Physicians concerned AI increases prior authorization denials

Reflects growing use of unregulated AI decision-making systems by health insurer industry

CHICAGO — Many physicians fear the health insurance industry's use of unregulated artificial intelligence (AI) automation and predictive technologies will increasingly override good medical judgment and systematically deny patients coverage for necessary medical care. According to a new survey from the American Medical Association (AMA), three in five physicians (61%) are concerned that health plans' use of AI is increasing prior authorization denials, exacerbating avoidable patient harms and escalating unnec-essary waste now and into the future.

Burdensome prior authorization requirements that conflict with evidence-based clinical practices and create hurdles to patient access to safe, timely, and affordable treatment have been a major impediment to patient care for decades. More recently, health insurers have turned to AI decision-making tools that generate prior authorization decisions with little or no human review. These AI tools have been accused of producing high rates of care denial – in some cases, 16 times higher than is typical.

"Using AI-enabled tools to automatically deny more and more needed care is not the reform of prior authorization physicians and patients are calling for," said AMA President **BRUCE A. SCOTT, MD**. "Emerging evidence shows that insurers use automated decision-making systems to create systematic batch denials with little or no human review, placing barriers between patients and necessary medical care. Medical decisions must be made by physicians and their patients without interference from unregulated and unsupervised AI technology."

To that end, the AMA firmly believes that AI must augment decision-making; be referred to as "augmented intelligence," and not remove humans from patient care, coverage, or treatment.

Notably, the AMA's Augmented Intelligence Research released earlier this month found that nearly half of all physicians (49%) ranked oversight of payers' use of AI in medical necessity determinations among the top three priorities for regulatory action. Moreover, recently passed AMA policy identifies significant concerns with insurer use of AI.

Physicians tell the AMA that delayed and disrupted care continues to be a predictable and maddening part of the patient experience, as widespread use of prior authorization programs by the health insurance industry persistently impedes the delivery of necessary medical treatments, jeopardizes quality care, and harms patients.

- **Patient Harm** – More than one in four physicians (29%) reported that prior authorization has led to a serious adverse event for a patient in their care, including hospitalization, permanent impairment, or death.
- **Poor Outcomes** – More than nine in 10 physicians (94%) reported that prior authorization has a negative impact on patient clinical outcomes.
- **Delayed Care** – More than nine in 10 physicians (93%) reported that prior authorization delays access to necessary care.
- **Disrupted Care** – More than four in five physicians (82%) reported that patients abandon treatment due to authorization struggles with health insurers.
- **Shifted Costs** – Four in five physicians (80%) reported that prior authorization delays or denials "at least sometimes" make patients pay out-of-pocket for medications.
- **Lost Workforce Productivity** – More than half of physicians (58%) who cared for patients in the workforce reported that prior authorizations have impeded a patient's job performance.

The substantial burdens associated with navigating the prior authorization process and fighting denials are contributing to physician burnout while forcing scarce resources to be redirected from patient care towards administrative tasks.

- **Added Burden** – Physicians reported completing an average of 39 prior authorizations per week, and nearly one in three physicians (31%) reported that prior authorization requests are often or always denied.
- **Physician Burnout** – Nearly nine in 10 physicians (89%) reported that prior authorization somewhat or significantly increases physician burnout.
- **Denial Trend** – Three-quarters of physicians (75%) reported the number of prior authorization denials has increased somewhat or significantly over the last five years.
- **Diverted Time and Resources** – The prior authorization workload for a single physician consumes 13 hours of physician and staff time each week, and two in five (40%) physicians employ staff members to work exclusively on tasks associated with prior authorization.

Not only does prior authorization negatively impact patient-centered care and add to crushing administrative burdens on physicians, but the AMA survey found it also results in significant waste and unnecessary costs across the entire health system.

- **Wasted Health Resources** – More than four in five physicians (88%) reported that prior authorization requirements lead to higher overall utilization of health care resources, resulting in unnecessary waste rather than cost savings. More specifically, physicians reported resources were diverted to ineffective initial treatments (77%), additional office visits (73%), urgent or emergency care (47%), and hospitalizations (33%) due to prior authorization requirements.

Despite mounting evidence that prior authorizations for drugs and medical services can be a hazardous and burdensome obstacle to patient-centered care, the AMA survey found the health insurance industry continues to show ineffectual follow-through on five key reforms that were mutually agreed to in January 2018 by the AMA and other national organizations

representing pharmacists, medical groups, hospitals and health insurers.

While UnitedHealthcare (UHC) and Cigna announced reductions in the number of services that require prior authorization in 2023, only 16% of physicians who work with UHC and 16% of physicians who work with Cigna reported that these changes have reduced the number of prior authorizations completed for these plans. In addition, physicians reported consistently high administrative burdens across all major health insurers when complying with prior authorization requirements. Physicians ranked UHC as the insurer with the most prior authorization hassles, with 72% of physicians giving UHC a "high" or "extremely high" burden rating. UHC was closely followed by Humana (64%), Anthem/Elevance (59%), Aetna (57%), Cigna (55%), and Blue Cross Blue Shield (54%) in high burden ratings for prior authorization.

The AMA continues to work on every front to right-size prior authorization programs so that physicians can focus on managing patient care rather than administrative burdens. Patients, physicians, and employers can learn more about reform efforts and share personal experiences with prior authorization at FixPriorAuth.org. ❖

FDA approves novel non-opioid treatment for moderate to severe acute pain

SILVER SPRING, MD — On Jan. 30, 2025, the U.S. Food and Drug Administration approved Journavx (suzetrigine) 50 milligram oral tablets, a first-in-class non-opioid analgesic, to treat moderate to severe acute pain in adults. Journavx reduces pain by targeting a pain-signaling pathway involving sodium channels in the peripheral nervous system, before pain signals reach the brain.

Journavx is the first drug to be approved in this new class of pain management medicines. The efficacy of Journavx was evaluated in two randomized, double-blind, placebo- and active-controlled trials of acute surgical pain, one following abdominoplasty and the other following bunionectomy. In addition to receiving the randomized treatment, all participants in the trials with inadequate pain control were permitted to use ibuprofen as needed for "rescue" pain medication. Both trials demonstrated a statistically significant superior reduction in pain with Journavx compared to placebo.

The safety profile of Journavx is primarily based on data from the pooled, double-blind, placebo- and active-controlled trials in 874 participants with moderate to severe acute pain following abdominoplasty and bunionectomy, with supportive safety data from one single-arm, open-label study in 256 participants with moderate to severe acute pain in a range of acute pain conditions.

The most common adverse reactions in study participants who received Journavx were itching, muscle spasms, increased blood level of creatine phosphokinase, and rash. Journavx is contraindicated for concomitant use with strong CYP3A inhibitors. Additionally, patients should avoid food or drink containing grapefruit when taking Journavx.

The application received Breakthrough Therapy, Fast Track and Priority Review designations by the FDA.

The FDA granted approval of Journavx to Vertex Pharmaceuticals Incorporated. ❖

FDA approves first rapid-acting insulin biosimilar product for treatment of diabetes

SILVER SPRING, MD — On Feb. 14, the U.S. Food and Drug Administration approved Merilog (insulin-aspart-szjj) as biosimilar to Novolog (insulin aspart) for the improvement of glycemic control in adults and pediatric patients with diabetes mellitus. Merilog, a rapid-acting human insulin analog, is the first rapid-acting insulin biosimilar product approved by the FDA. As a rapid-acting insulin, Merilog helps to lower mealtime blood sugar spikes to improve control of blood sugar in people with diabetes. The approval is for both a 3 milliliter (mL) single-patient-use prefilled pen and a 10 milliliter (mL) multiple-dose vial.

Merilog is the third insulin biosimilar product approved by the FDA and joins the two long-acting insulin biosimilar products approved in 2021 by the FDA. Approval of biosimilar products can increase patient access to safe and effective treatment options.

Like Novolog, Merilog should be administered within five to ten minutes prior to the start of a meal. Merilog is administered subcutaneously (under the skin) by injection into the stomach, buttocks, thighs or upper arms. Dosing of Merilog should be individualized and adjusted based on the patient's needs.

Merilog may cause serious side effects, including hypoglycemia (low blood sugar), severe allergic reactions and hypokalemia (low potassium in blood). Other common side effects may include injection site reactions, itching, rash, lipodystrophy (skin thickening or pitting at the injection site), weight gain and swelling of hands and feet.

"The FDA has now approved three biosimilar insulin products to treat diabetes," said Peter Stein, MD, director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research. "Today's approval highlights our continued efforts to improve the efficiency of the biosimilar approval process to help support a competitive marketplace and increase options for costly treatments, like insulin. Increasing access to safe, effective and high-quality medications at potentially lower cost remains a continued priority for the FDA."

The FDA granted approval of Merilog to Sanofi-Aventis U.S. LLC. ❖

FDA approves first treatment for cerebrotendinous xanthomatosis, a rare lipid storage disease

SILVER SPRING, MD — On Feb. 21, the U.S. Food and Drug Administration approved Ctexli (chenodiol) for the treatment of cerebrotendinous xanthomatosis (CTX) in adults. Ctexli is the first FDA-approved drug to treat CTX, a very rare lipid storage disease.

