ILLINOIS STATE MEDICAL SOCIETY

Resolution 02.2019-26
(A-19)

Introduced by: Harry Goldin, M.D., ISMS Member

Subject: Patient Access to Anti-Seizure Brand Medication

Referred to: Council on Economics

Whereas, FDA rules state that a generic drug's maximum concentration of active ingredient in the blood must not fall more than 20% below or 25% above that of the brand name, which means a potential range of 45%, even while generics are labeled as being the same as the brand-name drug; and

Whereas, physicians may require exact dosing of medications for patients with epilepsy and other seizure disorders in order to assure stable blood levels to control seizures and to minimize toxicity due to over dosage of the medication(s) due to fluctuating amounts of active ingredients in generics; and

Whereas, patients suffer when seizures are not controlled due to physical injury stemming from a seizure, danger of accidents while operating machinery and driving, loss of driver's license, embarrassment of a seizure in public, loss of employment and inability to care for one's family; and

Whereas, insurance companies have additional costs when a patient has a seizure stemming from ambulance rides, emergency department visits, hospitalizations and radiographs and scans to evaluate the seizure, and laboratory fees to evaluate drug levels; and

Whereas, insurance companies and their prescription benefit managers (PBM) often only cover generic anti-seizure medications; and

Whereas, patients who require branded drugs to control their seizures often must pay for these medications out of pocket, pay very high copays for the brand medication, or must do with the lower cost generic version and not have their seizures well controlled and have toxic effects due to variability of drug blood levels; and

Whereas, patients who require exact brand medication dosing in order to treat their seizure condition, and who, in the prescriber's opinion, cannot be subject to possible variations in blood drug levels as a result of generic drugs, and should not be financially punished for receiving brand-name medications; therefore, be it

RESOLVED, that the Illinois State Medical Society advocate for the inclusion of exceptions in state insurance and PBM laws that provide patient access to brand-name drugs that the prescriber feels are absolutely necessary for the patient's optimal care, and that access to such brand-name drugs comes with the same cost sharing and/or co-pay as the insurer's or PBM's preferred drug for the given medical condition.

Fiscal Note:

N/A

Existing ISMS policy related to this issue:

Prescription drugs may be dispensed only upon the authorization of a physician licensed to practice medicine in all its branches. Public health departments should not conduct drug dispensing and distribution programs without direct physician supervision of patients receiving medication. Only those generic drugs which are actually bio-equivalent should be included in the Illinois Formulary for the Drug Product Selection Program of the Illinois Department of Public Health (IDPH). ISMS urges IDPH to monitor and enforce proper generic drug substitution by pharmacists according to bio-equivalency based on the formulary. The package insert labeling pharmaceutical preparations is a guide for the clinical application of the product and should not be used as an absolute standard limiting the practice of medicine. (HOD 1982 Amended; Last BOT Review 2014)

Board of Trustees adopted Substitute Resolution 38 (A-07), Opposition to Pre-authorization for Prescriptions, as amended: that the ISMS support legislation to regulate the activities of pharmacy benefit managers (PBMs), including prohibiting them from switching properly prescribed medications to another therapeutic brand or generic without the specific approval of the prescriber; that the ISMS, through its Division of Member Advocacy, provide assistance to members who experience unnecessary hassles with the administrative policies of third party payers and PBMs with respect to drug benefit coverage, and create a mechanism to assist and encourage members to bring forward complaints about pharmacists or PBMs who inappropriately switch properly prescribed medications; that the ISMS urge PBMs and third party payers to make all policies related to drug coverage and formulary usage transparent for

prescribers and patients; that the AMA be directed to urge PBMs and Medicare Part D contractors to use evidence-based criteria for more uniformity in their coverage policies and to streamline any prior approval or exception processes; and that the ISMS policy support doctors being reimbursed for time spent reauthorizing patient prescriptions. (BOT 2008-APR)

It is the policy of ISMS to continue to work with appropriate state agencies, the pharmaceutical industry, and our congressional delegation to improve access to a broad range of affordable prescription drug products and promote awareness of the availability of low cost drug programs for needy seniors. (HOD 2002; Last BOT Review 2014; Reaffirmed 2018)

ISMS opposes restriction of insurance coverage for "off label" prescribing of medications unless concerns for safety or ineffectiveness can be documented in writing by the entity imposing the restriction and opposes managed care policies requiring substitution of cheaper medications without regard to side effects or compliance. (HOD 1996; Last BOT Review 2014)

ISMS supports the following health care system reform principles: … 'All patients should have access to a health benefit plan that would include catastrophic coverage as well as preventive services, appropriate screening, primary care, immunizations, and prescription drug coverage' (HOD 2007; Revised 2008; Reaffirmed 2011; Reaffirmed 2012; Reaffirmed 2015-JAN; Reaffirmed 2017;Reaffirmed 2018; Last BOT Review 2015)

ISMS opposes the policy of insurance companies denying payment for safe and efficacious drugs prescribed by physicians. (HOD 2009; Last BOT Review 2014)

ISMS encourages changes in U.S. law to permit Medicare to negotiate prices for prescription drugs with pharmaceutical manufacturers. (HOD 2016; Reaffirmed 2018)
ISMS strongly supports subsidization of prescription drugs for Medicare patients based on means testing. (HOD 2003; Last BOT Review 2014)

It is the policy of ISMS to allow pharmacies to share databases and information, regardless of pharmacy ownership, regarding a patient's controlled substance medication prescriptions and to share that information with the prescribing physicians. (HOD 2002; Last BOT Review 2014)

The pharmaceutical industry should be encouraged to discontinue mass advertisement of prescription drugs and pass on the savings to the patients. (HOD 1999; Last BOT Review 2013)

ISMS approves the concept that pharmaceutical products for inclusion in the Illinois Department of Healthcare and Family Services (IDHFS, formerly IDPA) Drug Manual be based on therapeutic effectiveness rather than cost. While ISMS members will continue to be cost conscious in all aspects of medical care, this care must be based upon therapeutic considerations and bioequivalence. (HOD 1981; Last BOT Review 2014)