Kansas Drug Utilization Review Newsletter

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Welcome to the spring 2011 edition of the "Kansas Drug Utilization Review Newsletter," published by Health Information Designs, Inc. (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Programs (KMAP).

Helpful Web sites	Helpful Numbers		In This Issue
KMAP Web site https://www.kmap-state-ks.us/ **KHPA Web site** http://www.khpa.ks.gov/	**Provider Customer Service** 1-800-933-6593 **Prior Authorization Help Desk** 1-800-285-4978	**Beneficiary Customer Service** 1-800-766-9012 **Pharmacy Help Desk** 1-866-405-5200	ADHD Drug Holidays Risk Evaluation and Mitigation Strategies (REMS) PDL Update

ADHD Drug Holidays

With summertime approaching, many parents may be considering whether to give their children a break from ADHD medications. This 'break' may also be known as a drug holiday or drug vacation.

A drug holiday is a short period of time when a chronically administered medication is purposely discontinued with the intention of reinitiating in the future. For ADHD, there is no clear recommendation regarding the appropriateness of drug holidays. Many practitioners feel that ADHD should be treated chronically since it is a chronic condition. Other practitioners, however, feel that drug holidays are not only acceptable, but recommended. Proponents of drug holidays point out that most ADHD medications are stimulants and, as such, can be taken on an 'as needed' basis.

Whether to partake in a drug holiday should be based on the individual patient. Certain patients may tolerate and benefit from a drug holiday while others may not. For example, a patient with academic difficulty but no difficulty with personal relationships or aggression may be an ideal candidate for a brief discontinuation of ADHD medication. A patient with year-round social problems, however, may be negatively impacted by a drug holiday. Since every patient is different, it is very important to take baseline functioning, social interaction, and side effects into consideration when considering a drug holiday.

Advantages of Taking a Drug Holiday:

- Physicians may take this opportunity to reassess ADHD symptoms and the need for medication.
- May reduce medication tolerance.
- May help to reduce the occurrence of side effects associated with many ADHD medications, such as poor appetite and insomnia.

Disadvantages of Taking a Drug Holiday:

- Some patients may experience difficulty readjusting to medication upon reinitiation.
- Unmedicated patients often have more traffic accidents (applicable to adolescents and adults), more social difficulties, and decreased quality of life.

Points to Consider:

- A drug holiday should usually only be considered for those taking stimulant medications. Non-stimulant medications, such as Strattera, should be taken on an ongoing basis. If Strattera is discontinued during a child's summer vacation, it should be reinitiated 3-4 weeks prior to the start of school.
- Every patient is different. The decision about whether a drug holiday is appropriate should be made by the patient, their physician, and their caregiver.
- If a drug holiday is initiated, there should be a plan in place regarding when to restart medication therapy.
- Drug holidays should be avoided at times of high stress or demand (i.e., the beginning of a new school year).

References on Page 4.

Risk Evaluation and Mitigation Strategy (REMS)

In September 2007, the Food and Drug Administration Amendments Act (FDAAA) was signed into law. This bill amended the Food, Drug and Cosmetic Act, giving the FDA more resources and authority to safeguard public health.

The FDAAA gives authority to the FDA to:

- require post approval studies, or
- request that safety information be provided in labeling, or
- require that a drug manufacturer submit and execute a Risk Evaluation and Mitigation Strategy (REMS)

REMS are required if a drug has serious side effects such as teratogenicity, cardiovascular side effects, causes liver damage, etc. This concept is not new to the FDA. Prior to the implementation of the FDAAA, there were certain drugs with special requirements (such as dispensing with a MedGuide) or special registration conditions that had to be met prior to dispensing to the patient. The drugs that had requirements in place prior to 2007 were part of a program called risk minimization action plans, or RiskMAPs, so they are not technically REMS drugs. However, the FDA is currently in the process of converting RiskMAPs to REMS.

There are different items REMS might require, for example:

- ***Confirmation of patient age*** – patients must be at least 18 years old to buy nicotine products.
- ***MedGuides*** – additional information that must be dispensed with certain classes of drugs, including prescription NSAIDs and antidepressants.
- ***Vaccine Information Statements (VIS)*** – these statements provide patients or their guardians with information about the risks and benefits of the vaccine to be given.
- ***Special training*** – healthcare professionals might be required to have special training before they prescribe or dispense a certain drug. For example, physicians must have at least eight hours of special training before they can write prescriptions for Suboxone® or Subutex®.
- ***Enrollment in special programs*** – the patient, prescriber, and/or pharmacy might be required to enroll in a special program in order for a drug to be prescribed or dispensed. Those patients taking thalidomide for multiple myeloma must register, along with their doctor and pharmacy, with the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.).
- ***Registries*** – patients taking clozapine must have their white blood cell count checked before they can have their prescription filled. This is for the patient's safety, but it also allows the drug companies to analyze the data and determine how often agranulocytosis occurs.
- ***Dispensing from specialty pharmacies*** – drugs for relatively rare diseases can be very expensive (such as bosentan) and are dispensed only from specialty pharmacies who have been certified.

