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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | | 06/30/25 | | Table of Contents | | 1 – FDA Approval Spotlight  2 – Guideline Updates  4 – Legislative News | | Contact Us  Acentra  2431 E. Glenn Ave., St 100  Auburn, AL 36830  334-352-8650  www.kepro.com  Acentra Account Manager  Alena Mitchell, PharmD  alena.mitchell@acentra.com | | West Virginia RDUR 2025 Quarter 2 Newsletter **FDA APPROVAL SPOTLIGHT**  **Journavx**  JOURNAVX Prescription & Dosage ...On January 30, 2025, the Food and Drug Administration (FDA) approved a first-in-class therapy for the treatment of moderate-to-severe acute pain, Journavx (suzetrigine). This novel therapy is a non-opioid analgesic and meant to help treat pain in patients that may not be good candidates for high doses of NSAIDs or opioids. Journavx acts as a selective antagonist to Nav 1.8 voltage-gated sodium channels, which are primarily found in peripheral neurons.  Journavx dosing is recommended as 100 mg orally for one loading dose on an empty stomach at least 1 hour prior to or 2 hours after a meal. Twelve hours after the loading dose, Journavx should be taken 50 mg orally every 12 hours with or without food for up to 14 days. Its use is contraindicated with concurrent strong CYP3A4 inhibitors, and dose reduction is recommended for concurrent use with moderate CYP3A4 inhibitors. (For this regimen, the first 4 doses are the same with a dose reduction 50 mg orally every 24 hours starting at the 5th dose.) Additionally, the same dose reductions is recommended for patients with Child-Pugh Class B hepatic impairment. Patients with Child-Pugh Class C hepatic impairment are recommended to avoid Journavx therapy.  In clinical trials, Journavx was compared to placebo and hydrocodone/ acetaminophen 5/325 mg orally every 6 hours as an active control starting at 4 hours after an abdominoplasty or 9 hours after a bunionectomy. Ibuprofen 400 mg orally every 6 hours as needed was also utilized as a rescue therapy in both clinical trials. Efficacy of pain relief was measured by a verbal categorical rating system (VRS) as mild, moderate, or severe pain, as well as an 11-point numeric pain rating scale. The primary endpoint was calculated as the time-weighted sum of pain intensity difference in the first 48 hours post-procedure. In both the abdominoplasty and bunionectomy trials, Journavx was superior to placebo but not to the active control in improving pain. Of note, in the bunionectomy trial, the hydrocodone/acetaminophen active control was statistically superior to Journavx. These results can be seen in the table below.   |  |  |  |  | | --- | --- | --- | --- | | ***Abdominoplasty*** |  |  |  | | **Efficacy Measure** | **Journavx**  **(N=447)** | **Placebo**  **(N=223)** | **Active Control**  **(N=448)** | | **LS Mean** | 118.4 | 70.1 | 111.8 | | **LS Mean Difference vs. Placebo**  **(95% CI)** | 48.4 (33.6, 63.1)  p<0.0001 | - | - | | **LS Mean Difference vs. Active Control (95% CI)** | 6.6 (-5.4,18.7) | - | - | | ***Bunionectomy*** |  |  |  | | **Efficacy Measure** | **Journavx**  **(N=426)** | **Placebo**  **(N=216)** | **Active Control**  **(N=431)** | | **LS Mean** | 99.9 | 70.6 | 120.1 | | **LS Mean Difference vs. Placebo**  **(95% CI)** | 29.3 (14.0, 44.6)  p=0.0002 | - | - | | **LS Mean Difference vs. Active Control (95% CI)** | -20.2 (-32.7, -7.7) | - | - |   Of note, in both trials, the majority of participants were female (≥85%) and white (≥70%). Medium time to meaningful time to pain relief was 119 minutes in the abdominoplasty trial and 240 minutes in the bunionectomy trial. The most common adverse reactions were pruritus/rash, muscle spasms, and increased creatine phosphokinase.  While these trials did not demonstrate promising results when compared to the active opioid control for acute pain treatment, they did demonstrate a statistically significant improvement in acute pain compared to placebo. It is worth noting that post-operative pain in the first 48 hours can be intense and accompanied by a wide variety of other discomfort; so this outcome is not necessarily unexpected. However, more research must be performed to fully elucidate Journavx’s place in therapy in the range of well-established acute pain treatments currently available.  ***References:***   * Vertex Pharmaceuticals Incorporated; Boston, MA. Journavx [package insert]. U.S. Food and Drug Administration website. <https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209s000lbl.pdf> * Bertoch T, D'Aunno D, McCoun J, Solanki D, Taber L, Urban J, Oswald J, Swisher MW, Tian S, Miao X, Correll DJ, Negulescu P, Bozic C, Weiner SG. Suzetrigine, a Nonopioid Na V 1.8 Inhibitor for Treatment of Moderate-to-severe Acute Pain: Two Phase 3 Randomized Clinical Trials. Anesthesiology. 2025 Jun 1;142(6):1085-1099. doi: 10.1097/ALN.0000000000005460. Epub 2025 Mar 21. PMID: 40117446; PMCID: PMC12061372.   **GUIDELINE UPDATES**  **ACP: Treatment and Prevention of Acute Episodic Migraines**  American College of Physicians unveils ...  On February 4, 2025 and March 18, 2025 respectively, the American College of Physicians (ACP) published two new evidence-based clinical guidelines on the prevention and treatment of acute episodic migraines. Of note, these documents distinguish the therapeutic approach from the prevention and treatment of chronic migraines by defining a diagnosis of episodic migraines as causing ≤14 headache days per month, while chronic migraines cause ≥15 headache days per month.  