

# New Mechanisms, New Options: Suzetrigine in Practice

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Pharmacy Forward: Advancing Practice for a  
Healthier Tomorrow!

OPA Annual Conference & Trade Show April 9-11, 2026



# Disclosure Statement

- Jessica Geiger has no relevant financial relationship(s) with ineligible companies to disclose.  
*and*
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.





## Learning Objectives

At the completion of this activity, the participant will be able to:

1. describe the pharmacologic properties and mechanism of action of suzetrigine in the management of acute pain;
2. review current clinical evidence supporting the use of suzetrigine as a non-opioid analgesic option; and
3. evaluate the potential place of suzetrigine in therapy compared with existing acute pain treatments.

# My Background



CLINICAL  
PHARMACIST  
PRACTITIONER



14+ YEARS OF  
EXPERIENCE IN PAIN  
MANAGEMENT



PAIN-RELATED  
TEACHING AND  
WRITING



DIRECT PATIENT  
CARE



MULTIDISCIPLINARY  
TEAMS

# Abbreviations

- APAP: Acetaminophen
- CI: Confidence Interval
- H/APAP: Hydrocodone/acetaminophen
- NSAID: Non-steroidal anti-inflammatory drug
- CNS: Central Nervous System
- GI: Gastrointestinal
- NPRS: Numerical Pain Rating Scale
- SPID48: Sum of pain intensity difference over 48 hours
- DPN: Diabetic Peripheral Neuropathy
- PLSR: Painful Lumbosacral Radiculopathy



**NBC NEWS** TRUMP ADMIN POLITICS U.S. NEWS WORLD LOCAL BUSINESS EDITORS' PICKS SHOPPING TIPLINE WATCH

HEALTH NEWS

## FDA approves new type of nonopioid painkiller for acute pain

The drug, [redacted], reduced pain after surgery in clinical trials. Experts hope it can lead to fewer opioid prescriptions.

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## New non-opioid painkiller approved by US health agency

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NEWS | 31 January 2025

## US drug agency approves potent painkiller – the first non-opioid in decades

The FDA's nod for suzetrigine bolsters confidence in the pharmaceutical industry's strategy to target sodium channels.

By Elin Oslgin



*The New York Times*

## *F.D.A. Approves Drug to Treat Pain Without Opioid Effects*

The drug, [redacted], blocks pain signals to the brain, making it nonaddictive.

- Pain is the most common reason that people seek healthcare

20.9% of adults experience chronic pain

70% of ED visits cite acute pain

80% of patients experience post-surgical pain

- Current treatment options can be limited

Side effects, medication interactions, disease state contraindications



125 million opioid prescriptions were written in 2023



# Medication Risks

## NSAIDs

- Bleeding, cardiac events, renal

## Acetaminophen

- Liver toxicity

## Opioids

- Respiratory depression, nausea, sedation, abuse/misuse





# NSAIDs

- Generally, avoid in patients on anticoagulation
- Risk for GI bleed increases with age
- Can contribute to increased blood pressure
- Can cause heart failure exacerbations
- Compromise renal function



# Acetaminophen

- Dose limitation
- Can contribute to hepatotoxicity



# Opioids

- Risk of respiratory depression
- Most guidelines do not recom



Un  
wid  
67-92  
having  
surgery

...age is  
non  
~75% don't use locked  
containers.



**Proper disposal is rare**

Fewer than **1 in 10** use FDA-recommend disposal methods.

**This is NOT an anti-opioid presentation**

# Suboptimal Post-surgical Pain

- Increased morbidity
- Impaired function
- Change in quality of life
- Slower recovery
- Potential longer opioid use after hospitalization
- Increased costs



What do the following medications have in common?

