

Journavx™ (suzetrigine)

Policy # 00932

Original Effective Date: 07/01/2025

Current Effective Date: 07/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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 Journavx™[‡] (suzetrigine) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for Journavx (suzetrigine) will be considered when the following criteria are met:

- Patient is using the requested drug for the treatment of moderate to severe acute pain as evidenced by a score of greater than or equal to 4 on the Numeric Pain Rating Scale (NPRS); AND
*(Note: This specific patient selection criterion is partially an additional Company requirement for coverage eligibility. Requests for pain severity not considered moderate to severe as evidenced by a NPRS score < 4 will be denied as not medically necessary** if not met).*
- Patient is 18 years of age or older; AND
- Patient has tried and failed (e.g. intolerance or inadequate response) at least TWO different GENERIC oral non-steroidal anti-inflammatory drugs (NSAIDs) at prescription strength doses (e.g., diclofenac, flurbiprofen, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen, piroxicam, etc.) unless there is clinical evidence or patient history that suggests the use of these generic products will be ineffective or cause an adverse reaction to the patient.; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g. intolerance or inadequate response) treatment with acetaminophen unless there is clinical evidence or patient history that suggests this product will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient selection 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 will use the requested medication in combination with other pharmacologic therapies commonly used to treat moderate to severe acute pain (e.g., acetaminophen, non-steroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, cyclooxygenase-2 [COX-2] inhibitors) 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient does not have severe hepatic impairment according to the prescriber.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Journavx (suzetrigine) when the patient does NOT have acute pain that is considered to be moderate to severe to be **not medically necessary.****

Based on review of available data, the Company considers the use of Journavx (suzetrigine) when the patient has NOT failed treatment with at least TWO different generic oral NSAIDs at prescription strength doses to be **not medically necessary.****

Based on review of available data, the Company considers the use of Journavx (suzetrigine) when the patient has NOT failed treatment with acetaminophen to be **not medically necessary.****

Based on review of available data, the Company considers the use of Journavx (suzetrigine) when the requested medication is NOT being used in combination with other pharmacologic therapies commonly used to treat moderate to severe acute pain to be **not medically necessary.****

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 Journavx (suzetrigine) when the patient selections criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

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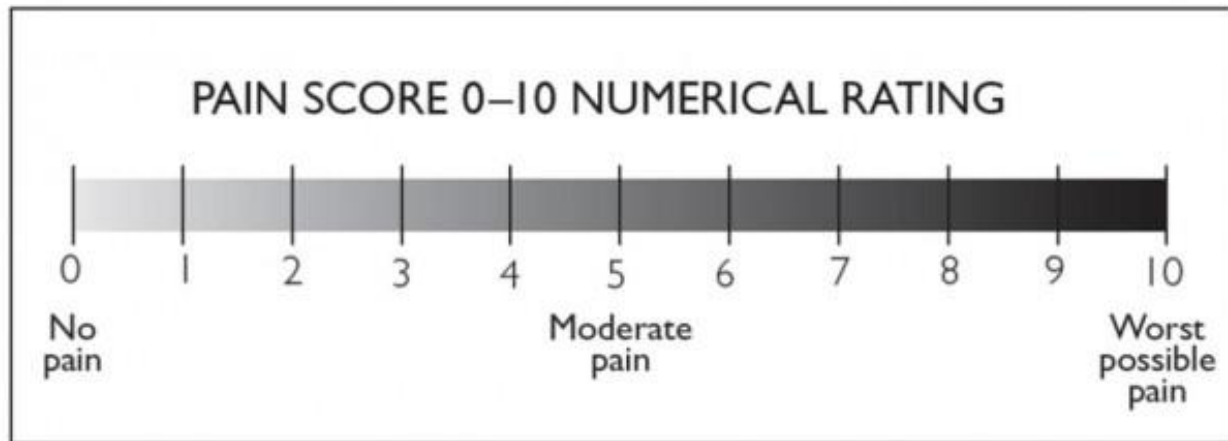
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Policy Guidelines

Numeric Pain Rating Scale

The numeric pain rating scale (NPRS) is a validated assessment tool for pain intensity.



