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New FDA Warning on Cetirizine and Levocetirizine

The U.S. Food & Drug Administration (FDA) issued a warning about rare, but severe, pruritus that may occur after discontinuing long-term use of cetirizine (Zyrtec) and levocetirizine (Xyzal). Additional warnings have been added to the labeling about this risk.

Between April 25, 2017, and July 6, 2023, the FDA identified 209 cases of pruritus following discontinuation of cetirizine or levocetirizine, with 197 reported domestically through the FDA Adverse Event Reporting System (FAERS). In all cases, itching began shortly after stopping the medication, typically within two days, and was often widespread and severe, significantly impacting quality of life. Most affected individuals had used the medication for over three months, with a median duration of 33 months, suggesting that long-term use may increase the risk of this reaction. Serious outcomes included disability (48 cases), hospitalization (3 cases), and reports of suicidal thoughts or self-harm (2 cases). Notably, 99% of patients who restarted and then stopped the medication again experienced a recurrence of symptoms. Restarting cetirizine or levocetirizine resolved pruritus in 90% of cases, and tapering after restarting helped in 38% of those who tried it. These findings highlight the importance of provider awareness and consideration of tapering strategies when discontinuing long-term antihistamine therapy.

[Guidelines](#) published by the American Academy of Allergy, Asthma and Immunology recommend inhaled corticosteroids as a first-line agent for allergic rhinitis. If antihistamines are warranted, second-generation, non-sedating agents are recommended over the older first-generation agents. There are several other second-generation agents available other than cetirizine and levocetirizine, such as loratadine, desloratadine, and fexofenadine. Antihistamine nasal sprays are also an option.

The Iowa Medicaid [Preferred Drug List \(PDL\)](#) contains several preferred agents that do not require prior authorization (PA). Providers are encouraged to review preferred options prior to prescribing medication(s).

New FDA Warning for Extended-Release Stimulants for ADHD

The U.S. Food & Drug Administration (FDA) now requires expanded labeling for extended-release stimulants used to treat attention-deficit/hyperactivity disorder (ADHD) to include a warning about the increased risks of weight loss and other adverse effects associated with their use in children under 6 years of age. Although extended-release stimulants are not approved for children younger than 6 years, they can be prescribed off label to treat ADHD. The labels of all stimulants used for the treatment of ADHD already contain a boxed warning about the high risk of abuse and dependence associated with their use.

The FDA's analysis of clinical trial data revealed that children under 6 years old being treated with extended-release formulations of amphetamine or methylphenidate experience higher plasma drug levels and greater rates of adverse reactions compared to older children receiving the same dosage. One of the most concerning findings was clinically significant weight loss, defined as a $\geq 10\%$ drop in CDC weight percentile, observed in both short- and long-term studies.

Children under 6 years old who are taking an extended-release stimulant and have weight loss or other adverse effects should be switched to an immediate-release stimulant.

[Guidelines](#) published by the American Academy of Pediatrics recommend first line treatment, for preschool-aged children (age 4 to 5 years) with ADHD, evidence-based PTBM and/or behavioral classroom interventions, if available. Methylphenidate may be considered if behavioral interventions do not provide significant improvement and there is moderate-to-severe continued disturbance in the 4- through 5-year-old child's functioning. In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication before the age of 6 years against the harm of delaying treatment.

FDA MedWatch Online Voluntary Reporting

Health professionals, consumers, and patients are encouraged to report observed or suspected adverse events with human medical products to the FDA. Voluntary reporting can assist the FDA in identifying an unknown risk for approved medical products. Reporting can be done through the [FDA online reporting portal](#) or by downloading, completing and submitting the FDA form 3500 (Health Professional) or 3500B (Consumer/patient) to MedWatch: The Safety Information and Adverse Event Reporting Program.

Information to report to MedWatch includes unexpected side effects or adverse events, product quality problems, product use/medication errors that can be prevented, and therapeutic failures.

Medicaid Statistics for Prescription Claims September through November 2025

	FFS	Wellpoint	Iowa Total Care	Molina Healthcare
Total \$ Paid	\$2,936,348	\$107,989,842	\$84,792,386	\$61,634,913
# Paid Claims	21,741	772,016	634,340	473,689
Unique Users	3,343	100,759	92,395	76,623
Avg Cost/Rx	\$135.06	\$139.88	\$133.67	\$130.12
Top 5 Therapeutic Class by RX Count <small>Therapeutic class taxonomy may differ among each plan</small>	Antidepressants	Antidepressants	Antidepressants	Antidepressants
	Anticonvulsants	ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant	Anticonvulsants	ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant
	ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant	Anticonvulsants	ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant	Anticonvulsants
	Antiasthmatic and Bronchodilator Agents			
	Antipsychotics/Antimanic Agents	Antipsychotics/Antimanic Agents	Antidiabetics	Antidiabetics
Top 5 Therapeutic Class by \$ Amount <small>(pre-rebate) Therapeutic class taxonomy may differ among each plan</small>	Antidiabetics	Antidiabetics	Antidiabetics	Dermatologicals
	Antipsychotics/Antimanic Agents	Dermatologicals	Dermatologicals	Antidiabetics
	Analgesics – Anti-Inflammatory	Antipsychotics/Antimanic Agents	Antipsychotics/Antimanic Agents	Antipsychotics/Antimanic Agents
	Dermatologicals	Analgesics – Anti-Inflammatory	Analgesics – Anti-Inflammatory	Analgesics – Anti-Inflammatory
	Anticonvulsants	ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant	Antiasthmatic and Bronchodilator Agents	Antiasthmatic and Bronchodilator Agents
Top 5 Drugs by Prescription Count	Albuterol Sulfate HFA	Trazodone	Albuterol	Albuterol Sulfate HFA
	Trazodone	Omeprazole	Trazodone	Sertraline
	Methylphenidate	Sertraline	Bupropion	Trazodone
	Gabapentin	Albuterol Sulfate HFA	Sertraline	Amoxicillin
	Escitalopram	Bupropion XL	Omeprazole	Bupropion XL
Top 5 Drugs by Paid Amount <small>(pre-rebate)</small>	Ozempic	Ozempic	Ozempic	Ozempic
	Humira Pen	Humira Pen	Dupixent	Dupixent
	Vraylar	Vraylar	Humira Pen	Vraylar
	Evrysdi	Dupixent	Vraylar	Humira Pen
	Dupixent	Mounjaro	Trikafta	Skyrizi Pen