



Journavx (suzetrigine) Quantity Limit Exceptions Criteria

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

Acute pain is generally sudden in onset and limited in duration. Acute pain is often caused by injury, trauma, or medical treatments such as surgery. Unresolved acute pain or subacute pain can evolve into chronic pain.

Nonopioid medications are part of the multimodal analgesia approach. Multimodal analgesia is used for perioperative pain management and other types of acute pain.

Journavx (suzetrigine) is a sodium channel blocker indicated for the treatment of moderate to severe acute pain, including postoperative pain, in adults. Journavx (suzetrigine) 50 mg has a coded quantity limit of 30 tablets per 14 days with a maximum 4 fills per 365 days. Use Journavx (suzetrigine) for the shortest duration, consistent with individual treatment goals. Use beyond 14 days for a single episode of acute pain has not been studied.

Definitions

"Acute pain" is defined as having a duration less than one (1) month.

"Subacute pain" is defined as having a duration of one (1) to three (3) months.

"Chronic pain" is defined as having a duration of greater than (>) three (3) months.

"Quantity Limit" refers to a restriction on the amount or quantity of medication that can be dispensed during a specific time period.

"Quantity Limit Exception" is a request to dispense a medication at a quantity or dosage that exceeds the plan's established quantity limit for a given time period.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

Indication-Specific Criteria

Acute Pain

The Plan considers Journavx (suzetrigine) quantities exceeding the established Plan limit of 4 fills per 365 days medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member has a diagnosis of moderate to severe acute pain; *AND*
3. The member requires Journavx (suzetrigine) for the treatment of a separate episode of acute pain (i.e., a different episode of acute pain from the member's dispensing history); *AND*
4. The member meets ONE (1) of the following:
 - a. The member is unable to use, or has tried and failed ALL of the following non-opioid pharmacologic therapies intended to treat pain:
 - i. Acetaminophen; *and*
 - ii. Gabapentinoid; *and*
 - iii. Oral nonsteroidal anti-inflammatory drug (NSAID) (see [Appendix A](#)); *or*
 - b. The member has plans to undergo a surgical procedure, and meets ONE of the following:
 - i. The member has one (1) risk factor for increased post-operative pain (see [Appendix B, Table 1](#)); *or*
 - ii. The surgical procedure is classified as a major surgery (see [Appendix B, Table 2](#)) *AND* the treating provider attests that other pharmacologic pain relief therapies are not appropriate; *AND*
5. Journavx (suzetrigine) is being prescribed at a dose and frequency that is within FDA approved labeling.

If the above prior authorization criteria are met, the requested product will be authorized for a one-time override for an additional fill.^[s]

Experimental or Investigational or unproven^[s]

Journavx (suzetrigine) for any other indication or use is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Administration exceeding twice daily maintenance dosing of the 50 mg tablets. The starting dose of Journavx (suzetrigine) is 100 mg followed by 50 mg twice daily no sooner than 12 hours after the initial 100 mg dose. Journavx (suzetrigine) has not been studied beyond 14 days, or at doses higher than 50 mg twice daily.
- Chronic pain. Journavx (suzetrigine) is not intended to treat chronic pain, and has only been studied in the acute pain setting (for no more than 14 days).

- Mild acute pain. Journavx (suzetrigine) has only been studied in those with moderate to severe pain, including post-operative pain. There are no high quality studies supporting the safety and efficacy of Journavx (suzetrigine) for the management of mild pain.
- Treatment of acute pain beyond 14 days for a single episode of acute pain.
- Treatment of pediatrics. The safety and efficacy of Journavx (suzetrigine) has not been established in pediatric populations.

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Appendix A

Examples of nonsteroidal anti-inflammatory drugs (NSAIDs) used for pain:

- diclofenac
- etodolac
- ibuprofen
- indomethacin
- ketorolac (short term [≤ 5 days])
- meclofenamate
- meloxicam
- naproxen
- sulindac

Note NSAID usage should be used in caution in those with pre-existing renal insufficiency, heart failure, predisposition to gastrointestinal hemorrhage, and in elderly patients. NSAID usage is contraindicated in known hypersensitivity of any components of the drug product, history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs, and in the setting of Coronary Artery Bypass Grafting (CABG) surgery.

Appendix B

Table 1: Risk Factors for Increased Post-Operative Pain

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

Table 2: Major versus Minor Surgeries

Major Surgeries	Minor Surgeries
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 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.

Clinical Guideline Revision / History Information

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