CTX is a genetic metabolic disorder caused by a mutation in a gene called CYP27A1 resulting in a deficiency of the enzyme that is important in the body's ability to break down fats. Due to reduced bile acid production in the liver, patients with CTX are unable to break down cholesterol in a normal way, resulting in deposition of atypical cholesterol metabolites (substances that result from the breakdown of cholesterol) in various places in the body including the brain, liver, skin and tendons, leading to damage to those organs and tissues. Ctexli works to replace deficient levels of one of the bile acids, reducing the abnormal deposits of cholesterol metabolites thought to be responsible for clinical abnormalities in CTX.

The efficacy of Ctexli for the treatment of patients with CTX was evaluated in a double-blind, placebo controlled, randomized crossover withdrawal trial. The 24-week trial demonstrated that treatment with Ctexli, 250 milligrams three times per day, resulted in significant reduction in plasma cholestanol and urine 23S-pentol (cholesterol metabolites that are markedly increased in CTX patients) compared to placebo treatment.

The prescribing information for Ctexli includes a warning for liver toxicity in all patients with increased risk for liver damage in patients with pre-existing liver disease or bile duct abnormalities. Patients should obtain liver blood tests before starting treatment, annually while on treatment and as clinically indicated. If signs of liver toxicity (e.g., stomach pain, nausea, fatigue, dark urine, bruising, yellowing of the eyes and skin, itching) occur, patients are advised to see their doctor and discontinue Ctexli.

The most common side effects of Ctexli are diarrhea, headache, abdominal pain, constipation, hypertension, muscular weakness and upper respiratory tract infection.

The recommended dosage is 250 milligrams, taken orally three times a day.

The FDA granted Ctexli Priority Review, Fast Track and Orphan Drug designations for this application.

The approval of Ctexli was granted to Mirum Pharmaceuticals Inc. ❖

NIH-funded clinical trial will evaluate new dengue therapeutic

BETHESDA, MD — A clinical trial supported by the National Institutes of Health (NIH) is testing an experimental treatment designed to help people suffering the effects of dengue, a mosquito-borne viral disease. The study is supported by NIH's National Institute of Allergy and Infectious Diseases (NIAID), and will involve exposing adult volunteers to a weakened strain of dengue virus that causes a mild form of the disease and administering an investigational therapeutic at various doses to assess its safety and ability to lessen symptoms.

Colorized image of an Aedes mosquito. This species can transmit multiple diseases. [NIAID]

Dengue is transmitted via infected Aedes mosquitoes and sickens as many as 400 million people each year, primarily in tropical and subtropical parts of the world, according to the U.S. Centers for Disease Control and Prevention. In 2024, dengue cases surged to record levels in the Americas with local U.S. transmission reported in Arizona, California, Florida, Hawaii, and Texas. Dengue is endemic in Puerto Rico, which reported nearly 1,500 cases last year. Most people with dengue do not develop symptoms, but those who do commonly experience severe headache and body aches, nausea and vomiting, fever and rash. One in 20 people who get sick with dengue progress to severe illness, which may lead to shock, internal bleeding, and death. There is currently no Food and Drug Administration-approved treatment for dengue.

"When caring for a patient who is critically ill with dengue, healthcare providers have few options other than providing supportive care," said NIAID Director **JEANNE MARRAZZO, MD, MPH**. "We must find safe and effective therapeutics to provide much-needed relief to people suffering from dengue."

The new clinical trial will test the ability of AV-1, an investigational human monoclonal antibody therapeutic developed by AbViro (Bethesda, Maryland), to mitigate clinical symptoms when administered before and after dengue virus infection. The results of a previously completed NIAID-supported Phase 1 trial indicated that AV-1 is safe in humans, providing the basis for the new clinical trial to test its safety and efficacy.

The Phase 2 clinical trial will enroll at least 84 healthy adult volunteers at two sites: the Johns Hopkins Bloomberg School of Public Health Center for Immunization Research in Baltimore, and the University of Vermont Vaccine Testing Center in Burlington. Following an initial screening and physical examination, volunteers will be randomly assigned to one of two groups. One group will receive AV-1 one day prior to being challenged with a mild strain of dengue virus, and the other will receive AV-1 four days after being challenged with the dengue virus. Each group will be further subdivided to receive 100 mg, 300 mg, or 900 mg of AV-1, delivered in a 60-minute intravenous

infusion. For each of the three dosage levels, 12 participants will receive the investigational monoclonal antibody, and two will receive a placebo.

