Suzetrigine for Acute Pain: Effectiveness and Value

Final Policy Recommendations

March 31, 2025

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the February 28, 2025 Midwest CEPAC public meeting on the use of suzetrigine for the treatment of acute pain. At the meeting, ICER presented the findings of its revised report on this treatment and the Midwest CEPAC voting council deliberated on key questions related to its comparative clinical effectiveness, potential other benefits and contextual considerations, and long-term value for money at the current price. Following the votes, ICER convened a Policy Roundtable of two patient experts, two clinical experts, two payers, and one representative from the pharmaceutical manufacturer to discuss how best to apply the evidence and votes to real-world practice and policy. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here, and a recording of the voting portion of the meeting can be accessed here. More information on Policy Roundtable participants, including conflict of interest disclosures, can be found in the Appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Sarah Emond, President and CEO, ICER. The main themes and recommendations from the discussion are organized by audience and summarized below.

Health Equity

All Stakeholders

Recommendation 1

All stakeholders have a responsibility and an important role to play in ensuring that all patients with acute pain are treated appropriately and equitably.

As also discussed in ICER's review of gene therapies for sickle cell disease, we repeatedly heard from multiple stakeholders about inadequate management of acute pain in Black Americans, as well as evidence that this inadequate management may be tied to both implicit and explicit bias.

We also heard from experts that overprescription of opioids was particularly common among White Americans in under-resourced communities, leading to high rates of OUD. We heard that, although this has improved somewhat, overprescription continues in many areas.

Patient groups and clinical societies should focus on education of providers and patients about appropriate and safe pain management, as well as recognition and avoidance of implicit bias. In order to create the conditions for equitable access, manufacturers should price medications according to value, and payers should consider long-term risk of OUD when designing coverage policies.

Recommendation 2

Stakeholders should adopt policies that promote the use of therapies that provide value over the long run.

In the US health system, payers may sometimes lack incentives to cover therapies that have a higher price even when these therapies may result in long-term savings. This can occur in part because patients/families frequently switch insurance providers, or patients move to government-provided insurance as they become older such that the payer who must reimburse for the therapy with long-term savings is different from the payer that experiences those savings. Payers, manufacturers, and the federal government should develop policies that enhance the use of therapies with higher upfront costs but greater long-term cost-effectiveness, whether these are gene therapies with very high initial prices, or a therapy like suzetrigine where savings will likely be realized years in the future.

Payers

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy: https://icer.org/wp-content/uploads/2020/11/Cornerstones-of-Fair-Drug-Coverage-_-September-28-2020.pdf

Drug-Specific Coverage Criteria: Suzetrigine

The large number of patients with acute pain and the additional cost of suzetrigine, particularly when compared with generic opioid and non-opioid oral analgesics, may lead payers to develop prior authorization criteria and to consider other limits on utilization.

None of these limits, however, should undermine the tenets of fair access to which all patients have a fundamental right. To explore the appropriate application of evidence to coverage policy, and to reflect the views of patient experts and clinicians on specific ways that payers might appropriately use coverage policy to manage resources prudently, we present the following perspectives on specific elements of cost sharing and coverage criteria for suzetrigine.

Coverage Criteria

- **Age:** Age criteria are likely to follow the FDA label and not be expanded to cover adolescents or children. As adolescents may be at particularly high risk of developing OUD after brief exposures to opioids for acute pain, payers should be ready to widen coverage for suzetrigine if research in younger patients leads to a label expansion.

- **Clinical eligibility**: We heard from clinical experts that there are no validated tools that are highly predictive of which patients will or will not develop OUD after a short course of opioids.

  Some payers are likely to develop eligibility criteria that initially allow treatment with suzetrigine only in patients who have previously been intolerant of opioids and NSAIDs or who are felt to be at particularly high risk of OUD (e.g., those with prior OUD) or complications from treatment with opioids and/or NSAIDs (e.g., elderly patients, debilitated patients).

- **Exclusion criteria**: There are no special medical comorbidities at this time that would serve as exclusion criteria for suzetrigine.

- **Duration of coverage and renewal criteria**: Initial coverage will likely be for a one-week course of treatment. Some procedures and injuries can be expected to have longer periods of moderate to severe pain (two to three weeks), and payers may consider renewal policies or initial dispensation of additional doses. The advantage of requiring renewal is that it would minimize waste if a patient finds treatment with suzetrigine inadequate or if pain resolves. The advantage of initially dispensing more doses is that patients in pain may find it difficult to manage requesting and accessing a renewal.

