Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

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).*

- 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)*

Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

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.****

Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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).

Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

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.

References

1. Lidoderm patches [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; January 2013.
2. White WT, Patel N, Drass M, Nalamachu S. Lidocaine patch 5% with systemic analgesics such as gabapentin: a rational polypharmacy approach for the treatment of chronic pain. Pain Med. 2003;4(4):321-30.
3. Galer BS, Gammaitoni AR, Oleka N, Jensen MP, Argoff CE. Use of the lidocaine patch 5% in reducing intensity of various pain qualities reported by patients with low-back pain. Curr Med Res Opin. 2004;20(Suppl 2):S5-12.
4. Gimbel J, Linn R, Hale M, Nicholson B. Lidocaine patch treatment in patients with low back pain: results of an open-label, nonrandomized pilot study. Am J Ther. 2005; 12:311-319.
5. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147:478-491.
6. Barbano RL, Herrmann DN, Hart-Gouleau S, Pennella-Vaughan J, Lodewick PA, Dworkin RH. Effectiveness, tolerability, and impact on quality of life of the 5% lidocaine patch in diabetic polyneuropathy. Arch Neurol. 2004;61(6):914-8.
7. DRUGDEX®‡ System. Thomson Reuters (Healthcare) Inc. Available at: http://www.thomsonhc.com. Search terms: lidocaine.
8. Meier T, Wasner G, Faust M, et al. Efficacy of lidocaine patch 5% in the treatment of focal peripheral neuropathic pain syndromes: a randomized, double-blind, placebo-controlled study. Pain. 2003;106(1-2):151-8.
9. Galer BS, Jensen MP, Ma T, et al. The lidocaine patch 5% effectively treats all neuropathic pain qualities: results of a randomized, double-blind, vehicle-controlled, three-week efficacy study with use of the neuropathic pain scale. Clin J Pain. 2002;18:297-301.
10. Devers A, Galer BS. Topical lidocaine patch relieves a variety of neuropathic pain conditions: an open-label study. Clin J Pain. 2000;16:205-8.
11. Dworkin RH, Backonja M, Rowbotham MC, et al. Advances in neuropathic pain: diagnosis, mechanisms, and treatment recommendations. Arch Neurol. 2003;60(11):1524-34.

12. Herrmann DN, Barbano RL, Hart-Gouleau S, et al. An open-label study of the lidocaine patch 5% in painful idiopathic sensory polyneuropathy. Am Acad Pain Med. 2005;6(5):379-384.
13. Fleming JA, O'Connor BD. Use of lidocaine patches for neuropathic pain in a comprehensive cancer centre. Pain Res Manage. 2009;14:381-388.
14. Bril V, England J, Franklin GM, et al. Evidence-based Guideline: Treatment of Painful Diabetic Neuropathy Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology. Epub ahead of print April 11, 2011.
15. Dworkin RH, O'Connor AB, Audette J, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. Mayo Clin Proc. 2010;85:S3-S14.
16. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care Res. 2012;64:465-474. Available at: http://www.rheumatology.org/practice/clinical/guidelines/osteoarthritis.asp.
17. Galer BS, Sheldon E, Patel N, et al. Topical lidocaine patch 5% may target a novel underlying pain mechanism in osteoarthritis. Curr Med Res Opin. 2004;20(9):1455-8.
18. Gammaitoni AR, Galer BS, Onawala R, et al. Lidocaine patch 5% and its positive impact on pain qualities in osteoarthritis: results of a pilot 2-week, open-label study using the Neuropathic Pain Scale. Curr Med Res Opin. 2004;20(Suppl 2):S13-9.
19. Burch F, Codding C, Patel N, Sheldon E. Lidocaine patch 5% improves pain, stiffness, and physical function in osteoarthritis pain patients. Osteoarthritis Cartilage. 2004;12(3):253-5.
20. Stitik TP, Altschuler E, Foye PM. Pharmacotherapy of osteoarthritis. Am J Phys Med Rehabil. 2006;85(11 Suppl): S15-S28.
21. Kivitz A, Fairfax M, Sheldon EA, et al. Comparison of the effectiveness and tolerability of lidocaine patch 5% versus celecoxib for osteoarthritis-related knee pain: post hoc analysis of a 12-week, prospective, randomized, active-controlled, open-label, parallel-group trial in adults. Clin Ther. 2008;30:2366-2377.
22. Nalamachu S, Crockett RS, Mathur D. Lidocaine patch 5 for carpal tunnel syndrome: how it compared with injections: a pilot study. J Fam Pract. 2006;55(3):209-214.
23. Nalamachu S, Crockett RS, Gammaitoni AR, Gould EM. A comparison of the lidocaine patch 5% vs. naproxen 500 mg twice daily for the relief of pain associated with carpal tunnel syndrome: a 6-week, randomized, parallel-group study. MedGenMed. 2006;8(3):33.

24. American Academy of Orthopaedic Surgeons. Clinical practice guideline on the treatment of carpal tunnel syndrome. September 2008. Available at: http://www.aaos.org/research/guidelines/CTStreatmentguide.asp.
25. Dalpiaz AS, Lordon SP, Lipman AG. Topical lidocaine patch therapy for myofascial pain. J Pain Palliat Care Pharmacother. 2004;18(3):15-34.
26. Dalpiaz AS, Dodds TA. Myofascial pain response to topical lidocaine patch therapy: case report. J Pain Palliat Care Pharmacother. 2002;16(1):99-104.
27. Affaitati G, Fabrizio A, Savini A, et al. A randomized, controlled study comparing a lidocaine patch, a placebo path, and anesthetic injection for treatment of trigger points in patients with myofascial pain syndrome: evaluation of pain and somatic pain thresholds. Clin Ther. 2009;31:705-720.
28. Lin YC, Kuan TS, Hsieh PC, et al. Therapeutic effects of lidocaine patch on myofascial pain syndrome of the upper trapezius: a randomized, double-blind, placebo-controlled study. Am J Phys Med Rehabil. 2012;91:871-882.
29. Ingalls NK, Horton ZA, Bettendorf M, et al. Randomized, double-blind, placebo-controlled trial using lidocaine patch 5% in traumatic rib fractures. J Am Coll Surg. 2010;210:205-209.
30. Ztlido. [package insert]. Scilex Pharmaceuticals. San Diego, California. Updated November 2018.
31. Qutenza [package insert]. Averitas Pharma. Morristown, New Jersey. Updated July 2020.

Policy History

Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

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

Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

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
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.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

09/05/2024 Medical Policy Committee review
09/11/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 09/2025

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 2023 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

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 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.

Topical Pain Patches

Policy # 00365
Original Effective Date: 10/16/2013
Current Effective Date: 10/14/2024

**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: 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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.