Background/Overview

Journavx is a sodium channel blocker approved for the treatment of moderate to severe acute pain in adults. Journavx is a first-in-class oral non-opioid analgesic that works by selectively blocking the Nav1.8 voltage-gated sodium channel expressed in peripheral sensory neurons, thereby inhibiting the transmission of pain signals to the brain. Journavx is available as a 50 mg tablet. The recommended first dose is 100 mg, followed by 50 mg every 12 hours thereafter. The label states that patients should use Journavx for the shortest duration, consistent with their individual treatment goals, and notes that use of Journavx for the treatment of moderate to severe acute pain has not been studied beyond 14 days. Patients with moderate hepatic impairment have higher systemic exposure of Journavx than those with normal hepatic function which may increase the risk of adverse reactions. Dose adjustments should be made for patients with moderate hepatic impairment and use in patients with severe hepatic impairment should be avoided.

Acute pain is defined by the Centers for Disease Control and Prevention (CDC) as pain that has lasted for less than a month and has a known cause, like an injury, trauma, surgery, or infection. Acute pain can be experienced from outpatient medical procedures, like a wisdom tooth extraction, or injuries, like a broken bone. Acute pain normally gets better as your body heals. There are many options for reducing acute pain including pharmacological and non-pharmacological approaches. Non-pharmacological treatment options include application of heat or ice, physical therapy, acupuncture, acupressure, massage, spinal manipulation, transcutaneous electrical nerve stimulation (TENS), exercise, etc. Medications commonly utilized for the treatment of moderate to severe acute pain include NSAIDs (oral or topical), acetaminophen, and opioids. Combining an NSAID with acetaminophen, either taken together or in an alternating fashion, is also a common treatment strategy. Adjunctive medications are also used to augment the pain control of analgesics, including muscle relaxants, caffeine, or gabapentinoids. Management of acute pain is often a multimodal approach which aims to decrease reliance on a single class of agents, reduce side effects, and minimize the use of opioids.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Journavx, a sodium channel blocker, was approved in early 2025 for the treatment of moderate to severe acute pain in adults.

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 regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Journavx was evaluated in two randomized, double-blind, placebo-controlled, multicenter, Phase III pivotal studies in patients with acute post-surgical pain (i.e., abdominoplasty [NAVIGATE 2] and bunionectomy [NAVIGATE 1]). Patients received Journavx, placebo, or hydrocodone bitartrate/acetaminophen (HB/APAP) for up to 48 hours. Rescue medication with ibuprofen (400 mg every 6 hours) was permitted as needed for pain relief. For both studies, the primary efficacy endpoint was the time-weighted sum of the pain intensity difference from 0 to 48 hours (SPID48) in the Journavx arm compared with the placebo arm. A key secondary endpoint was SPID48 in the Journavx arm compared with HB/APAP.

In NAVIGATE 2 [n = 1,118], Journavx demonstrated a statistically significant superior reduction in acute pain compared with placebo (least-squares [LS] mean SPID48 difference 48.4; $p < 0.0001$). Journavx did not achieve its first key secondary endpoint of superior reduction in acute pain vs. HB/APAP (LS mean SPID48 difference 6.6; $p = 0.2781$). During the 48-hour treatment period, 81.0% vs. 87.9% of patients utilized rescue medication in the Journavx and placebo groups, respectively (nominal $p = 0.0237$). The median time to meaningful pain relief (defined as a ≥ 2 -point reduction in the numeric pain rating scale [NPRS]) was 119 minutes and 480 minutes for Journavx and placebo, respectively.

In NAVIGATE 1 [n = 1,073], Journavx demonstrated a statistically significant superior reduction in acute pain compared with placebo (LS mean SPID48 difference 29.3; $p = 0.0002$). Journavx did not achieve its first key secondary endpoint of superior reduction in acute pain vs. HB/APAP (LS mean SPID48 difference -20.2; $p = 0.0016$ favoring HB/APAP). During the 48-hour treatment period, 85.4% and 85.6% of patients utilized rescue medication in the Journavx and placebo groups, respectively (p -value not statistically different). The median time to meaningful pain relief (as previously defined) was 240 minutes for patients in the Journavx group compared with 480 minutes in the placebo group.

References

1. Journavx [package insert]. Vertex Pharmaceuticals, Inc. Boston, Massachusetts. Updated January 2025.
2. Approach to the management of acute pain in adults. UpToDate. Updated April 2025.

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3. “Opioid Therapy and Different Types of Pain.” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, www.cdc.gov/overdose-prevention/manage-treat-pain/index.html. Accessed May 2025.
4. Journavx Drug Evaluation. Express Scripts. Updated February 2025.

Policy History

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06/05/2025 Medical Policy Committee review

06/11/2025 Medical Policy Implementation Committee approval. New policy.

06/04/2026 Medical Policy Committee review.

06/10/2026 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2027

*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.

**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.

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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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.