Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCANA054.1025	**ANALGESICS AND ANESTHETICS** **JOURNAVX®** (suzetrigine tablet)
Effective Date: 1/1/2026	**Review/Revised Date**:08/25 (MTW)
Original Effective Date: 06/25	**P&T Committee Meeting Date**: 04/25, 10/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-Approved Indications

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met or if the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit applies.

REQUIRED MEDICAL INFORMATION:

1. One of the following:
    a. Diagnosis of moderate to severe acute pain.
    b. Member has a surgical procedure scheduled within the next 30 days that is expected to result in moderate to severe acute pain, such as an invasive procedure that affects vital tissues or organs and requires longer recovery periods (for example, open-heart surgery, organ transplant, reconstructive surgery, knee or hip joint replacement, cesarean section)
2. Medicaid quantity limit exception requests must also meet both of the following:
    a. Patient has not already received 14 days of therapy for the same indication

b. Documentation that the patient is failing to receive adequate pain relief from, or has contraindications to, both acetaminophen and a non-steroidal anti-inflammatory agent (such as ibuprofen)

EXCLUSION CRITERIA:
- Use for chronic pain or sciatica
- Concurrent use with opioid medications

AGE RESTRICTIONS:
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization will be approved for one month. No reauthorization.

QUANTITY LIMIT:
Commercial: Seven tablets per 75 days
Medicaid: Quantities up to five tablets per 30 days may be covered without prior authorization. If a quantity limit exception is approved, up to 30 tablets (a 15-day supply) per 30 days may be approved.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Suzetrigine is a selective blocker of the $Na_V1.8$ voltage-gated sodium channel.

Suzetrigine is given as an oral tablet taken every twelve hours after an initial starting dose of two tablets. The package insert notes that use of suzetrigine for the treatment of acute pain has not been studied beyond 14 days.

FDA APPROVED INDICATIONS:
Treatment of moderate to severe acute pain in adults.

POSITION STATEMENT:
- Acute pain is the physiologic response to noxious stimuli that can become pathologic, typically with sudden onset, is time limited, and can motivate behaviors to avoid potential or actual tissue injury[6]. Acute paint typically lasts up to 7 days, however prolongations up to 30 days are common. Prolongations between 30-90 days are not well defined and are considered “subacute”. Pain lasting longer than 90 days is considered chronic.
- Management typically includes non-opioid medications (such as NSAIDs, acetaminophen), opioids, and nonpharmacologic therapies. Other medications that can be useful in certain situations include gabapentinoids (gabapentin, pregabalin), ketamine, IV lidocaine, topical lidocaine, glucocorticoids, alpha-2 receptor agonists, skeletal muscle relaxants. Management is typically multimodal, consisting of multiple pharmacologic and/or nonpharmacologic therapies.
- Suzetrigine was approved based on two phase 3, randomized, double-blind, placebo-controlled and active-controlled trials over a duration of 48 hours. Both trials included adults with moderate to severe acute pain. Trial 1/Navigate 2 evaluated patients with pain within four hours after abdominoplasty, and Trial 2/Navigate 1 included patients with pain within nine hours after removal of a ropivacaine nerve block post bunionectomy. Individuals were randomized to either suzetrigine, placebo, or hydrocodone/acetaminophen 5-325 mg.
    - The primary endpoint of the SPID48 (time-weighted sum of pain intensity difference from 0 to 48 hours) compared to placebo was met in both trials with suzetrigine demonstrating statistically significant and clinically meaningful reduction in pain versus placebo. The least squares mean difference in SPID48 between suzetrigine and placebo was 48.4 (95%CI:33.6,63.1;P<0.0001) after abdominoplasty and 29.3 (95%CI:14.0,44.6; P=0.0002) after bunionectomy.
        - Participants were allowed rescue medication with ibuprofen 400 mg every six hours as needed. For the primary endpoint, pre-rescue pain scores carried forward for 6 hours following use of rescue medication. The difference in SPIB48 compared to placebo with and without tracking pain scores after taking ibuprofen were similar.
    - Neither trial achieved the first key secondary endpoint of superiority of suzetrigine versus hydrocodone/acetaminophen on the SPID48.

