Fluoroquinolone Toxicity and FQAD

A concise clinical briefing for prescribers

Fluoroquinolones are among the most widely prescribed antibiotics, and most patients tolerate them without incident. In a subset, however, they can cause serious, sometimes lasting injury beyond an ordinary side effect — fluoroquinolone toxicity — spanning tendon, nerve, muscle, and CNS tissue.

When disabling, persistent, and multi-system, that toxicity has a name the FDA introduced: Fluoroquinolone-Associated Disability (FQAD) — sometimes delayed and distinct from the acute reactions most familiar at prescribing. The FDA named and operationally defined it in 2015; uncommon per prescription, but far from rare in absolute numbers.

FDA-recognized

Named & operationally defined by the FDA (2015): adverse effects across ≥2 body systems, persisting ≥30 days after stopping the drug.

Codeable in ICD-10-CM

Took effect Oct 1, 2025 for U.S. billing (incl. Medicare/Medicaid). Adverse-effect codes: **T36.AX5A** (initial) · **T36.AX5D** (subsequent) · **T36.AX5S** (sequela).

Not rare in absolute terms

Uncommon per course, but common in numbers: fluoroquinolones are dispensed on the scale of tens of millions of U.S. courses each year.

The codes (maintained by CMS/CDC, not the FDA) can support diagnosis documentation and disability applications; coverage of any related test or treatment still depends on plan policy and medical necessity. They capture fluoroquinolone adverse effects used alongside the relevant manifestation diagnoses — e.g., peripheral neuropathy or tendinopathy, with "sequela" added if indicated. A dedicated FQAD-specific code does not yet exist.

What may be new to you

› **The regulatory trajectory has only escalated.** FDA warnings moved from a single risk to a class-wide caution: tendon rupture (2008, boxed warning) → irreversible peripheral neuropathy (2013) → reserved for patients with no alternative for sinusitis, bronchitis exacerbations, and uncomplicated UTI (2016) → aortic aneurysm/dissection and mental-health & blood-sugar warnings (2018).

› **The injury is multi-mechanism — not idiosyncratic or psychosomatic.** Several identifiable mechanisms are in play: mitochondrial dysfunction, GABA-A receptor antagonism (CNS/neuropsychiatric effects), topoisomerase and mitochondrial-DNA effects, and magnesium chelation among them. This multi-target profile explains the multi-system pattern — tendon, nerve, muscle, CNS — and is precisely why these presentations should not be dismissed as anxiety or deconditioning.

› **Presentation is delayed and multi-system — which is why it is missed.** Onset can lag exposure by days to weeks and cross organ systems at once, so the temporal link to a short antibiotic course is easily overlooked at follow-up.

› **Formal diagnostic criteria now exist.** Stefan Pieper, MD — a practicing physician — has published (Springer) a classification of the FQAD clinical picture and a proposed diagnostic tool built for everyday practice. The point is recognition: a patient in front of you can be identified against defined criteria.

For clinicians who want to look further

Pieper S. *Fluoroquinolone-Associated Disability FQAD: Side-effects of Fluoroquinolones.* **Springer, 2nd ed., 2026.** — the clinical classification and diagnostic-criteria framework.

Fluoroquinolone Toxicity Study, NFP **fq100.org** — independent 501(c)(3) nonprofit funding cellular- and molecular-level research into the mechanism of injury.

FDA Citizen Petition Docket **FDA-2026-P-5116** — requests standardized informed-consent language for systemic fluoroquinolones covering multi-system, persistent, and delayed effects; does not seek to restrict access. Searchable at regulations.gov.

DIMD Initiative druginducedmito.org — systems-level mechanistic framework; open-access (Zenodo DOI 10.5281/zenodo.20399689).

U.S. FDA Drug Safety Communications on fluoroquinolones, 2008–2018.

Scan to learn more

Compiled by Johanna Ihli, BSN — former critical-care RN, DIMD Initiative. Shared as educational context on mechanism, evidence, and diagnosis; it does not offer individualized treatment recommendations.

fq100.org

druginducedmito.org