1. Carbamazepine
2. Suzetrigine
3. Ropivacaine



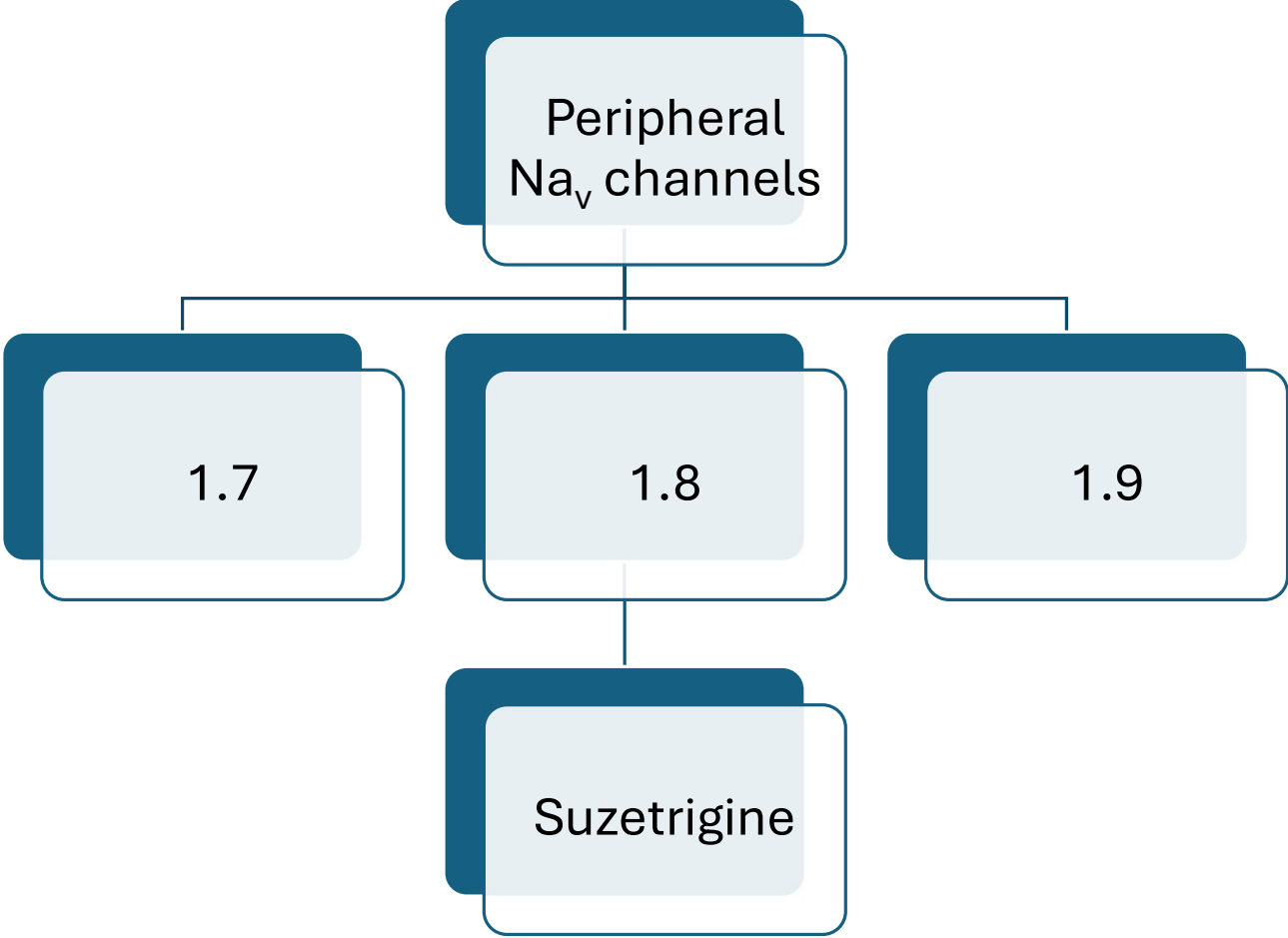


# Mechanism of Action

# Voltage gated sodium channels

- $\text{Na}_v$  channels facilitate the influx of sodium
  - Generates an action potential
    - This sends a signal
- 9  $\text{Na}_v$  subtypes
  - Mostly in CNS
- Antiepileptics, Anesthetics, Antiarrhythmics
  - All rely on sodium channel blockade