  - For the second key secondary endpoint of time to ≥2-point reduction in numeric pain rating scale, suzetrigine had a more rapid onset of clinically meaningful pain relief versus placebo after abdominoplasty (119min versus 480mins, nominal P<0.0001) and bunionectomy (240mins versus 480mins, nominal P=0.0016)
  - Most common adverse reactions (> incidence compared to placebo): pruritus, muscle spasms, increased CPK, rash
- There are no trials looking at the safety or efficacy of suzetrigine used in combination with opioid analgesics.
- Institute for Clinical and Economic Review (ICER)[4]:
  - The evidence for suzetrigine for the treatment of acute pain in comparison with no systemic treatment, in comparison with opioid analgesics, and in comparison with NSAIDs are all promising but inconclusive (P/I)
  - Treatment with suzetrigine is slightly cost saving (~$400 over a lifetime) relative to opioid therapy while producing greater health benefits, due to the lifetime costs and harms of opioid use disorder (OUD), and assuming a wide range of estimates of OUD risk
  - Compared with hydrocodone-acetaminophen, suzetrigine is less costly and more effective in all areas; cost per quality-adjusted life year (QALY) gained, cost per equal value of life years gained (evLY) gained, cost per life year gained, and cost per OUD case averted
  - Assuming a one-week course of treatment with opioids results in at least two cases of OUD out of 100,000 people over the subsequent three years, suzetrigine is estimated to meet commonly used cost effectiveness thresholds (based on the WAC price)
- Suzetrigine is currently in phase 3 trials looking at use in diabetic peripheral neuropathy. Studies evaluating efficacy in lumbosacral radiculopathy pain (sciatica) have been discontinued due to a lack of efficacy over placebo in a phase 2 trial.

Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs (Youth with Special Healthcare Needs (YSHCN)) as they turn 21. This benefit applies when a condition is determined to impact the ability to grow, develop or participate in school and the applicable criteria above are met.

REFERENCE/RESOURCES:

1. Journavx® (suzetrigine) prescribing information. Vertex Pharmaceuticals Incorporated. Boston, MA. Revised 1/2025.

2. Journavx® (suzetrigine tablet) In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. Accessed February 24, 2025
3. Journavx® (suzetrigine tablet) In: Lexi-Drugs Online [Internet database]. Hudson, OH: Lexi-Comp, Inc. Updated periodically. Accessed February 24, 2025
4. Rind DM, McQueen B, Nikitin D, et al. Suzetrigine for Acute Pain; Effectiveness and Value. Final Report. Institute for Clinical and Economic Review, March 31, 2025. https://icer.org/wp-content/uploads/2025/03/ICER_Acute-Pain_Final-Report_For-Publication_033125.pdf
5. Dowell D, Ragan KR, Jones CM, et al. Centers for Disease Control and Prevention (CDC). CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. Recommendations and Reports / November 4, 2022 / 71(3);1–95. Available at: https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm
6. Kent ML, Tighe PJ, Belfer I, et al. The ACTTION-APS-AAPM Pain Taxonomy (AAAPT) Multidimensional Approach to Classifying Acute Pain Conditions. Pain Med. May 1 2017;18(5):947-958. doi:10.1093/pm/pnx019
7. Lopez A, Jones J, Menzie AM, et al. An evaluation of the prevalence of acute and chronic pain medication use in the United States: a real-world database analysis. Presented at: ASRA Annual Pain Medicine Meeting; November 10-11, 2023; New Orleans, LA.
8. 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 Jun 1;142(6):1085-1099. doi: 10.1097/ALN.0000000000005460. Epub 2025 Mar 21. PMID: 40117446; PMCID: PMC12061372.