnoses

*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);

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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.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.

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