PHARMACY COVERAGE GUIDELINE

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

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 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. 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.

Criteria:

- **Criteria for therapy:** Journavx (suzetrigine) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Pain Specialist
  2. Individual is 18 years of age or older
  3. Individual has a confirmed diagnosis of moderate to severe **acute** pain that is not adequately controlled
  4. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
     a. Pain is rated as ≥4 on the Numeric Pain Rating Scale (NPRS)

b. Pain is described as moderate or severe pain on the Verbal Categorical Rating Scale (VRS)

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual is **NOT** using any of the FDA-label contraindication medications (e.g., strong CYP3A4 inhibitors such as protease inhibitors (e.g., nelfinavir, telaprevir, boceprevir, ritonavir or ritonavir containing products), azole antifungals (e.g., voriconazole, posaconazole, itraconazole, ketoconazole), antibiotics (e.g., clarithromycin, troleandomycin, chloramphenicol), others)

7. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **ALL** the following where clinically appropriate:
   a. Acetaminophen
   b. **ONE** non-steroidal anti-inflammatory agent
      i. Celecoxib
      ii. Ibuprofen
      iii. Naproxen
      iv. Indomethacin
   c. **ONE** Gabapentinoid (e.g., gabapentin, pregabalin)
   d. Hydrocodone with acetaminophen

8. Individual has **ONE** of the following:
   a. A confirmed diagnosis of opioid use disorder (OUD)
   b. **THREE** of the following risk factors for opioid misuse or abuse:
      i. Prior history of substance use disorder, including tobacco or alcohol use disorder
      ii. Family history of a substance use disorder
      iii. Younger age generally less than 40 to 45 years
      iv. More severe pain
      v. Co-occurring mental disorders including depression, posttraumatic stress disorder, and anxiety disorders
      vi. History of legal problems or incarceration
      vii. History of childhood maltreatment (e.g., sexual, physical, or emotional abuse or neglect)

9. Individual is not currently taking any other drugs which cause severe adverse reactions or any significant drug interactions requiring discontinuation

10. Individual is not using strong and moderate CYP3A4 inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, armodafinil, bexarotene, bosentan, dabrafenib, dexamethasone, others

11. Individual does not have severe hepatic impairment (Child-Pugh Class C)

12. Individual does not have renal impairment of eGFR < 15 mL/min

Approval duration: 14 days
Use of Journavx for the treatment of moderate to severe acute pain **has not been studied beyond 14 days**

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- 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**

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.

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 ≥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):
- 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 February 10, 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.

ORIGINAL EFFECTIVE DATE: 02/20/2025 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE:

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.

Mariano ER. Approach to the management of acute pain in adults. In: UpToDate, Maniker R, Crowley M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through January 2025. Topic last updated August 21, 2024. Accessed February 11, 2025.

Schwenk ES. Nonopioid pharmacotherapy for acute pain in adults. In: UpToDate, Maniker R, Crowley M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through January 2025. Topic last updated January 10,2025. Accessed February 11, 2025.

Rind DM, McQueen B, Nikitin D, etal: 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.

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.