Script Notes

Keystone First

The Pharmacy and Therapeutics Newsletter for Keystone First Participating Providers

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In this issue

Antipsychotic prior authorization criteria for minors: Why are they important?

Key points

- Prescribing of antipsychotics in children and adolescents increased from 0.16 percent in 1993 – 1998 to 1.07 percent in 2005 – 2009.[4]
- Antipsychotics have a number of adverse effects, such as diabetes and weight gain, that can be more pronounced in children and adolescents.[5,6]
- State-mandated prior authorization criteria for Medicaid-insured minors were put in place to combat inappropriate prescribing practices and monitor for side effects.[4]
- Monitoring should include measurement of body mass index (BMI), blood glucose levels, lipid profiles, involuntary movements, and cardiovascular measurements such as blood pressure. [6,8]
- Policies have led to a decrease in antipsychotic prescribing, but limited data is currently available about the impact on other prescribing practices and side effect monitoring.[12]

Use of antipsychotics

Antipsychotic medications help control the manifestations of psychosis, such as delusions and hallucinations, by blocking specific dopamine and serotonin receptors (note: only certain antipsychotics affect both).[1,2] Historically, antipsychotic medications were limited to use in patients with severe psychotic conditions such as schizophrenia. With the development of newer and "safer" antipsychotic medications (commonly known as atypical antipsychotics) in the 1990s and 2000s, prescribing of these medications increased.[3] During this period, clinicians also began prescribing these medications for clinically supported, but not U.S. Food and Drug Administration (FDA) approved, indications. This increase in use was especially evident in children and adolescents, where it is estimated that prescribing at office visits increased from 0.16 percent in 1993 – 1998 to 1.07 percent in 2005 – 2009. In addition, the use of these medications has been found to be five times greater in Medicaid-insured minors than privately insured minors.[4] Despite these medications being considered safer than their older counterparts, many concerns exist about the risks they pose to patients, especially to children and adolescents.

Reasons for concern

Antipsychotics have a number of side effects (Table 1), and evidence suggests that many of these adverse effects may be more severe in minors than in adults.[5 – 7] Because of these adverse events, agencies such as the American Diabetes Association (ADA), American Psychiatric Association (APA), and American Academy of Child and Adolescent Psychiatry (AACAP) have published reports that address these side effects and give recommendations for medication use and monitoring (Table 2).[6,8] Even though recommendations for monitoring from these organizations were published as early as 2004, many patients are still not being monitored appropriately. An analysis by Community Care Behavioral Health (CCBH), a Pennsylvania Medicaid behavioral health organization, found that "52.6 percent of pediatric recipients receiving an antipsychotic medication did not receive routine monitoring of lipids or glucose… [and] only 29.9 percent of pediatric recipients receiving an antipsychotic medication were monitored for both glucose and lipids."[7]

There is also growing concern about how, when, and by whom these medications are prescribed. A study of antipsychotic medication use among 12 million children and adolescents found that many children do not receive behavioral therapy services in addition to pharmacologic therapy. The study also found that antipsychotics are being prescribed for off-label conditions without psychiatric consultation and in combination with other antipsychotics.[9] Due to these findings, government reports called on state agencies to implement practices that help ensure the safe and effective use of antipsychotic medications in children.[4]

Table 1. Side effects of antipsychotic medications[5, 6]

Weight gain	Cardiovascular events
Type II diabetes	Hypertension
Dyslipidemia	Hyperprolactinemia
Extrapyramidal symptoms	Sedation

Table 2. Select recommendations from the American Academy of Child and Adolescent Psychiatry Practice Parameters for Atypical Antipsychotics report[6]