A list of drugs with approved REMS can be found on the FDA website at www.fda.gov.

References:

Guidance for Industry: Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications. U.S Department of Health and Human Services/Food and Drug Administration; September 2009.

Food and Drug Administration Amendments Act (FDAAA) of 2007. www.fda.gov. Accessed 5/2011.

Drugs with REMS and other special prescribing/dispensing requirements. Pharmacist's Letter/Prescriber's Letter 2010;26(11):261111.

Rosiglitazone REMS

Rosiglitazone has been on the market for many years, but there is now evidence to suggest that it can increase the risk of heart problems. In September 2010, the Food and Drug Administration (FDA) mandated several new requirements for users of rosiglitazone: (1) patients who are currently taking rosiglitazone may continue, but they must sign a consent that documents their understanding of the risks associated with continued therapy; and (2) patients who are new to rosiglitazone must show that their diabetes has not been adequately controlled with other non-thiazolidinedione antidiabetic agents and that they are not candidates for pioglitazone therapy. This is just one example of the Risk Evaluation and Mitigation Strategies (REMS) the FDA has developed in response to safety concerns regarding drugs that are currently on the market.

Preferred Drug List

Below is a list of current preferred agents. A complete list of both preferred and non-preferred agents may be found on the KHPA Web site. The Preferred Drug List may be updated at any time; please visit the KHPA Web site for the most recent version.

http://www.khpa.ks.gov/pharmacy/pharmacy_druglist.html

Allergy Agents

Non-Sedating Antihistamines

Claritin® (loratadine)
Zyrtec® (cetirizine)

Analgesics

Long-Acting Opioids

Morphine Sulfate ER
-Generics Only
OxyContin® (oxycodone SR)

Muscle Relaxants (Skeletal)

Flexeril 10mg® (cyclobenzaprine)
Parafon Forte DSC® (chlorzoxazone)
Robaxin® (methocarbamol)
Robaxin-750® (methocarbamol)
Robaxisal® (methocarbamol/aspirin)

Muscle Relaxants (Spasticity)

Lioresal® (baclofen)
Zanaflex® (tizanidine)
-Tablets Only

Oral NSAIDs

Advil® (ibuprofen)
Aleve® (naproxen)
Anaprox® (naproxen sodium)
Anaprox DS® (naproxen sodium)
Ansaid® (flurbiprofen)
Arthrotec® (diclofenac/misoprostol)
Cataflam® (diclofenac potassium)
Clinoril® (sulindac)
Daypro® (oxaprozin)
EC-Naprosyn® (naproxen)
Indocin® (indomethacin)
Lodine® (etodolac)
Meclomen® (meclofenamate)
Mobic® (meloxicam)
Motrin® (ibuprofen)
Motrin IB® (ibuprofen)
Nalfon® (fenoprofen)
Naprelan® (naproxen sodium)
Naprosyn® (naproxen)
Orudis® (ketoprofen)
Orudis KT® (ketoprofen)
Oruvail® (ketoprofen)
Ponstel® (mefenamic acid)
Toradol® (ketorolac)
-Limit 5 Day Supply
Tolectin DS® (tolmetin)
Tolectin 600® (tolmetin)
Voltaren® (diclofenac sodium)
Voltaren XR® (diclofenac sodium)

Topical NSAIDs

Voltaren® (diclofenac sodium, topical)

Triptans

Amerge® (naratriptan)
Imitrex® (sumatriptan)
Maxalt® (rizatriptan)
Relpax® (eletriptan)

Antihyperlipidemics

Fibric Acid Derivatives

Lopid® (gemfibrozil)
TriCor® (fenofibrate)

Statins

Lipitor® (atorvastatin)
Zocor® (Simvastatin)

Anti-Infectives

Anti-Herpes Virus Agents

Valtrex® (valacyclovir)
Zovirax® (acyclovir)
-Oral Dosage Forms Only

Biologic Agents

Crohn's Disease

*Clinical PA may be required

Humira® (adalimumab)
Remicade® (infliximab)

