

Employer Update: Tylenol™ (Acetaminophen) & Autism, and Leucovorin in Autism Treatment

This brief is an effort to provide our members key facts and information regarding the Administration’s announcements on Monday about the potential link between Tylenol/acetaminophen and autism.

KEY TAKEAWAYS

- No proven causal link between acetaminophen use in pregnancy and autism (ACOG 2025)¹.
- Acetaminophen remains first-line for fever/pain in pregnancy when clinically needed and is the safest over-the-counter alternative in pregnancy among all analgesics and antipyretics; aspirin and ibuprofen have well-documented adverse impacts on the fetus².
- Leucovorin (folinic acid) shows promising results in language/communication for a subset of children with autism, but use is off-label.

Acetaminophen (Tylenol™) & Autism

Evidence: Some observational studies show associations with ASD/ADHD, but no causation proven^{3,4,5,6}.

FDA: It is important to note that while an association between acetaminophen and neurological conditions has been described in many studies, a causal relationship has not been established and there are contrary studies in the scientific literature. It is also noted that acetaminophen is the only over-the-counter drug approved for use to treat fevers during pregnancy, and high fevers in pregnant women can pose a risk to their children⁷.

Medical Organizations: ACOG & medical societies reaffirm safety when used prudently.

Employer Message: Current medical guidance supports acetaminophen as the preferred first-line option for pain or fever in pregnancy, especially for more severe symptoms, but it should always be used under an obstetrician’s guidance.

Leucovorin (Folinic Acid) in Autism

Mechanism: Active folate; supports metabolism in a subset of ASD children with folate receptor autoantibodies (FRAA).

Evidence: Randomized clinical trials (RCT) show improved verbal communication, especially in FRAA-positive children. However, more studies are needed.

Benefit Recommendation: Consider coverage when prescribed by developmental/neurology specialists, with documented rationale.

Communications: Leucovorin (folinic acid) is an emerging, specialist-guided therapy that may benefit communication in some children with autism; while it remains off-label, it may be covered when recommended and prescribed by a specialist as part of a broader care plan.

Support: Offer navigation to Obstetrician and Autism specialists.

¹ <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2025/09/acetaminophen-use-in-pregnancy-and-neurodevelopmental-outcomes>

² <https://www.fda.gov/media/188843/download?attachment>

³ <https://www.mountsinai.org/about/newsroom/2025/mount-sinai-study-supports-evidence-that-prenatal-acetaminophen-use-may-be-linked-to-increased-risk-of-autism-and-adhd>

⁴ <https://jamanetwork.com/journals/jama/fullarticle/2817406>

⁵ <https://ysph.yale.edu/news-article/what-the-research-says-about-autism-and-tylenol-use-during-pregnancy/>

⁶ <https://www.autismspeaks.org/science-news/tylenol-and-autism>

⁷ <https://www.fda.gov/news-events/press-announcements/fda-responds-evidence-possible-association-between-autism-and-acetaminophen-use-during-pregnancy>