Recommendation 1. Prior to the initiation of and during treatment with an atypical antipsychotic agent (AAA), the general guidelines that pertain to the prescription of psychotropic medications should be followed (CS). These principles include a careful diagnostic assessment; attention to comorbid medical conditions; a review of other drugs the patient is being prescribed; the creation of a multidisciplinary plan, including education and psychotherapeutic interventions for the treatment and monitoring of improvement; and a thorough discussion of the risks and benefits.
Recommendation 8. The simultaneous use of multiple AAAs has not been studied rigorously and generally should be avoided (NE).
Recommendation 10. The acute and long-term safety of these medications in children and adolescents has not been fully evaluated and therefore careful and frequent monitoring of side effects should be performed (CG).
Recommendation 11. BMI should be obtained at baseline and monitored at regular intervals throughout treatment with an AAA (CS).
Recommendation 12. Careful attention should be given to the increased risk of developing diabetes with the use of AAA, and blood glucose levels and other parameters should be obtained at baseline and monitored at regular intervals (CS).
Recommendation 13. In those patients with significant weight changes and/or a family history indicating high-risk, lipid profiles should be obtained at baseline and monitored at regular intervals (CG).
Recommendation 14. Measurements of movement disorders using structured measures, such as the Abnormal Involuntary Movement Scale, should be done at baseline and at regular intervals during treatment and during tapering of the AAA (CS).
Recommendation 15. Due to limited data surrounding the impact of AAAs on the cardiovascular system, regular monitoring of heart rate, blood pressure, and electrocardiogram (EKG) changes should be performed (CG).

Evidence base for practice parameters

Clinical Standard [CS]	Applied to recommendations that are based on rigorous empirical evidence and/or overwhelming clinical consensus.
Clinical Guideline [CG]	Applied to recommendations that are based on strong empirical evidence and/or strong clinical consensus.
Not Endorsed [NE]	Applied to practices that are known to be ineffective or contraindicated.

Steps taken

A study published in March 2015 stated that Pennsylvania was one of 31 states to implement prior authorization criteria for the use of atypical antipsychotics in children.[4] By the end of 2015, Pennsylvania required its fee-for-service Medicaid and Medicaid managed care organizations to develop and implement consistent policies regarding authorization and reauthorization criteria for antipsychotic medications.[10] These policies are based off the recommendations published by the AACAP and ADA.

In November 2015, Keystone First adopted prior authorization criteria to ensure antipsychotic medications are being prescribed properly and monitoring is taking place at regular intervals. This aligns the plan's criteria with the state's guidance, and helps ensure high-quality care for our members under 18 years of age who are prescribed an oral antipsychotic agent. The criteria require documentation of indication, prescriber specialty, use of non-pharmacologic therapy, metabolic and movement disorder monitoring, and a treatment plan for the patient. The criteria also contain special provisions for concurrent use of multiple antipsychotic medications.[11] Thus, the criteria help ensure the medication is being prescribed properly and monitoring is taking place at regular intervals. In addition to prior authorization policies, a number of states have implemented a variety of mental health consultation and prescriber education programs.[3,4,10]

Results

Nationwide, although still at high levels, the use of antipsychotic medications in children has slowed with the a implementation of prior authorization policies and other programs. A study published in June 2016 found that "use of antipsychotics among all Medicaid-insured children peaked in 2008 at 1.86 percent and declined slightly to 1.73 percent by 2010."[12] The authors also found that rates of concurrent antipsychotics use, behavioral therapy, and side effect monitoring either decreased or remained relatively constant during the study period.[12] In Pennsylvania, a CCBH study found that the rate of lipid and glucose lab monitoring among their children and adolescent members receiving antipsychotics increased 7 percent from

2012 to 2014, but still remained low.[13] Based on the results of both studies, there is room for improvement in these areas. In addition to the impacts on antipsychotic prescribing practices, there are some potential unintended consequences of the prior authorization policies. The consequences include administrative burden on provider offices and health plans; off-label use of other medications, such as anticonvulsant mood stabilizers; and inadequate treatment of patients' conditions.[4]

The importance of proper antipsychotic prescribing and monitoring in youths and the need to assess these practices is reflected in the creation of Healthcare Effectiveness Data and Information Set (HEDIS) measures for these medications. The measures investigate the first-line use of psychosocial care, the use of multiple concurrent antipsychotics, and the rates of metabolic screening in children receiving antipsychotic medications.[12,14] Although limited data is available to date on the impact of the prior authorization policies, the introduction of HEDIS measures and heightened awareness of the issues surrounding these medications will likely lead to more published data and studies. Using this information, policies can be refined to minimize unintended consequences and ensure antipsychotics are being used safely and effectively in children and adolescents.