# Nav 1.8

- Voltage gated sodium channel
- When inhibited = decreased pain signals
- Not expressed in the brain or spinal cord
  - Should not exhibit CNS side effects



# Suzetrigine



**FDA approved in January 2025**

Tx of moderate to severe acute pain



**Administration**

100mg x 1 dose, followed by 50mg Q12H



## Mechanism of Action

Binds to  $\text{Na}_v 1.8$ , closes the channel and prevents a pain signal from being transmitted

Suzetrigine is  
**SELECTIVE** to this  
channel

Limits CNS effects

# Pharmacology

	Suzetrigine	M6-suz
Absorption time	3 hours	10 hours
Steady state	3 days	5 days
Half-life	24 hours	22 hours
Protein binding	High	
Excretion	Feces and Urine	
Metabolism	CYP 3A4 substrate CYP 3A4 inducer	



What do the studies say?

## Phase 3 Program:

- NAVIGATE-1 and NAVIGATE-2
- Single-arm, open-label study



### PAIN MEDICINE

## Suzetrigine, a Non-Opioid Na<sub>v</sub>1.8 Inhibitor for Treatment of Moderate-to-Severe Acute Pain: Two Phase 3 Randomized Clinical Trials

Bertoch, Todd MD; D'Annunzio, Dominick MD; McCoun, Jessica MD; Solanki, Daneshvari MD; Taber, Louise MD; Urban, Joshua MD; Oswald, Jessica MD, MPH; Swisher, Matthew W. MD; Tian, Simon MD; Miao, Xiaopeng PhD; Correll, Darin J. MD; Negulescu, Paul PhD; Bozic, Carmen MD; Weiner, Scott G. MD, MPH

[Author information](#)

*Anesthesiology* ( );10.1097/ALN.0000000000005460, March 21, 2025. | DOI: 10.1097/ALN.0000000000005460



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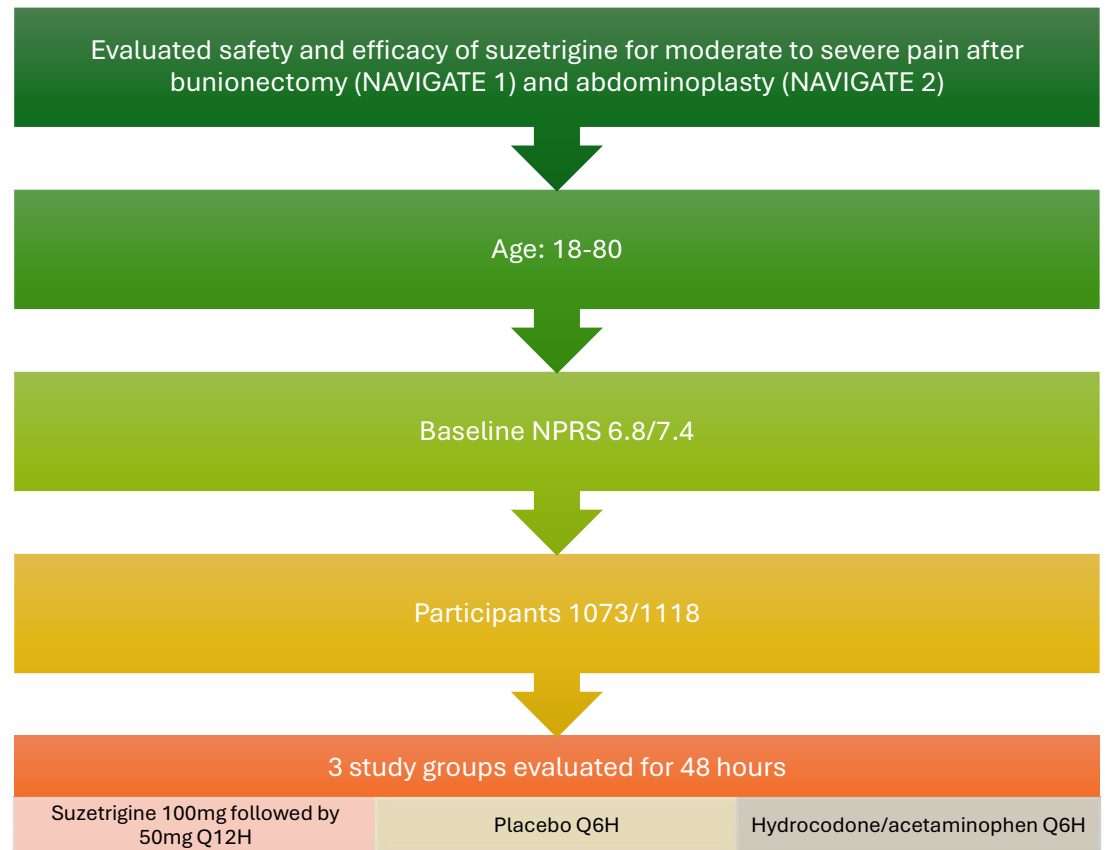
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# NAVIGATE 1 and 2



