Clinical Policy: Suzetrigine (Journavx)

Reference Number: CP.PMN.301
Effective Date: 06.01.25
Last Review Date: 05.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Suzetrigine (Journavx™) is a sodium channel blocker.

FDA Approved Indication(s)

Journavx is indicated for the treatment of moderate to severe acute pain in adults.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Journavx is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Moderate to Severe Acute Pain (must meet all)**:**

1. Diagnosis of moderate to severe acute pain;
2. Age ≥ 18 years;
3. Member meets one of the following (a, b, or c):
   a. Recent (within the last 7 days) major surgery or traumatic injury (e.g., crush injuries, spinal cord injury, burns, broken or dislocated bones);
   b. Member has plans to undergo a surgical procedure, and one of the following (i or ii):
      i. Member has one or more risk factors for increased post-operative pain (see *Appendix D*);
      ii. Surgical procedure is classified as major and associated with moderate to severe post-operative pain (see *Appendix D*);
   c. Failure of at least two analgesic medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], aspirin, acetaminophen, tramadol, opioids; *see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;
4. Prescribed as a component of multimodal analgesia (see *Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 150 mg (3 tablets) on day 1, then 100 mg (2 tablets) per day.

Approval duration: 14 days

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Moderate to Severe Acute Pain (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. Total duration of therapy does not exceed 14 days;
4. If request is for a dose increase, new dose does not exceed 100 mg (2 tablets) per day.

Approval duration: 14 days

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

APAP: acetaminophen
FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drugs

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Class	Commonly Used Examples	Dose Limit/ Maximum Dose
NSAIDs	ibuprofen (Motrin®), naproxen (Anaprox®, Anaprox DS®), indomethacin (Indocin®), diclofenac (Voltaren®), meloxicam (Mobic®), nabumetone (Relafen®), ketoprofen,	Varies according the agent used
Non-opioid analgesics	aspirin, acetaminophen (APAP) (Tylenol®), gabapentin	Varies according the agent used
Opioids	codeine, codeine/APAP, hydrocodone/APAP, oxycodone, tramadol, morphine	Varies according the agent used

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use with strong CYP3A inhibitors
- Boxed warning(s): none reported

Appendix D: General Information

- Risk factors for increased post-operative pain include:
  - History of physical, emotional, or sexual abuse
  - History of anxiety
  - History of drug or alcohol abuse
  - Preoperative NSAID or disease-modifying antirheumatic drug use
  - Current opioid use
  - Psychological conditions other than anxiety
  - Current smoker

- There are two main classes of surgery:
  - Major – Major surgeries are complex, invasive procedures that affect vital tissues or organs, addressing critical conditions and requiring longer recovery periods. Examples include open-heart surgery, organ transplant, reconstructive surgery, knee or hip joint replacement, cesarean section, etc.
  - Minor – Minor surgeries are generally superficial and do not require penetration of a body cavity. Examples include skin excision, biopsies, laparoscopy, tooth extractions, carpal tunnel release, etc.
  - NSAID usage should be used in caution in those with pre-existing renal insufficiency, heart failure, predisposition to gastrointestinal hemorrhage, and in elderly patients.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Moderate to severe acute pain	The recommended starting dose is 100 mg. Then starting 12 hours after the initial dose, take 50 mg PO BID.	150 mg/day on day 1, otherwise 100 mg/day

VI. Product Availability

Tablet: 50 mg

VII. References

1. Journavx Prescribing Information. Boston, MA: Vertex Pharmaceuticals; January 2025. Available at: https://pi.vrtx.com/files/uspi_suzetrigine.pdf. Accessed February 11, 2025.
2. Jones J, Correll DJ, Lechner SM, et al. Selective inhibition of Na v1.8 with VX-548 for acute pain. NEJM 2023;389(5):393-405.
3. Dowell D, Ragan KR, Jones CM, Baldwin GT, and Chou R. CDC clinical practice guideline for prescribing opioids for pain – United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1-95.
4. Armstrong AD, Hassenbein SE, Black S, et al. Risk factors for increased postoperative pain and recommended orderset for postoperative analgesic usage. Clin J Pain 2020;36(11):845-851.
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6. Policy Statement: Optimizing the treatment of acute pain in the emergency department. American College of Emergency Physicians. April 2017. Available at: https://www.acep.org/siteassets/new-pdfs/policy-statements/optimizing-the-treatment-of-acute-pain-in-the-ed.pdf. Accessed February 20, 2025.
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8. ACS trauma quality programs. Best practices guidelines for acute pain management in trauma patients. November 2020. Available at: https://www.facs.org/media/exob3dwk/acute_pain_guidelines.pdf. Accessed February 20, 2025.

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10. Patzkowski J and Patzkowski M. AAOS/METRIC Clinical practice guideline summary: Pharmacologic, physical, and cognitive pain alleviation for musculoskeletal extremity/pelvis surgery. Journal of the American Academy of Orthopedic Surgeons 2022;30(18)L1152-1160.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	03.11.25	05.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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