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FDA Medwatch update

Edex (alprostadil for injection) 10 mcg two-pack by Endo Pharmaceuticals: recall — potential lack of sterility assurance

Issue: Endo Pharmaceuticals Inc. is recalling one lot of Edex (alprostadil for injection) 10 mcg to the consumer level. This product recall is due to the detection by Endo of a defect in the crimp caps used in the manufacture of the subject product lot. This defect has the potential to lead to a loss of container closure integrity, which could impact the product's sterility assurance and may lead to serious adverse events such as infections, both localized at the site of injection and systemically. The recall applies to the 10 mcg strength, packaged in a two-pack carton (NDC 52244-010-02), product lot number 207386, expiration date May 2019. The affected lot was distributed from December 13, 2016, through February 13, 2017, to wholesale distributors and retail pharmacies throughout the United States.

Recommendation: Consumers in possession of any unused prescribed Edex 10 mcg product bearing lot number 207386 should immediately discontinue use of the product and return the unused product. Please contact Inmar at **1-844-529-1586**, Monday through Friday (9 a.m. to 5 p.m. ET) or email **edex@inmar.com**.

Avella Specialty Pharmacy unexpired sterile injectable products labeled "latex free": recall — products may contain synthetic or natural latex

Issue: Advanced Pharma Inc., doing business as Avella of Houston, is conducting a voluntary recall of all unexpired sterile injectable products labeled "latex free" that were produced at Advanced Pharma Inc.'s Houston location between September 1, 2016, and February 16, 2017, to the user level (hospitals and institutions) because such products may contain synthetic latex and/or natural latex. These products were distributed directly to health care facilities (hospitals and institutions).

Avella and Advanced Pharma have been unable to confirm with clarity whether their "latex free" label statements are accurate in all cases. The risk of potential adverse events related to a latex allergy, while rare, can range from local site reactions, including swelling and inflammation, to allergic reactions that could be life-threatening to users sensitive to latex.

Recommendation: Customers in Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Mississippi, North Carolina, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, or Virginia who have any of the affected medications labeled "latex free" that are being recalled should immediately discontinue use and return the unused portion to Avella Specialty Pharmacy. For a full list of Advanced Pharma products, please visit **www.advancedpharma.com**.

Ibuprofen Lysine Injection, 20 mg/2 mL (10 mg/mL) by Exela Pharma Sciences: recall — particulate matter

Issue: Exela Pharma Sciences, in association with marketer X-Gen Pharmaceuticals Inc., is voluntarily recalling lot number PLND1613 of Ibuprofen Lysine Injection, 20 mg/2 mL (10 mg/mL), vials to the hospital or user level. Ibuprofen Lysine Injection is indicated to close a clinically significant patent ductus arteriosus (PDA) in premature infants weighing between 500 g and 1500 g, who are no more than 32 weeks of gestational age, when usual medical management is ineffective. Some of the vials have been found to contain particulate matter.

Particulate matter has the potential to block blood vessels, provoke an immune reaction, and/or lead to microinfarcts that could be life threatening. Neither Exela nor X-Gen has received any reports of adverse events related to this recall.

Background: Ibuprofen Lysine Injection is indicated to close a clinically significant patent ductus arteriosus (PDA) in premature infants weighing between 500 g and 1500 g, who are no more than 32 weeks of gestational age, when usual medical management is ineffective. The product is packaged in three 2 mL single-dose vials per carton.

- NDC 39822-1030-2.
- Lot PLND1613.
- Expiration date February 2018.

Recommendation: X-Gen is notifying its distributors and customers by emails and fax communications and is arranging for return of all recalled products. Consumers, distributors, and retailers who have the Ibuprofen Lysine Injection that is being recalled should stop using it and return it to their wholesaler or distributor, to X-Gen, or to Exela.

