Pharmacy Policy Bulletin: J-1444 Journavx (suzetrigine)– Commercial and Healthcare Reform	
Number: J-1444	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial** **Prior Authorization (1.)**: **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Quantity Limits = Safety/Specialty **2.** Quantity Limits = Safety/Specialty + Dose Opt **3.** Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRXC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1444-001	**Original Date:** 03/24/2025
Effective Date: 03/24/2025	**Review Date:** 01/29/2025

Drugs Product(s):	• Journavx (suzetrigine)
FDA-Approved Indication(s):	• Treatment of moderate-to-severe acute pain in patients.

Background:	• Journavx (suzetrigine) is a first-in-class, non-opioid analgesic indicated for the treatment of moderate-to-severe acute pain. It is the first medication in a new class of pain medication to be approved in over 20 years. In clinical trials, Journavx has not shown evidence of addictive potential. • Journavx, a sodium channel blocker, has a novel mechanism of action. It is a selective blocker of the Nav1.8 voltage-gated sodium channel, which is involved in pain signal transmission. Journavx selectively inhibiting Nav1.8 channels, inhibiting transmission of pain signals to the spinal cord and brain. Since this unique mechanism of action works in the periphery, it may offer a non-addictive pain relief option. • Acute pain is a physiologic response to noxious stimuli that can become pathologic. Acute pain is usually sudden in onset and time limited; it is often caused by injury, trauma, or medical treatments such as surgery. The Center for Disease Control (CDC) in its Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022, defines acute pain as < 1-month, subacute pain

	as 1-3 months, and chronic pain as a duration of > 3 months. Use of Journavx for the treatment of acute pain has not been studied beyond 14 days. • Acute pain, though ubiquitous often does not require specific treatment. However, more than 80 million people in the US take prescription medication for acute pain annually, and about half of these prescriptions are opioids. • The American Academy of Family Physicians in their 2021 Pharmacologic Therapy for Acute Pain guidelines recommends acetaminophen, nonselective NSAIDs, and selective COX-2 NSAIDs for mild-to-moderate pain. Acetaminophen plus NSAID combinations are recommended for mild-to-moderate pain that is refractory to either agent alone. Opioid plus acetaminophen or NSAID combinations are recommended for persistent moderate-to-severe pain. Full agonist opioids are recommended for persistent severe pain. • Nonpharmacologic treatment options for acute pain include ice, heat, elevation, rest, immobilization, and exercise. • Prescribing Considerations: ○ Journavx should be used for the shortest duration, consistent with individual patient treatment goals. ○ Journavx will not be covered for longer than 14 days; the use of Journavx for the treatment of acute pain has not been studied beyond 14 days. Additional courses of therapy will only be approved when the prescriber attests that the member is experiencing a new episode of moderate-to-severe acute pain. ○ The starting dose of Journavx is 100 mg; take this dose on an empty stomach at least 1 hour before or two hours after food. Starting 12 hours after the starting dose, take Journavx 50 mg every 12 hours with or without food. ○ Journavx should not be used in patients with severe hepatic impairment. The recommended dosage for patients with moderate hepatic impairment is lower than in patients with normal hepatic function. Use of Journavx in patients with moderate hepatic impairment may increase the risk of adverse reactions. ○ Journavx may interact with other drugs; always check drug interactions before the use of Journavx. The use of Journavx with strong CYP3A inhibitors is contraindicated. Reduce the Journavx dose when used concomitantly with moderate CYP3A inhibitors. Avoid concomitant use of Journavx with strong and moderate CYP3A inducers. Medications that are substrates of the CYP3A enzyme may become less effective during treatment with Journavx; the dose of the substrate medication may need to be adjusted when starting or stopping Journavx. ○ Avoid food or drink containing grapefruit during treatment with Journavx. ○ Journavx-treated patients using hormonal contraceptives containing progestins other than levonorgestrel and norethindrone should use additional nonhormonal contraceptives (such as condoms) or use alternative contraceptives (such as a combined oral contraceptive containing ethinyl estradiol as the estrogen and levonorgestrel or norethindrone as the progestin, or an intrauterine system) during treatment with Journavx and for 28 days after discontinuation of Journavx.

Approval Criteria

I. Approval Criteria

When a benefit, coverage of Journavx may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.
B. The member has a diagnosis of moderate-to-severe acute pain. (ICD-10: R52)
C. The prescriber attests that the episode of acute pain is anticipated to last less than one (1) month.
D. The prescriber attests that the treatment of pain is not amenable to conservative measures such as acetaminophen, NSAIDs, and non-pharmacologic measures.

II. Quantity Limits

When a prior authorization is approved, quantities exceeding 29 tablets in a 90-day period may be approved for an additional course of therapy when all of the following criteria are met **(A., B., and C.)**:

A. The prescriber attests that the member is experiencing a new episode of moderate-to-severe acute pain, separate and distinct from the previous episode. Use of Journavx beyond 14 days of therapy for a single episode of acute pain is not covered.
B. The prescriber attests that the new episode of acute pain is anticipated to last less than one (1) month.
C. The prescriber attests that the treatment of pain is not amenable to conservative measures such as acetaminophen, NSAIDs, and non-pharmacologic measures.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.
III. The use of Journavx beyond 14 days of therapy for a single episode of acute pain is not covered.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 14-day authorization may be granted.
- An additional 29 tablets may be authorized for each distinct episode of acute pain in the past 90 days.

Automatic Approval Criteria

None

References:

1. Journavx [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated: January 2025.
2. Vertex. Press Release. Vertex Announces FDA Approval of Journavx (suzetrigine), a First-in-Class Treatment for Adults with Moderate-to-Severe Acute Pain. Available at: https://www.news.vrtx.com/news-releases/news-release-details/vertex-announces-fda-approval-journavxtm-suzetrigine-first-class. Accessed January 31, 2025.
3. Dowell D, Ragan KR, Jones CM, et al. CDC Clinical Practice Guidelines for Prescribing Opioids for Pain – United States, 2022. Available at: https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm#. Accessed January 28, 2025.

4. U.S. Food & Drug Administration. FDA News Release. FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain. Accessed January 31. 2025.
5. Clinical Pharmacology On-Line, Tampa, FL: Elsevier 2025. Accessed February 6, 2025.
6. Amaechi O, Huffman MM, Featherstone K, Pharmacologic Therapy for Acute Pain. *American Family Physician* July 2021, vol 104, n.1
7. Centers for Disease Control. Nonopioid Therapies for Pain Management. Available at: https:/www.cdc.gov/overdose-prevention/hcp/clinical-care/nonopioid-therapies-for-pain-management.html. Accessed February 7, 2025.