

## PHARMACY COVERAGE GUIDELINE

### JOURNAVX™ (suzetrigine) oral Generic Equivalent (if available)

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#### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

#### **Scope**

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

#### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
  - This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
  - Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
  - The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
  - The “Description” section describes the Service.
  - The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
  - The “Resources” section lists the information and materials we considered in developing this PCG
  - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
  - Information about medications that require prior authorization is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).
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## Medical Necessity Requirements for JOURNAVX (suzetrigine)

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### Criteria for Initial Therapy:

#### **Prescriber Qualifications**

- Prescribed by a physician specializing in pain management or in consultation with a pain specialist

#### **Indication**

- Moderate to severe acute pain that is not adequately controlled

#### **Age Requirement**

- 18 years or older

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#### Baseline Clinical Evaluation

- Pain is expressed as **ONE** of the following:
  - Graded as greater than or equal to 4 on the Numeric Pain Rating Scale (NPRS)
  - Described as moderate or severe on the Verbal Categorical Rating Scale (VRS)

#### Alternative Therapies

- Failure (trial for at least three months duration), contraindication, intolerance, or not a candidate for:
  - Acetaminophen
  - **ONE** non steroidal anti inflammatory agent such as:
    1. Celecoxib
    2. Ibuprofen
    3. Naproxen
    4. Indomethacin
  - **ONE** Gabapentinoid (e.g., gabapentin, pregabalin)
  - Hydrocodone with acetaminophen

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- There is **NONE** of the following:
  - Concomitant use with strong CYP3A4 inhibitors (e.g., nelfinavir, telaprevir, boceprevir, ritonavir or ritonavir containing products, voriconazole, posaconazole, itraconazole, ketoconazole, clarithromycin, troleandomycin, chloramphenicol)
  - Concomitant use with strong or moderate CYP3A4 inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, armodafinil, bexarotene, bosentan, dabrafenib, dexamethasone)
  - Severe hepatic impairment (Child Pugh Class C)
  - Renal impairment with estimated glomerular filtration rate less than 15 mL/min

#### Additional Requirements

- **ONE** of the following:
  - Confirmed diagnosis of opioid use disorder
  - **THREE** of the following risk factors for opioid misuse or abuse:
    1. Prior history of substance use disorder (including tobacco or alcohol),
    2. Family history of substance use disorder
    3. Age less than 40 to 45 years
    4. Severe pain
    5. Co occurring mental disorders (e.g., depression, posttraumatic stress disorder, anxiety disorders)
    6. History of legal problems or incarceration
    7. History of childhood maltreatment (e.g., sexual, physical, emotional abuse or neglect)

#### Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (Numeric Pain Rating Scale and Verbal Categorical Rating Scale values)

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- Supporting clinical documentation

#### Initial Therapy Criteria Approval Duration

- 14 days OR end of plan year
  - **Note:** Use of Journavx for the treatment of moderate to severe acute pain has not been studied beyond 14 days
  - **Request for Continuation of Therapy (renewal therapy):** Review will follow Initial Therapy Criteria
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#### Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
  2. Off-Label Use of Cancer Medications
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#### Description:

Journavx (suzetrigine) is indicated for the treatment of moderate to severe acute pain in adults. Journavx (suzetrigine) is a selective blocker of the NaV1.8 voltage-gated sodium channel. NaV1.8 is expressed in peripheral sensory neurons including dorsal root ganglion neurons, where its role is to transmit pain signals. By selectively inhibiting NaV1.8 channels, suzetrigine inhibits transmission of pain signals to the spinal cord and brain. Suzetrigine has a major active metabolite, M6-SUZ, that is a less potent inhibitor of NaV1.8 than suzetrigine by 3.7-fold.

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#### Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

#### **Numeric Pain Rating Scale (NPRS):**

- It is a scale for self-report of pain, with the respondent selecting a number that best reflects the intensity of their pain using an 11-point (0 to 10) scale, with zero meaning “no pain” and 10 meaning “the worst pain imaginable”
- Pain rated  $\geq 4$  on NPRS at baseline confirms individual has sufficient pain
- NPRS is frequently used in bunionectomy studies and is recognized by the FDA as a valid pain intensity measure

#### **Verbal Categorical Rating Scale (VRS):**

- A four-level scale (pain rated as none (1), mild (2), moderate (3), or severe (4))

#### **Sum of the Pain Intensity Difference (SPID):**

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- A measure derived from the NPRS that summarizes treatment response over a clinically relevant period (e.g., SPID-48 hours). Higher SPID values represent greater reduction in pain.

#### **Resources:**

Journavx (suzetrigine) product information, revised by Vertex Pharmaceuticals, Inc. 01-2025. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed November 10, 2025.

Mariano ER. Approach to the management of acute pain in adults. In: UpToDate, Maniker R, Li H, Nussmeier NA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through November 2025. Topic last updated August 18, 2025. Accessed December 15, 2025.

Schwenk ES. Nonopioid pharmacotherapy for acute pain in adults. In: UpToDate, Maniker R, Li H, Nussmeier NA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through November 2025. Topic last updated September 04, 2025. Accessed December 15, 2025.

Bertoch T, D'Aunno D, McCoun J, et al. Suzetrigine, a Nonopioid Na V 1.8 Inhibitor for Treatment of Moderate-to-severe Acute Pain: Two Phase 3 Randomized Clinical Trials. *Anesthesiology* 2025 Mar 21; 142 (6):1085-1099. [10.1097/ALN.0000000000005460](https://doi.org/10.1097/ALN.0000000000005460). Accessed December 15, 2025.

Rind DM, McQueen B, Nikitin D, et al: Suzetrigine for Acute Pain; Evidence Report. Institute for Clinical and Economic Review, February 5, 2025 <https://icer.org/assessment/acute-pain-2025/>. Accessed February 11, 2025. Re-evaluated December 15, 2025.

Jones J, Correll DJ, Lechner SM, et al.: Selective Inhibition of NaV1.8 with VX-548 for Acute Pain. *NEJM* 2023 Aug 3; 389 (5): 393-405. Accessed February 11, 2025. Re-evaluated December 15, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT05558410: A Phase 3, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After an Abdominoplasty. Available from: <http://clinicaltrials.gov>. Last update posted August 27, 2024. Last verified August 2024. Accessed February 11, 2025. Re-evaluated December 15, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT05553366: A Phase 3, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After a Bunionectomy. Available from: <http://clinicaltrials.gov>. Last update posted December 16, 2024. Last verified December 2024. Accessed February 11, 2025. Re-evaluated December 15, 2025.