Vancomycin Hydrochloride for Injection, USP by Hospira: recall — particulate matter in vial

Issue: Hospira Inc. is voluntarily recalling one lot of Vancomycin Hydrochloride for Injection, USP (NDC: 0409-6510-01, Lot 591053A, expiration date November 1, 2017), to the hospital and retail level due to a confirmed customer report of the presence of particulate matter within a single vial. The product is packaged in a carton containing 1x100 mL vial. The lot was distributed from August 2016 through September 2016 in the United States.

If particulate is administered to a patient, it may result in local swelling, irritation of blood vessels or tissue, blockage of blood vessels, and/or low-level allergic response to the particulate. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the physician to visually inspect the product for particulate matter and discoloration prior to administration.

Recommendation: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform health care professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations that may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations, and facilities of the recall to the hospital and retail level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States.

Chlorhexidine gluconate: drug safety communication — rare but serious allergic reactions

Issue: FDA is warning that rare but serious allergic reactions have been reported with the widely used skin antiseptic products containing chlorhexidine gluconate. Although rare, the number of reports of serious allergic reactions to these products has increased over the last several years.

As a result, FDA is requesting the manufacturers of over-the-counter (OTC) antiseptic products containing chlorhexidine gluconate to add a warning about this risk to the drug facts labels. Prescription chlorhexidine gluconate mouthwashes and oral chips used for gum disease already contain a warning about the possibility of serious allergic reactions in their labels. In 1998, FDA issued a Public Health Notice to warn health care professionals about the risk of serious allergic reactions with medical devices such as dressings and intravenous lines that contain chlorhexidine gluconate.

Recommendation: Health care professionals should always ask patients if they have ever had an allergic reaction to any antiseptic before recommending or prescribing a chlorhexidine gluconate product. Advise patients to seek immediate medical attention if they experience any symptoms of an allergic reaction when using the products. Consider using alternative antiseptics such as povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, or parachlorometaxylenol (PCMX) when any previous allergy to chlorhexidine gluconate is documented or suspected.

PNC-27 products: FDA warning — do not use for treatment or cure for cancer

Issue: FDA is warning consumers not to purchase or use PNC-27, a product promoted and sold through **http://pnc27.com**, as a treatment or cure for cancer. An FDA laboratory discovered the bacteria Variovorax paradoxus in a PNC-27 solution sample for inhalation. Consumers who use a contaminated product are at risk for serious, potentially life-threatening infections. Consumers at higher risk include vulnerable populations, such as young children, elderly people, pregnant women, and individuals with weakened immune systems. FDA has not evaluated or approved PNC-27 as safe and effective to treat any disease, including any form of cancer. The agency has not received reports of illnesses or serious adverse events related to PNC-27.

Recommendation: FDA recommends patients with cancer discuss treatment options with a licensed health care professional. Patients who have used any PNC-27 product and have concerns should contact their health care provider as soon as possible.

Product updates

Drug	Indication	Mechanism of action (MOA)	Usual dose	Dosage forms and strength
Xermelo®	Indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.	Telostristat ethyl is a tryptophan hydroxylase inhibitor that inhibits the production of serotonin by carcinoid tumors and reduces the frequency of carcinoid syndrome diarrhea.	Oral: 250 mg three times daily with food	Tablet, oral: 250 mg
Siliq®	Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.	Brodalumab human interleukin-17 receptor antagonist monoclonal is an antibody that inhibits the inflammatory response that plays a role in the development of plaque psoriasis.	Subcutaneous: 210 mg weekly for three weeks followed by 210 mg every two weeks	Prefilled syringe, subcutaneous: 210 mg/1.5 mL
Emflaza®	Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.	Deflazacort is a corticosteroid with concentration-dependent, anti-inflammatory, and immunomodulatory effects that inhibits IL-1-beta-stimulated IL-6 production from human osteoblast-like cells and chondrocytes.	Oral: 0.9 mg/kg/day	Tablet, oral: 6 mg, 18 mg, 30 mg, 36 mg Suspension, oral: 22.75 mg/ml
Parsabiv®	Indicated for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease undergoing dialysis.	Etelcalcetide is a calcimimetic that lowers the level of parathyroid hormone. Plecanatide is a guanylate cyclase-C agonist that replicated uroguanylin, an endogenous human GI peptide thought to stimulate fluid secretion resulting in regular bowel function.	IV: Once every three weeks after a hemodialysis session is completed	Injection, IV: 2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2mL
Trulance®	Indicated for the treatment of chronic idiopathic constipation (CIC) in adults.	Plecanatide is a guanylate cyclase-C agonist that replicated uroguanylin, an endogenous human GI peptide thought to stimulate fluid secretion resulting in regular bowel function.	Oral: 3 mg daily	Tablet, oral: 3 mg

References:

Xermelo [package insert]. Lexicon Pharmaceuticals Inc. March 2017.

