



BlueCross BlueShield of Montana

FDA Reclassifies Select ADHD Generic Drugs

In November 2014, the U.S. Food and Drug Administration (FDA) announced a classification change for methylphenidate hydrochloride extended release tablets manufactured by Mallinckrodt and Kudco. According to the FDA, these drugs are no longer considered to be generic equivalents for the Janssen-manufactured brand drug Concerta, a treatment for Attention Deficit Hyperactivity Disorder (ADHD) in adults and children. This change resulted from a post-marketing data analysis that showed these drugs do not provide the same therapeutic effect as Concerta.*

The above classification change may affect members with Blue Cross and Blue Shield of Montana (BCBSMT) prescription drug coverage as follows:

- While methylphenidate hydrochloride extended release tablets manufactured by Mallinckrodt and Kudco cannot be automatically substituted for the brand Concerta at the pharmacy, they are still FDA-approved drugs.
- If prescribed, the Mallinckrodt and Kudco manufactured drugs may be considered for coverage, but at the member's non-preferred brand benefit, or highest out-of-pocket payment level.**

If your patients have questions regarding their prescription drug benefits, please advise them to contact the number on the back of their member ID card.

*For additional information, refer to the [FDA release](#).

**The Janssen-manufactured authorized generic (marketed by Actavis) also may be considered for coverage as a non-preferred brand drug for BCBSMT members.

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The information mentioned here is for informational purposes only and is not a substitute for the independent medical judgment of a physician. Physicians are instructed to exercise their own medical judgment. Pharmacy benefits and limits are subject to the terms set forth in the member's certificate of coverage which may vary from the limits set forth above. The listing of any particular drug or classification of drugs is not a guarantee of benefits. Members should refer to their certificate of coverage for more details, including benefits, limitations and exclusions. Regardless of benefits, the final decision about any medication is between the member and their health care provider.