

Winsett Wellness

Child, Adolescent & Adult Psychiatric Care

THE USAGE OF MEDICATIONS

There are times we prescribe medications which are not labeled specifically for usage in a particular condition. This is because the U.S. Food and Drug Administration (FDA) indications for any given drug are based on their review and acceptance of studies which have been submitted to them for usage in specific diagnoses rather than symptoms. Medications treat symptoms, not diagnoses. There are times when a medication is found to be useful for one symptom or disorder, but clinical experience reveals that it is also useful in other areas. When this occurs, pharmaceutical companies occasionally conduct new medication trials to seek additional FDA approval. This pursuit of "indication for use" from the FDA is a business decision that many pharmaceutical companies decide not to make because of the extremely high cost of medication research and testing and the fact that the medication has already received approval for prescribing. Most pharmaceutical companies decide to rely upon providers learning the additional uses through articles published in medical journals, professional educational forums, and collegial networking. The usage of medications without FDA indication for a certain condition is referred to as "off-label" use.

There are special circumstances regarding children. All medications are "approved by the FDA" for a specific marketed indication based on registration trials and clinical trial research. Most of all, the medications that pediatric providers use are used "off-label." Considering the complications of testing medication on children (a child cannot sign a waiver stating that he/she understands the risks of being involved in medication research), there are few medications that are "approved" by the FDA for children. An example of an "off-label" use of medication with which you might be acquainted would be amoxicillin. Amoxicillin was widely used with adults, and its success in treating infection led to its almost immediate embrace by pediatric providers. Because it was already being used with children, the manufacturer never sought an approved indication and, to this day, amoxicillin is not "approved" by the FDA for use in children, although its use is nearly universal.

It is important for you to understand that the medications we recommend and prescribe have been shown to be helpful in the hands of many providers. We want you to be informed of the possible benefits and side effects of these medications and encourage you to read all you can and ask any questions that you have. We are committed to pursuing a plan of action, which leads to the lowest dosage of medication and the smallest number of medications used, consistent with optimal level of wellness. Our goal for the medication we prescribe is to treat and reverse as many symptoms as possible while pursuing additional non-medication strategies. Counseling and lifestyle changes can further add to recovery from the presenting symptoms in the short-run. This will also enable the medication itself to work more effectively and may, in the long run, possibly negate the need for some, or all, of the medications originally prescribed.

Please feel free to express concerns or questions you may have during your visit. We endeavor to provide you all the information we can to help you make informed decisions concerning you or your child's care.

PRINT PATIENT NAME:

SIGNATURE OF PATIENT (IF 16 OR OLDER):

DATE:

SIGNATURE OF PARENT OR LEGAL GUARDIAN:

DATE: