



AMERICAN ACADEMY OF NEUROLOGY

POSITION STATEMENT ON THE COVERAGE OF ANTICONVULSANT DRUGS FOR THE TREATMENT OF EPILEPSY NOVEMBER 2006

The American Academy of Neurology (AAN), representing over 19,000 neurologists and neuroscience professionals, has taken an active interest in the clinical, ethical and policy considerations concerning the coverage of anticonvulsant drugs for people with epilepsy. The AAN has developed evidence-based guidelines which strongly support complete physician autonomy in determining the appropriate use of anticonvulsants for their patients with epilepsy. Based on this evidence, the AAN has adopted the following principles concerning coverage of anticonvulsants for adults and children with epilepsy.

The AAN opposes generic substitution of anticonvulsant drugs for the treatment of epilepsy without the attending physician's approval. The FDA has allowed for significant differences between name-brand and generic drugs. This variation can be highly problematic for patients with epilepsy. Even minor differences in the composition of generic and name-brand anticonvulsant drugs for the treatment of epilepsy can result in breakthrough seizures.

- Anticonvulsant drugs for the treatment of epilepsy differ from other classes of drugs in several ways that make generic substitution problematic.
- For anticonvulsant drugs, small variations in concentrations between name-brands and their generic equivalents can cause toxic effects and/or seizures when taken by patients with epilepsy.
- The AAN opposes all state and federal legislation that would impede the ability of physicians to determine which anticonvulsant drugs to prescribe for the treatment of patients with epilepsy.
- The AAN believes that formulary policies should recognize and should support complete physician autonomy in prescribing, and patients in accessing, the full range of anticonvulsants for epilepsy.
- The AAN opposes policies that would result in arbitrary switching among anticonvulsants. Therefore, the AAN opposes generic substitution of anticonvulsants for patients with epilepsy at the point of sale (e.g., in the pharmacy), without prior consent of the physician and the patient.

- The AAN supports legislation that would require informed consent of physicians and patients before generic substitutions of anticonvulsants are made at the point of sale.
- The AAN believes that the use of anticonvulsant drugs in the treatment of epilepsy should be distinguished from the use of anticonvulsant drugs in treating other disorders. The AAN recognizes that different strategies may be appropriate in using anticonvulsants for the treatment of conditions other than epilepsy.
- Unlike other diseases, a single breakthrough seizure due to change in delivered medication dose can have devastating consequences, including loss of driver's license, injury, and even death.

The AAN supports the use of newer-generation anticonvulsant drugs in the treatment of epilepsy. Newer generation anticonvulsant drugs generally result in fewer and less-severe side-effects, although they may be more expensive to prescribe. For patients with epilepsy, the AAN does not believe that economic considerations alone should determine the prescribing pattern of physicians. The AAN believes that physicians should make every effort to identify when patients may be effectively treated with less expensive alternatives. However, the discretion for this decision should remain with the prescribing physician and should not be determined by coverage limitations.

- Physicians should have prescribing access to all anticonvulsants for the treatment of epilepsy, including newer-generation drugs.
- The AAN recognizes that, unlike in most other conditions, requiring the "fail first" approach (i.e., using trial and error in determining the best treatment option) will put patients with epilepsy at risk for breakthrough seizures, accidents, injury and loss of income.
- The AAN believes that preventing access to newer-generation anticonvulsants for the treatment of epilepsy is not cost effective in the long term. Newer drugs may have less tendency to produce some of the side effects associated with older medications, including osteoporosis, cognitive impairment, sedative impairment and depression, all of which require costly medical interventions.
- The AAN opposes cost-based strategies such as high co-pays on newer generation AEDs that effectively limit therapy options for lower-income patients.

The AAN opposes prior authorization requirements by public and private formularies. Prior authorization (i.e., requiring a physician to seek approval to prescribe a drug before the drug may be dispensed) is one method formularies may utilize to limit access to anticonvulsant drugs for the treatment of epilepsy.

- The AAN opposes prior authorization for anticonvulsant drugs in the treatment of epilepsy.
- Prior authorization impedes patient access to quality care and places an unnecessary and costly administrative burden on physicians.
- Prior authorization may affect compliance among patients with epilepsy, creating additional barriers that discourage them from seeking appropriate medication that will prevent future seizures.

Ensuring appropriate coverage of anticonvulsant drugs for the treatment of epilepsy contributes to ethical, high-quality neurological care. The AAN is pleased to serve as a resource for healthcare professionals, policy makers, and the public on this important issue.

