Generic Name: suzetrigine

Therapeutic Class or Brand Name: Journavx™

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: 6/2/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Medication is requested for the treatment of moderate-to-severe acute pain and ONE of the following criteria are met:
   A. Documented history of opioid use disorder (OUD).
   B. Documented history of severe allergic reaction or severe adverse reaction to opioids.

II. Treatment duration is for 14 days or less.

III. Age 18 years or older.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Concomitant use with strong CYP3A inhibitors (such as clarithromycin, itraconazole, ketoconazole, mifepristone, ritonavir, darunavir, etc.)
- Severe hepatic impairment (Child-Pugh Class C)
- Treatment duration is greater than 14 days.

OTHER CRITERIA

- Concomitant use with moderate CYP3A4 inhibitors (such as fluconazole, amiodarone, diltiazem, verapamil, grapefruit, etc.) requires dosage modification.
- Use in patients with moderate hepatic impairment (Child-Pugh Class B) requires dosage modification.
- There is a drug interaction between Journavx™ and hormonal contraceptives containing progestins other than levonorgestrel and norethindrone. Patients using Journavx™ concomitantly with hormonal contraceptives containing any other progestin should use

alternative contraceptives during treatment and for 28 days after discontinuation of Journavx™.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- For patients with no hepatic impairment and taking no CYP3A-affecting drugs:
  - 30 tablets per 14 days
- For patients with moderate hepatic impairment (Child-Pugh Class B), or those taking moderate CYP3A inhibitors:
  - 17 tablets per 14 days

APPROVAL LENGTH

- **Authorization:** One course of therapy, up to 14 days.
- **Re-Authorization:** Renewal not available. The use of Journavx™ for the treatment of moderate-to-severe acute pain has not been studied beyond 14 days. Chronic use is not covered. Any request for additional treatment courses will be evaluated as a new request and reviewed based on clinical appropriateness.

APPENDIX

N/A

REFERENCES

1. Journavx™. Prescribing Information. Vertex Pharmaceuticals; January 2025. Accessed February 20, 2025. https://pi.vrtx.com/files/uspi_suzetrigine.pdf
2. Bertoch T, D'Aunno D, McCoun J, et al. Suzetrigine, a Non-Opioid NaV1.8 Inhibitor for Treatment of Moderate-to-Severe Acute Pain: Two Phase 3 Randomized Clinical Trials. *Anesthesiology*. 2025. https://doi.org/10.1097/ALN.0000000000005460