- **Provider restrictions**: We suggest that there be no restrictions on which providers can prescribe suzetrigine. Suzetrigine appears safer than some commonly used medications that are broadly prescribed by generalists and specialists.

- **Determination of coverage:** Payers have an obligation to make it easy for providers and patients to quickly determine whether suzetrigine will be covered. Patients in acute pain need to know that they will receive prescribed medication without delay, and providers need to be able to prescribe a medication that will be covered.

- **Copays and deductibles:** As noted, there has been overprescription of opioids to low-income White communities. When developing policies around copays and deductibles for suzetrigine, payers should consider that higher levels of cost-sharing are likely to particularly incentivize low-income patients to choose an inexpensive medication such as an opioid.

Step Therapy

Step therapy is particularly problematic with medications for acute pain.

Payers are likely to find that it will be difficult to implement step therapy for suzetrigine. The complication of OUD is one that will not be recognized in time to change to an alternative treatment. While payers may wish to require that patients try to manage their pain with NSAIDs before filling a prescription for suzetrigine, given the course of acute pain it may be hard for most payers to expediently manage requests for suzetrigine due to inadequate relief with NSAIDs.

If payers wish to implement such policies, they may want to consider novel protocols or prescriptions (such as covering suzetrigine if a patient receives a prescription saying it can only be filled if a patient reports inadequate pain relief with NSAIDs) that can allow management of pain without further payer contact from a patient or provider.

Manufacturers

Recommendation 1

Manufacturers should set prices that are aligned with net benefit. Vertex deserves recognition for appropriately pricing suzetrigine.

ICER's analysis suggests that suzetrigine is priced well within a cost-effective price range, assuming that the risk of OUD after a short course of opioids is nonzero.

Recommendation 2

The manufacturer should conduct additional research on suzetrigine to answer open questions.

Unanswered questions around efficacy include the benefits of suzetrigine for different types of pain and with and versus other methods of pain management. These include additional trials in bony pain, trials in patients with headache, and trials of combining suzetrigine with NSAIDs and/or acetaminophen. We heard from clinical experts that this sort of combination treatment to potentially achieve synergistic pain relief will likely be an early use case with suzetrigine for providers and patients.

As noted above, avoiding opioids may be particularly important in adolescents with acute pain. Research will be needed on safety and efficacy of suzetrigine in a younger population to allow any label expansion to such patients.

Trials are needed comparing the efficacy of suzetrigine with that of high-dose NSAIDs. Until such studies are performed, it will be difficult to justify treating patients with suzetrigine in the absence of a contraindication to NSAIDs or inadequate pain relief with NSAIDs.

Clinicians and Clinical Societies

Recommendation 1

Clinical societies should rapidly update treatment guidelines for patients with acute pain.

Guidelines that discuss the appropriate use of suzetrigine for acute pain are needed to harmonize management of a ubiquitous condition. Payers look to such guidelines when developing coverage policies. Guidelines should address which patients are most appropriate for treatment with suzetrigine, duration of treatment, and combination treatment, and should be updated as trial evidence and clinical experience evolve. Guidelines should also address the appropriate use of NSAIDs. We heard from clinical experts that, as part of the strategy to promote opioid use that led to the US opioid crisis, there was likely an intentional attempt to exaggerate concerns about the safety of NSAIDs. While NSAIDs have some safety issues, guidelines can help providers recognize when they can and cannot be safely prescribed, at what dose, and for what duration.

Recommendation 2

Clinicians and clinical societies should advocate for broader patient access to multimodal pain management.

We heard from clinical experts and patient groups that multimodal pain management that combines pharmacologic and non-pharmacologic interventions is typically the safest and most effective way to manage pain. However, we also heard from these groups that such management is unavailable in most clinical locations. Clinicians and clinical societies have particular obligations to prevail on healthcare organizations to expand patient access (location of services, time of day, practitioners employed, and networks for referral) to multimodal pain management.

Patient Organizations

Recommendation 1

Patient organizations have a vital role to play to promote objective descriptions of the risks and benefits of therapies in order to support shared decision-making for every patient.

Many stakeholders must assume some responsibility for the opioid crisis. Patients were among those most harmed. As such, patient groups have a particular ability to present unbiased information on the benefits and potential harms of all pain medications; for opioids in particular, additional education should be provided on the risks of developing OUD when pain is treated with opioids.

Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the February 28th, 2025 Public meeting of Midwest CEPAC.

Appendix Table 1. ICER Staff and Consultants and COI Disclosures

ICER Staff and Consultants*	
Michael Distefano, PhD, Assistant Professor, University of Colorado Anschutz Medical Campus	**Sarah Emond, MPP,** President and CEO, ICER
Kelsey Gosselin, MA, Program Director, ICER	**Grace Ham, MSc,** Senior Program and Events Coordinator, ICER
Woojung Lee, PharmD, PhD, Associate Director of Health Economics and Decision Modeling, ICER	**Brett McQueen, PhD,** Associate Professor, University of Colorado Anschutz Medical Campus
Dmitriy Nikitin, MSPH, Senior Research Lead, ICER	**Dan Ollendorf, PhD, MPH,** Chief Scientific Officer and Director of HTA Methods and Engagement, ICER
Marie Phillips, BA, Research Assistant, ICER	**Finn Raymond, BS,** Research Assistant, ICER
David Rind, MD, MSc, Chief Medical Officer, ICER	**Sol Sanchez, BS**, Research Assistant, ICER
Temiwunmi Shobanke, MS, Program Manager, ICER	**Antal Zemplenyi, PhD, MSc,** Visiting Research Associate, University of Colorado Anschutz Medical Campus

*No conflicts of interest to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.

Appendix Table 2. Midwest CEPAC Panel Member Participants and COI Disclosures

Midwest CEPAC Member	Conflict of Interest
Eric Armbrecht, PhD, Professor, Saint Louis University	No conflicts to disclose.
Alan Balch, PhD, CEO, Patient Advocate Foundation and the National Patient Advocate Foundation	No conflicts to disclose.
Bijan Borah, PhD, Professor of Health Services Research, Mayo Clinic College of Medicine and Science	No conflicts to disclose.
Donald Casey, MD, MPH, MBA, MACP, FAHA, Associate Professor of Internal Medicine, Rush Medical College	No conflicts to disclose.
Gregory Curfman, MD, Executive Editor, JAMA, American Medical Association	No conflicts to disclose.
Sneha Dave, Executive Director, Generation Patient	No conflicts to disclose.
Yngve Falck Ytter, MD, AGAF, Professor, Pharmacy Practice, University of Arkansas for Medical Sciences, College of Pharmacy	No conflicts to disclose.
Heather Guidone, BCPA, Program Director, Center for Endometriosis Care	No conflicts to disclose.
Jill Johnson, PharmD, Professor, Pharmacy Practice, University of Arkansas for Medical Sciences, College of Pharmacy	No conflicts to disclose.
Jayani Jayawardhana, PhD, Associate Professor, University of Kentucky	No conflicts to disclose.
David Kim, PhD, Assistant Professor, University of Chicago	No conflicts to disclose.
Timothy McBride, PhD, Washington University in St. Louis	No conflicts to disclose.
Jimi Olaghere, Patient Advocate	Mr. Olaghere participated in a clinical trial conducted by Vertex in a different disease area.
Stuart Winston, DO, Patient Experience Lead Consultant, Trinity Health IHA Medical Group	No conflicts to disclose.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Vicky Brown, PharmD, BCOP, Associate Vice President Clinical Drug Strategy, Humana	Dr. Brown is a full-time employee at Humana.
Jaime Rubin Cahill, MA, MPH, Vice President, Health Economics and Outcomes Research, Vertex Pharmaceuticals	Jaime Rubin Cahill is a full-time employee at Vertex Pharmaceuticals.
David Dohan, MD, MHCM, Medical Director of Pharmacy, Point32 Health	Dr. Dohan is a full-time employee at Point32 Health.
Benjamin Friedman, MD, MS, Professor of Emergency Medicine, Montefiore-Einstein	No conflicts to disclose.
Nicole Hemmenway, Chief Executive Officer, US Pain Foundation	Nicole Hemmenway is a full-time employee of the US Pain Foundation. The US Pain Foundation receives greater than 25% of funding from health care

	companies, industry groups, family foundations, and individual donors.
Andrew Kolodny, MD, Medical Director, Opioid Policy Research, Heller School for Social Policy and Management, Brandeis University	Dr. Kolodny has served as an expert witness in litigation involving the opioid industry.
Gabriel Smith, Patient, Arlington Chronic Pain Support Group	No conflicts to disclose.