The guidelines for the prevention of acute episodic migraines have three main recommendations:  ***Recommendation 1:*** Preventative monotherapy should be initiated in all nonpregnant adults in outpatient settings with a history of episodic migraines. One of the following therapies may be utilized: beta blocker (specifically metoprolol or propranolol), antiepileptic drug (specifically valproic acid or one of its derivatives), SNRI (specifically venlafaxine), TCA (specifically amitriptyline).  ***Recommendation 2:*** For patients who do not tolerate or adequately respond to one of the above preventative therapies, a calcitonin gene-related peptide (CGRP) antagonist (specifically atogepant or rimegepant) or a CGRP monoclonal antibody should be initiated in nonpregnant adults in outpatient settings with a history of episodic migraines.  ***Recommendation 3:*** For patients who do not tolerate or adequately respond to one of the above CGRP therapies, topiramate should be initiated in nonpregnant adults in outpatient settings with a history of episodic migraines.  For the active treatment of acute episodic migraines, the ACP guidelines have two main recommendations, depending on which over-the-counter therapy is initially used to treat the active migraine:  ***Recommendation 1:*** For patients who do not adequately respond to nonsteroidal anti-inflammatory drug (NSAID), a combination of a triptan and an NSAID should be initiated in nonpregnant adults in outpatient settings with active moderate to severe acute episodic migraines.  ***Recommendation 2:*** For patients who do not adequately respond to acetaminophen, a combination of a triptan and acetaminophen should be initiated in nonpregnant adults in outpatient settings with active moderate to severe acute episodic migraines.  Of note, these recommendations do not distinguish between preferred and non-preferred triptans or NSAID therapies. Also, as neither documents gives guidance for specific dosing of any therapy, they recommend that any treatment or preventative medication be initiated at the lowest effective dose. Both of the guidelines only contain recommendations for nonpregnant and nonlactating adults in outpatient settings. Patients who require emergent-level care are not included in these recommendations. Additionally, the guidelines emphasize the importance of nonpharmacologic care, such as trigger identification and avoidance.  ***References:***   * Qaseem A, Cooney TG, Etxeandia-Ikobaltzeta I, Wilt TJ, Harrod CS, Tice JA, Crandall CJ; Clinical Guidelines Committee of the American College of Physicians; Hicks LA, Cross JT Jr, Fitterman N, Lewis J, Linsky AM, Maroto M, Miller MC, Obley AJ, Owens DK, Shekelle PG, Shamliyan T, Yost J. Prevention of Episodic Migraine Headache Using Pharmacologic Treatments in Outpatient Settings: A Clinical Guideline From the American College of Physicians. Ann Intern Med. 2025 Mar;178(3):426-433. doi: 10.7326/ANNALS-24-01052. Epub 2025 Feb 4. Erratum in: Ann Intern Med. 2025 Jul 22. doi: 10.7326/ANNALS-25-03082. PMID: 39899861. * Qaseem A, Tice JA, Etxeandia-Ikobaltzeta I, Wilt TJ, Harrod CS, Cooney TG, Crandall CJ; Clinical Guidelines Committee of the American College of Physicians; Hicks LA, Balk E, Cross JT Jr, Fitterman N, Lewis J, Linsky AM, Maroto M, Miller MC, Obley AJ, Owens DK, Shekelle PG, Shamliyan T, Yost J. Pharmacologic Treatments of Acute Episodic Migraine Headache in Outpatient Settings: A Clinical Guideline From the American College of Physicians. Ann Intern Med. 2025 Apr;178(4):571-578. doi: 10.7326/ANNALS-24-03095. Epub 2025 Mar 18. PMID: 40096690.   **LEGISLATIVE NEWS**  **Consolidations Appropriations Act (Sec. 203)**  Legal Services | ASUCD On March 9, 2024, the Consolidated Appropriations Act (CAA 2024) was enacted. This act covers several federal agencies but specifically targets state Medicaid programs and Children’s Health Insurance Programs (CHIP) with several provisions. These provisions focus mainly on mental health and substance use disorder (SUD). For example, CAA 2024 requires the Health and Human Services (HHS) secretary to annually publish all Medicaid and CHIP services covering mental health and SUD to their members. It also expands Medicaid coverage to psychiatric patients residing in eligible institutions for mental diseases and incarcerated patients.  Specific to Medicaid Drug Utilization Review (DUR), CAA 2024 requires more thorough review of antipsychotic use and monitoring for adult members in institutional settings. Starting in 2026, state Medicaid programs will be required to perform reviews through DURB programs for antipsychotic use in all adults receiving home-based and community-based services or institutional care. Previously, states were only required to review antipsychotic use in pediatric members through the SUPPORT Act.  There is little guidance as to what specific monitoring parameters will be required. Additionally, some DURB programs may have difficulty isolating patients in institutional care settings for the purposes of a retrospective intervention, due to the formatting of claims data received. From a retrospective drug utilization review (RDUR) perspective, interventions may target overutilization/underutilization of antipsychotics, appropriate monitoring of adverse drug events, duplicate antipsychotic therapy, etc. It remains to be seen how the Centers for Medicare and Medicaid Services (CMS) will enforce this particular legislation, but the expectation is that further guidance will be published as the deadline for initiating these services nears.  ***References:***   * "Consolidated Appropriations Act, 2024 (P.L. 118-42): Medicaid and Medicare Provisions." *Congress.gov*, Library of Congress, 22 July 2025, <https://www.congress.gov/crs-product/R48075>. * "H.R.6 - 115th Congress (2017-2018): SUPPORT for Patients and Communities Act." *Congress.gov*, Library of Congress, 24 October 2018, https://www.congress.gov/bill/115th-congress/house-bill/6. |