# NAVIGATE 1 and 2

Used NPRS

Primary endpoint

- SPID48 between suzetrigine and placebo

Secondary endpoint

- SPID48 between suzetrigine and H/APAP
- Time to  $\geq 2$  point reduction in NPRS





# What's SPID got to do with it?



HIGHER SPID SUGGESTS BETTER  
PAIN REDUCTIONS



IT IS AN FDA VALIDATED  
OUTCOME MEASURE FOR PAIN  
TRIALS

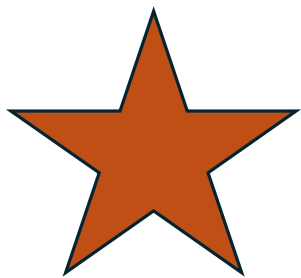


DIFFICULT TO INTERPRET  
CLINICALLY



# Primary endpoint

	Suzetrigine SPID48	Placebo SPID48	SPDI48 difference	Conclusion
NAVIGATE-1	99.9	70.6	29.3 (95% CI)	Suzetrigine statistically better
NAVIGATE-2	118.4	70.1	48.4 (95% CI)	Suzetrigine statistically better



Primary endpoint met in both trials



# Secondary endpoint

	Suzetrigine SPID48	H/APAP SPID48	SPDI48 difference	Conclusion
NAVIGATE-1	99.9	120.1	-20.2 (95% CI)	H/APAP statistically better
NAVIGATE-2	118.4	111.8	6.6 (95% CI)	Comparable



Secondary endpoint NOT met in either trials



- Evaluated adverse events (primary endpoint) and participant perspective of effectiveness (secondary endpoint)
- Suzetrigine used for up to 14 days in various surgeries or in non-surgical pain
- 83% reported good, very good, or excellent

Journal of Pain Research Dovep  
Taylor & Frai

Open Access Full Text Article ORIGINAL RESE

## Suzetrigine, a Non-Opioid Na<sub>v</sub>1.8 Inhibitor With Broad Applicability for Moderate-to-Severe Acute Pain: A Phase 3 Single-Arm Study for Surgical and Non-Surgical Acute Pain

Jessica McCoun<sup>1</sup>, Peter Winkle<sup>2</sup>, Daneshvari Solanki<sup>3</sup>, Joshua Urban<sup>4</sup>, Todd Bertoch<sup>5</sup>, Jessica Oswald<sup>6</sup>, Matthew W Swisher<sup>7</sup>, Louise Anne Taber<sup>8</sup>, Tiffany Healey<sup>9</sup>, Ina Jazic<sup>10</sup>, Darin J Correll<sup>11</sup>, Paul A Negulescu<sup>12</sup>, Carmen Bozic<sup>13</sup>, Scott G Weiner<sup>14</sup> On behalf of the VX-548-107 Study Team

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# Chronic Pain?