Before or after AV-1 dosing, each volunteer will receive an injection of attenuated (weakened) dengue virus. In earlier studies using this challenge virus, most volunteers developed a rash, and some had other mild dengue symptoms, such as joint and muscle pain or headache. None of the volunteers developed dengue fever or severe dengue.

Volunteers will participate in regular follow-up visits with study staff for at least 155 days to carefully monitor the effects of the investigational monoclonal antibody. Through physical exams, diary cards and blood samples, researchers will document how the volunteers' immune systems respond to the dengue virus challenge, how quickly the virus vanishes from their bloodstream and any symptoms they may experience. The researchers will use this information to determine how AV-1 affects the volunteers' ability to recover from dengue compared to placebo and to determine the dosages at which AV-1 may be effective.

If AV-1 shows promising results in this clinical trial, researchers may pursue further clinical evaluations of its safety and efficacy against dengue virus. For more information about the study, visit ClinicalTrials.gov and search the identifier NCT06799741. ❖

Senate commission, URI launch study to examine feasibility of state's first public medical school

KINGSTON — A Rhode Island State Senate study commission and the University of Rhode Island will partner with one of the nation's leading medical education consultants to study the feasibility of launching the Ocean State's first public medical school.

Following a competitive request process, Tripp Umbach has been selected to lead the feasibility study.

The study follows the formation of a Rhode Island State Senate special commission, appointed by Senate President **DOMINICK J. RUGGERIO** in July and co-chaired by URI President **MARC PARLANGE** and Sen. **PAMELA J. LAURIA**. The commission is charged with studying the state's health care workforce with a focus on educating and retaining primary care physicians, as well as examining how a medical school at URI could help alleviate that critical need.

"Few issues are as important as health care, and right now, our health care system is in critical condition," Ruggerio said when appointing the commission. "Strengthening the primary-care pipeline is an essential part of our work to make health care more accessible and affordable for Rhode Islanders."

Tripp Umbach is a nationally regarded firm with leadership in economic impact studies and consultation services for academic medical campuses and medical schools. Over the past three decades, the firm has measured the economic impact of all U.S. allopathic medical schools and more than 400 teaching hospitals for the Association of American Medical Colleges.

"We are excited to partner with such an experienced firm as Tripp Umbach," said **BARBARA WOLFE**, URI provost and executive vice president for academic affairs. "They have worked extensively with both allopathic and osteopathic medical schools. This includes public universities with medical schools centered on primary and community care, such as the University of Houston and Washington State University."

As part of the study, Tripp Umbach will collaborate with a broad range of stakeholders throughout the state, including local and statewide health care organizations, federal and state agencies, research institutions, medical education providers, and policymakers and professional associations. Their collective input will help shape the study's direction and outcomes.

Complementing the work of the Senate Commission, the study will evaluate the need and feasibility of developing a medical education program at URI, recently named the number one public university in New England by *The Wall Street Journal*. The study will also examine and make recommendations regarding workforce development, medical school models, enrollment projections, accreditation standards, financial viability and required resources, capacity to support clinical training, and medical research opportunities.

"Through numerous undergraduate and graduate programs in health care fields, including several that are nationally ranked, URI is enhancing the physical and mental health of individuals and communities locally and globally," said Parlange. "We are dedicated to broadening our impact for the good of the state, and we look forward to partnering with health care providers and elected officials to examine the need for and feasibility of a public medical school for the benefit of all Rhode Islanders."

Rhode Island is experiencing a net loss of primary care clinicians, and the shortage is expected to worsen in the years ahead. The inability of many Rhode Island residents to find primary care physicians is resulting in the use of community health centers and urgent care facilities to meet their medical needs, which strains resources and creates additional pressures on the health care system.

"As a double alumna of the University of Rhode Island, I am proud to co-chair the Senate commission, which could help reshape the future of higher education at the University," said Sen. Lauria. "The central question before our commission is how we can best address the serious challenges facing primary care in our state. Rhode Island is on track to be short about 100 primary care providers by 2030, which could leave 180,000 Rhode Islanders without access to primary care coverage. It is imperative that we act thoughtfully, expeditiously, and decisively to strengthen the primary care workforce and pipeline in Rhode Island."

While Rhode Island is home to a private medical school, no new medical schools have been established in the state since 1972 and no public medical school exists in the state. The final feasibility report is expected in June 2025. The special commission is scheduled to issue its recommendations to the Senate no later than Dec. 20, 2025. ❖