

Asking for the Code (oral and injectable/IV products)

The below are **suggestions** that may provide a better chance of obtaining the diagnostic code for fluoroquinolone adverse effects

- Stay within standard medical documentation language similar to what's outlined below
- Indicate your main adverse effects in alignment with those that the FDA has recognized in its warnings
- Avoid direct confrontational approach

1. State the exposure, medical context, and purpose of request – for example:

“I was treated with a fluoroquinolone antibiotic and my symptoms began during and/or after taking it. My symptoms have persisted beyond the normal treatment period, and I'm concerned about a possible adverse drug reaction to this antibiotic. Could you please document this as an adverse effect of a fluoroquinolone in therapeutic use and include the specific diagnoses that match my symptoms, using the new ICD-10 coding? I'm asking that the reaction and the organ-specific problems are formally recorded in my medical record.”

2. Provide your list of experienced adverse effects that align with FDA recognized warnings in these categories for the best possible opportunity to receive the code – see FDA warnings July 2016 & 2013. Please see our downloadable form - *ICD10 Diagnosis Code and FDA Warnings***

- ✓ tendons
- ✓ muscles
- ✓ joints
- ✓ nerves*
- ✓ central nervous system

To see if your adverse effects are associated with any of the above systems, please see our downloadable form - *Adverse Effects Evaluation Form***

***Note for nerves:** The FDA's peripheral neuropathy warning focuses more on classic sensory and motor neuropathy symptoms (tingling, numbness, weakness, burning pain), rather than listing autonomic specific symptom examples. Issues in the autonomic system (part of the peripheral system) may or may not be applicable.

3. Ongoing adverse effects:

If you are told that ongoing adverse drug effects are not realized, point physician to the **FDA Drug Safety Communication, July 26, 2016**, indicating body systems and potential permanent damage.

Additional note for tendons: you can note that FDA approved prescribing information for fluoroquinolones states that tendon injury including tendon rupture can occur during therapy or after completion of therapy, and cases have been reported up to several months after finishing treatment. Ciprofloxacin, moxifloxacin, and levofloxacin all carry the same FDA statement as below:

Ciprofloxacin (CIPRO) label: page 11, section 5.2 “Tendinitis and Tendon Rupture.” The sentence includes “as long as several months after completion of fluoroquinolone therapy.”

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/019537s090%2C020780s047lbl.pdf

➡ The new code does not by itself establish causation; causation depends on the broader clinical documentation and medical evidence.

**** Please review the Help Page in addition to this form on additional suggested steps & downloadable forms mentioned above**