References

American Medical Association. AMA Policy H-115.974 Prescription Labeling

American Medical Association. AMA Policy H-125.984 Generic Drugs

American Medical Association. AMA Policy H-125.993 Legislation Prohibiting Therapeutic Substitution

French JA, Kanner AM, Bautista, J et al., "Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new onset epilepsy; Efficacy and tolerability of the new antiepileptic drugs II; Treatment of refractory epilepsy"; Reports of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society; Special Article; *Neurology* 2004;62:1252-1260.

Approved:

AAN Executive Committee ~ November 2, 2006 (Policy 2006-72)

Potential Complications of Substitution: Seizures and Toxicity

Physician Surveys on Generic Substitution

Location (Reference)	Seizure Activity or Toxicity After Generic Substitution
UK ¹	29% increase in seizures or toxicity 11% validated; 10% unproven
Canada ²	14% reported having problems
USA ³	Brand-to-Generic 68% reported breakthrough seizures 56% reported increased adverse events Generic-to-Generic 33% reported breakthrough seizures 27% reported increased adverse events
Multinational ⁴	23% attributed breakthrough seizures to generic medication
USA ⁵	65% of physicians reported having a patient experience breakthrough seizures 35% of patients thought substitution is linked to breakthrough seizures

1. Crawford P, et al. *Seizure*. 1996;5:1-5; 2. Guberman A, Corman C. *Can J Neurol Sci*. 2000;27:37-43; 3. Wilner AN. *Epilepsy Behav*. 2004;5:995-998; 4. Haskins LS, et al. *Epilepsy Behav*. 2005;:98-105; 5. Berg MJ, Gross RA. Abstract presented at: American Epilepsy Society 60th Annual Meeting; December 1-5, 2006; San Diego, CA.

Written Testimony of
Nancy McDonald
Wednesday, March 12, 2008
Joint Committee on Public Health

SB654, An Act Concerning the Availability of Prescribed Antiepileptic Drugs

Thank you for the chance to speak in support of Senate Bill #654.

My name is Nancy McDonald and I live in Monroe, originally from Norwalk. I am the mother of an adult son with epilepsy. He's almost 34 and struggles with horrific seizures, pretty much on a monthly basis. Because of the nature of his seizures, he strives to make a living and to hold down a job. He's had numerous jobs and they all have either ended up letting him go, or not advancing him because of the violent seizures he has. I've witnessed these attacks on many occasions and they are horrible. I've seen his tongue swollen three times it's size from him biting down on it during a seizure. I've seen his body stiffen up like a surf board in the back of my car during a tonic/colonic seizure, and then slam down, and his head hit the back car window with a sickening crash.

No mother should have to endure knowing at any given time without warning their son may go into a horrible tonic/colonic convulsion never knowing what damage he may be doing to his body and his brain. I've been informed by doctors that the more seizures a person has, the more the brain is conditioned to have seizures. Not only that, but due to the lack of oxygen during one of his seizures, brain damage can be very real. My son's doctor has recently increased his medicine dosage and we can only hope that this will help for now. Currently, my son takes two different medicines, Depakote and Tegretol. Our concern now is that with these drugs coming off patent shortly, the same manufacturer be what he receives each and every time he renews his prescription so that we can better track and manage his medications. If we have to worry that he may be getting a different manufactured version at any given time, how do we do that?

The goal for a person with epilepsy is no seizures with as few side-effects as possible. With a consistent supply of medication that goal is much more likely to be achieved. This bill is a critical tool to help my son who has epilepsy attempt to achieve the goal of becoming seizure free. No one wants to hire or keep a person who has severe seizures. Because of that, you can imagine what my son's life is like. When there's no work, there's not only no income, there's no insurance, no place to live, no food, etc. I am here to plead with you as the protectors of the people of CT, to pass this bill, so that we can be assured the medicine my son is prescribed is the exact dosage he needs so he won't have a break-through seizure or become toxic. I can't tell you enough about the worry I experience as his mother except to say when my son has a seizure, the pain is so intense, that not only does my heart ache, but my skin hurts, as well. Knowing the medicine my son's doctor prescribes is exactly what my son is getting would only help to alleviate the anxiety we have to endure on a daily basis. I hope you realize the responsibility of helping pass this bill for those who suffer with this debilitating condition and for the family members who love them.

Thank you again for giving me the chance to tell you our story.