**2 Phase II studies – Pain associated with DPN and PLSR**



# DPN



Statistical decrease in NPRS after 12 weeks compared to pregabalin



Breakthrough therapy designation



Phase III studies are underway evaluating a 70mg daily dose





# Implications

- Additional medication for DPN
- Less potential for side effects
- eGFR  $\geq 15$  mL/min does not require dose adjustment





# PLSR

- Suzetrigine AND placebo showed statistically significant pain reduction
- Placebo had increased side effects
- Phase III trial is proposed





# Other Publications

# Since release

- >60 papers published
  - Pharmacology
  - Editorials/Commentary
  - Medication class overviews
  - Considerations for other indications
    - Palliative care
  - Meta-analysis
  - Perspective on value
  - Case report on side effects



# Palliative Care - Pakistan

- Access to opioids is restricted
  - 2% of patients have access
- Concerns about opioid misuse and regulatory restrictions
- Evaluating suzetrigine as an alternative for pain management
  - Hope is for better patient outcomes by incorporating suzetrigine



# Perspective on Value

- Evaluated NAVIGATE 1 and 2
- Clinical comparison
  - Bunionectomy had delayed pain relief when compared to abdominoplasty
    - Potentially due to use of ropivacaine
  - Bunionectomy had similar rates of rescue as placebo
- Limitations in clinical evidence
  - Short and long-term risks are not fully understood
  - Unsure about addiction risk



# Perspective on Value

- Evaluated NAVIGATE 1 and 2
- Financial comparison
  - Suzetrigine is more costly than H/APAP
- Limitations in cos-effectiveness
  - Cost of potential OUD is not included in use of H/APAP



# Case Report

- 48yo female, s/p ulnar shortening osteotomy
- 6 weeks post-operatively, suzetrigine was trialed d/t inadequate pain control
- Patient report:
  - 45 minutes after taking the 1<sup>st</sup> suzetrigine dose felt painful “pins and needles” sensations in upper and lower extremities
- Advised to stop the medication, sx resolved ~ 18 hours after ingestion
  - Aligns with medication pharmacology



# What do the experts think?

- Need more information about safety and efficacy
  - Evaluation is currently limited
- Gaps in use
  - Cardiothoracic and vascular practice, pediatrics and chronic pain
- “Cautious optimism”
- Fast track approval has resulted in poor outcomes in the past
- “Hopeful substitute for opioids”



# What do the experts think?

- May increase risk of thrombosis in perioperative patients
- Question speed of onset
- Concern around lack of superiority to opioid group in studies





## Place in Therapy

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Opioid adverse events

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GI contraindications to NSAIDs

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Allergies to other options

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Patients with decreased access

# The flip side



More studies  
are needed



Costly (~\$233  
for a 30ds)



Insurance  
concerns



Prescriber  
comfort



No long-term  
safety data

Which of the following patients MAY benefit from a trial of suzetrigine?

- A. 35yo female who has a 1yo child, currently taking progestogen birth control who is scheduled for an ankle surgery
- B. 82yo male s/p hip replacement, CrCl<40 mL/min
- C. 60yo with a history of opioid use disorder and GI bleed



# Answer

Potentially all of them! (We just might need to know more)

- A. Encourage to use other birth control
- B. CrCl and age may preclude NSAIDs, unsure if the patient has had opioid related side effects
- C. Current evidence points to non-addictive potential of suzetrigine, which may be a better option



# Highlights

Study results not available beyond 14 days\*

Not studied in eGFR < 15 mL/min

Dose adjustment required in hepatic failure

Less incidence of side effects (even when compared to placebo)

# Clinical pearls

- Not a controlled substance
- To date, no evidence of addictive potential
- Only indicated for treatment of moderate to severe ( $\geq 4$ ) acute pain in adults
- Contraindicated with strong CYP3A inhibitors
- Additional contraception should be used if on progestins other than levonorgestrel or norethindrone



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# Need More Information?

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