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Formulary additions

Drug	Indication	Mechanism of action (MOA)	Usual dose	Dosage forms and strength
Prilosec® Oral Suspension (for members younger than 8 years old)	Indicated for: • Treatment in adults of duodenal ulcer and gastric ulcer. • Treatment in adults and children of gastroesophageal reflux disease (GERD) and maintenance of healing of erosive esophagitis.	Omeprazole belongs to a class of antisecretory compounds that suppress gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell.	For pediatric patients: Weight: Dose 5 < 10 kg: 5 mg daily 10 < 20 kg: 10 mg once daily > 20 kg: 20 mg once daily	Delayed-Release Oral Suspension: 2.5 mg and 10 mg packets
Generic Natroba®	Indicated for the topical treatment of head lice infestations in patients 6 months of age and older.	Spinosad causes neuronal excitation in insects. After periods of hyperexcitation, lice become paralyzed and die.	• For topical use only. • Apply product to dry scalp and hair using only the amount needed to cover the scalp and hair. • Rinse off with warm water after 10 minutes. • Repeat treatment only if live lice are seen seven days after first treatment.	Topical Suspension: 0.9%
Odefsey®	Indicated as a complete regimen for the treatment of HIV-1 infection in patients 12 years of age and older as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL; or to replace a stable antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) for at least six months with no history of treatment failure.	Odefsey is a fixed-dose combination of antiretroviral drugs emtricitabine, rilpivirine, and tenofovir alafenamide.	Recommended dosage: one tablet taken orally once daily with a meal.	Tablet: 200 mg of emtricitabine, 25 mg of rilpivirine, and 25 mg of tenofovir alafenamide
Genvoya®	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older weighing at least 35 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least six months with no history of treatment failure.	Genvoya is a fixed-dose combination of antiretroviral drugs elvitegravir (plus the CYP3A inhibitor cobicistat), emtricitabine, and tenofovir alafenamide.	Recommended dosage: One tablet taken orally once daily with food in patients 12 years of age and older with body weight at least 35 kg and a creatinine clearance greater than or equal to 30 mL per minute.	Tablets: 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide
Descovy®	Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.	Descovy is a fixed-dose combination of antiretroviral drugs emtricitabine (FTC) and tenofovir alafenamide (TAF).	Recommended dosage: One tablet taken once daily with or without food in patients 12 years old and older with body weight at least 35 kg and a creatinine clearance greater than or equal to 30 mL per minute.	Tablets: 200 mg of emtricitabine and 25 mg of tenofovir alafenamide

References:

Natroba package insert. Revised December 2014. Available at www.natroba.com/Full%20Prescribing%20Information.pdf.

Prilosec Oral Suspension package insert. Revised September 2012. Available at www.accessdata.fda.gov/drugsatfda_docs/label/2012/019810s096lbl.pdf.

Odefsey package insert. Revised April 2017. Available at www.gilead.com/~/media/files/pdfs/medicines/hiv/odefsey/odefsey_pi.pdf?la=en.

Genvoya package insert. Revised April 2017. Available at www.gilead.com/~/media/files/pdfs/medicines/hiv/genvoya/genvoya_pi.pdf.

Descovy package insert. Revised April 2017. Available at www.gilead.com/~/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf?la=en.

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The Quarterly Pharmacy and Therapeutics Newsletter

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Formulary website access

Access the Keystone First website 24 hours/7 days a week at www.keystonefirstpa.com/apps/formulary/index.aspx.

The formulary is updated quarterly. We recommend adding this link as a favorite in your computer's web browser for easy access.

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