Biologic Agents

Adult Rheumatoid Arthritis

*Clinical PA may be required

Enbrel® (etanercept)
Humira® (adalimumab)

Ankylosing Spondylitis

*Clinical PA may be required

Enbrel® (etanercept)
Humira® (adalimumab)
Remicade® (infliximab)

Juvenile Idiopathic Arthritis

*Clinical PA may be required

Enbrel® (etanercept)
Humira® (adalimumab)
Orencia® (abatacept)

Plaque Psoriasis

*Clinical PA may be required

Enbrel® (etanercept)
Humira® (adalimumab)
Remicade® (infliximab)

Psoriatic Arthritis

*Clinical PA may be required

Enbrel® (etanercept)
Humira® (adalimumab)
Remicade® (infliximab)

Ulcerative Colitis

*Clinical PA may be required

Remicade® (infliximab)

Cardiovascular Agents

ACE Inhibitors

Accupril® (quinapril)
Capoten® (captopril)
Lotensin® (benazepril)
Monopril® (fosinopril)
Prinivil® (lisinopril)
Vasotec® (enalapril)
Zestril® (lisinopril)

ARBs

Avapro® (irbesartan)
Avalide® (irbesartan/HCTZ)
Cozaar® (losartan/HCTZ)
Diovan® (valsartan)
Diovan HCT® (valsartan/HCTZ)
Hyzaar® (losartan)
Micardis® (telmisartan)
Micardis HCT® (telmisartan/HCTZ)

Beta-Blockers

Betapace® (sotalol)
Betapace AF® (sotalol AF)
Blocadren® (timolol)
Corgard® (nadolol)
Coreg® (carvedilol)
Coreg CR® (carvedilol CR)
Inderal® (propranolol)
InnoPran XL® (propranolol XL)
Kerlone® (betaxolol)
Lopressor® (metoprolol tartrate)
Propranolol Intensol® (propranolol)
Sectral® (acebutolol)
Tenormin® (atenolol)
Toprol XL® (metoprolol succinate)
Visken® (pindolol)

CCBs (Dihydropyridines)

Adalat CC® (nifedipine ER)
Cardene® (nicardipine IR)
DynaCirc® (isradipine IR)
DynaCirc CR® (isradipine CR)
Norvasc® (amlodipine)
Procardia XL® (nifedipine ER)

ACE Inhibitor/CCB Combos

Lotrel® (benazepril/amlodipine)

ARB/CCB Combos

Exforge® (amlodipine/valsartan)

Cardiovascular Agents

CCBs (Non-Dihydropyridines)

Calan® (verapamil IR)
Calan SR® (verapamil SR)
Cardizem® (diltiazem IR)
Covera HS® (verapamil ER)
-Brand Name Only
Diltia XT® (diltiazem SR)
-& AB Rated Generics
Isoptin SR® (verapamil SR)
Tiazac® (diltiazem)
-& AB Rated Generics
Verelan® (verapamil SR)

Central Nervous System

Adjunct Antiepileptics

Keppra® (levetiracetam)
Lyrica® (pregabalin)
Neurontin® (gabapentin)
Zonegran® (zonisamide)

Non-Benzo Sedative Hypnotics

Zolpidem
-Generics Only

Novel Sleep Agents

Rozerem® (ramelteon)

Diabetic Agents

Alphaglucosidase Inhibitors

Glyset® (miglitol)

Biguanides

Glucophage® (metformin)
Metformin ER
-Generics Only

DPP-4 Inhibitors

Januvia® (sitagliptan)
Onglyza® (saxagliptan)

Meglitinides

Starlix® (nateglinide)

Insulin (Delivery Systems)

All Multi-dose vials

Long-Acting Insulins

Lantus® (insulin glargine)
-Vials Only

2nd Generation Sulfonylureas

Amaryl® (glimepiride)
DiaBeta® (glyburide)
Glucotrol® (glipizide)
Glucotrol XL® (glipizide XL)
Glucovance® (glyburide/metformin)
Glynase PresTab® (glyburide micronized)
Micronase® (glyburide)

Thiazolidinediones

Actos® (pioglitazone)
ACTOplus Met® (pioglitazone/metformin)
Avandamet® (rosiglitazone/metformin)
Avandaryl® (rosiglitazone/glimepiride)
Avandia® (rosiglitazone)
Duetact® (pioglitazone/glimepiride)

