Psychotropic Medication Off-Label Use FAQ

What is "Off-Label" use or prescribing?

"Off-Label" prescribing refers to the practice of using a drug for an indication not approved by the FDA or in other ways inconsistent with labeling. The FDA does not regulate drug prescribing or medical practice and recognized certain patient situations may benefit from off-label prescribing. When this occurs the prescriber has the responsibility to be well informed regarding the scientific rationale for off-label use. In child and adolescent psychiatry, off-label prescribing is a common occurrence necessitated by a relative lack of pediatric clinical trials compared to the database available from adults (1).

Who is qualified to prescribe medications for off-label use in children and adolescents?

The FDA does not regulate physician and other health provider practice. In fact, the FDA has stated that it does "not limit the manner in which a practitioner may prescribe an approved drug." Studies and expert clinical experience often support the use of medication for an "off-label" use. Physicians should utilize the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what they feel is best for each individual patient (2).

Who regulates "Off-Label" use?

In the United States, no law prohibits a physician or other healthcare practitioner from prescribing an approved medication for other uses than their specific FDA-approved indications. Once a drug has been approved for sale for one purpose, physicians are free to prescribe for any purpose that in their professional judgment is both safe and effective, and are not limited to official, FDA-approved indications (1).

When a physician prescribes psychotropic medications for "off-label" purposes to treat a mental diagnosis outlined in the DSM-IV are they prescribing outside of Parameters or outside the standard of care or accepted practice? Each time a child is prescribed medication(s) for off-label purposes should they be referred for formal PMUR?

As noted, off-label prescribing is based on the individual situation and needs of a child as well as their previous response to medications which are FDA approved for use in children. If there are questions about the off-label use of a particular medication, this should be discussed during the medication consent process. Any questions regarding this practice are best directed to the prescribing physician as well as any requests for changes to be made.

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How does Cenpatico monitor off-label prescribing to ensure child safety to children in Foster Care?

A combination of automated pharmacy claims screening, Health Passport information, and assessments done by Cenpatico Service Managers are used to monitor off-label prescribing.

References

1) Devane, C.L. (2012) Off-Label Prescribing of Drugs in Child and Adolescent Psychiatry, in Pharmacotherapy of Child and Adolescent Psychiatric Disorders, Third Edition (eds D. R. Rosenberg and S. Gershon), John Wiley & Sons, Ltd, Chichester, UK. Doi: 10.1002/9781119958338.ch3
2) Advisory Committee on Psychotropic Medications. *The use of psychotropic medications for children and youth in the Texas foster care system.* Texas Department of Family and Protective Services, September 1, 2004.