Gastrointestinal Agents

Serotonin 5HT3 Antagonists

Zofran® (ondansetron)
Zofran ODT® (ondansetron)

Pancreatic Enzyme Replacements

Creon® (pancrelipase)
Zenpep® (pancrelipase)

Proton Pump Inhibitors

Dexilant® (dexlansoprazole)
Prevacid® (lansoprazole)
Prevacid SoluTab® (lansoprazole)
Prilosec® (omeprazole)

Gastrointestinal Agents

H_2 Antagonists

Pepcid® (famotidine)
Zantac® (ranitidine)

Gout Agents

Xanthine Oxidase Inhibitors

Zyloprim® (allopurinol)

Injectables

Erythropoiesis Stimulating Agents

Procrit® (epoetin alfa)

Growth Hormones

*Clinical PA is required for all agents

Genotropin® (somatropin)
Genotropin MiniQuick® (somatropin)
Saizen® (somatropin)
Tev-Tropin® (somatropin)

Nasal Agents

Intranasal Antihistamines

Astelin® (azelastine)

Intranasal Corticosteroids

Flonase® (fluticasone)
Nasonex® (mometasone)
Veramyst® (fluticasone)

Ophthalmic Agents

Ophthalmic Antihistamine/Mast Cell Stabilizer Combos

Zaditor® (ketotifen)

Ophthalmic Prostaglandin Analogs

Travatan® (travoprost)
Travatan Z® (travoprost)
Xalatan® (latanoprost)

Ophthalmic NSAIDs

Acular® (ketorolac)
Acuvail® (ketorolac)
Ocufen® (flurbiprofen)
Voltaren® (diclofenac)

Osteoporosis Agents

Bisphosphonates

Fosamax® (alendronate)
Fosamax Plus D® (alendronate/cholecalciferol)

Respiratory

Inhaled Corticosteroids

Flovent® (fluticasone)
Pulmicort Respules® (budesonide)
-6 & Under Only
QVAR® (beclomethasone)

Inhaled Long Acting Inhaled $Beta_2$ Agonists

Foradil® (formoterol)
Serevent® (salmeterol)

Inhaled Long Acting Inhaled $Beta_2$ Agonists/Corticosteroid Combos

Advair® (fluticasone/salmeterol)
Dulera® (formoterol/mometasone)
Symbicort® (budesonide/formoterol)

Inhaled Short Acting Inhaled $Beta_2$ Agonists

ProAir HFA® (albuterol)
Proventil® (albuterol)
Ventolin® (albuterol)
Ventolin HFA® (albuterol)

Urologic Agents

Anticholinergics

Detrol® (tolterodine)
Detrol LA® (tolterodine LA)
Ditropan® (oxybutynin)
Ditropan XL® (oxybutynin XL)
Toviaz® (fesoterodine)
Vesicare® (solifenacin)

This list was updated on **05/01/11**. Please visit the KHPA Web site for the most current version.

ADHD Drug Holidays (continued)

References from Page 1:

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Martins S, Tramontina S, Polanczyk G, Eizirik M, Swanson JM, Rohde LA. Weekend Holidays During Methylphenidate Use in ADHD Children: A Randomized Clinical Trial. *J Child Adolesc Psychopharmacol*. 2004;14(2):195-206.

Pliszka S, AACAP Work Group on Quality Issues: Practice Parameter for the Assessment and Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder. *J Am Acad Child Adolesc Psychiatry*. 2007;46(7):894-921.

Wysong P, Adler L. Long-Term Treatment of ADHS, in Medscape Psychiatry and Mental Health. New York, NY: 2003, Accessed 2011 Jan 20. Available from: http://www.medscape.org/viewarticle/457174.

Health Information Designs, Inc. (HID) was founded in 1976 with a mission to provide drug utilization review (DUR) services for state Medicaid agencies. In 1997, HID was acquired by HDI Solutions and subsequently has experienced strong and steady growth as a premium healthcare and pharmacy support services provider.

Currently, HID works with government agencies in 26 states, including Medicaid agencies and Boards of Pharmacy. HID's efforts in these states monitor, manage or administer more than one-third of the nation's Medicaid budget. The work performed by HID has a daily impact on the healthcare of more than 17.5 million Americans.

HID currently lists among our clients 18 state Medicaid programs, nine state health department programs, and several commercial pharmacy benefit management (PBM) organizations. To serve this geographically-widespread client base, in addition to our home offices in Auburn, Alabama, we have staff in Arkansas, Connecticut, Kansas, Maryland, Mississippi, Texas and Wisconsin.

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