Nevada Department of Health and Human Services

Division of Health Care Financing and Policy

Pharmacy/DME Program MONTHLY News

PHARMACY AND DME IN THE NEWS

Pharmacy/DME in the News

GSK BUYS $300 MILLION STAKE IN 23ANDME FOR DRUG RESEARCH DATA – GlaxoSmithKline (GSK), a British pharmaceutical company, acquired a $300 million stake in the consumer genetics company 23andMe. GSK and 23andMe will partner to develop drugs more efficiently with a quicker identification process of patients for clinical trials.

This deal will allow GSK to utilize the 5 million customer database that 23andMe has built. Roughly 80% of the customers have already agreed to share their deidentified data for research. One of the first projects will be to recruit patients to test a new treatment for Parkinson's disease. Using the 23andMe database, GSK will be able to identify customers who know their leucine-rich repeat kinase 2 variant status.

Several red flags on ethical use have been raised since announcing the partnership. One of the major questions is whether participants truly understood when they agreed to release their data to be used in research. Another key issue is that they do not have representative samples, so the benefit may not be generalized to the total population. Customers who can afford the DNA/ancestry tests are most likely from a higher socioeconomic class, with higher education levels, often excluding minorities. Lastly, will people be willing to continue to participate in the future if they think their health data is being sold to big pharma.

SENATE CONFIRMS JAMES CARROLL AS NEW DRUG CZAR – The US Senate appointed James W. Carroll to serve as the director of the Office of National Drug Control Policy (ONDCP). This post is informally known as the nation's drug czar. He will be at the forefront of federal efforts to combat the national opioid epidemic. He has previously worked as Washington counsel for Ford Motor Company and general counsel for Ford Motor Company Fund.

FDA APROVED RECORD NUMBER OF DRUGS IN 2018- The US Food and Drug Administration (FDA) approved 59 new drugs, including 19 first-in-class agents, 34 novel drugs for rare diseases, and 7 biosimilars. One of the most notable drugs approved in 2018 was Epidiolex, the first drug derived from a purified formulation of cannabidiol for the treatment of seizures.

Several drugs were approved to treat rare or orphan diseases including the first oral medication in 15 years to treat Fabry disease. Another notable drug approval includes the first-in class agent lofexidine hydrochloride. This is the first nonopioid drug approved to help reduce opioid withdrawal symptoms.

CMS APPROVES REIMBURSEMENT FOR EXPAREL USE IN AMBULATORY SURGERY CENTERS IN 2019- Exparel has been designated with a payment status of "allowed" by the Healthcare Common Coding System (HCPCS). Exparel is a non-opioid option that provides lasting pain control for postsurgical patients. This drug has a broad indication for infiltration across surgical procedures and can act as an interscalene brachial plexus nerve block for procedures such as rotator cuff repair and shoulder arthroplasty. Ambulatory Surgery Centers (ASC) can now provided improved access to the drug for post operation pain management while reducing opioid use.

RETHINKING HOW ANTIBIOTICS ARE PRESCRIBED –Antibiotic stewardship programs can be found in hospitals across the United States and around the world. These programs are very reliant upon restrictive practices, such as requiring approval before prescribing certain antibiotics, or using persuasive practices such as clinical discussions regarding continued use of antibiotics. These practices can be successful but often rely on external motivators. Introduction of clinical frameworks are showing useful to clinicians to help recognize and guide them through a logical sequence of questions and potential solutions.

The Agency for Healthcare Research and Quality (AHRQ) Safety Program for Improving Antibiotic Use is using adaptive change theories and evidence-based diagnostic and treatment practices to promote change within clinical practice. The AHRQ is focusing on clinicians incorporating four moments of antibiotic decision making when prescribing an antibiotic. The main goal is that clinicians and prescribers will be equipped with information to help guide appropriate, evidence-based decisions in antibiotic therapies. The moments include:

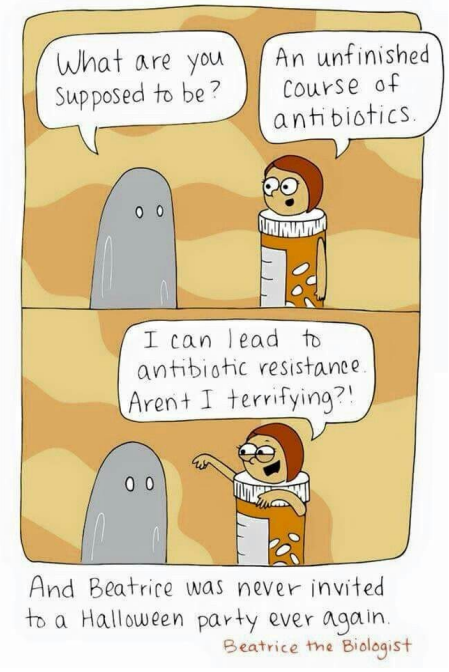
- Moment 1: Does the patient have an infection that requires antibiotics?
- Moment 2: Have I ordered appropriate cultures before starting antibiotics? What empirical antibiotic therapy should I initiate?
- Moment 3: A day or more has passed. Can I stop antibiotics? Can I narrow therapy? Can I change from intravenous to oral therapy?
- Moment 4: What duration of antibiotic therapy is needed for this patient's diagnosis?

U.S. KIDS OFTEN GET INAPPROPRIATE ANTIBIOTICS IN THE ED – A cross-sectional retrospective study using the National Hospital Ambulatory Medical Care Survey ED data found that in U.S. emergency departments (ED), especially non-pediatric, children were more likely to receive antibiotics inappropriately. Overall, 23% of emergency department visits by children resulted in an antibiotic prescription. Acute respiratory infections (55%) accounted for the most prescriptions written, followed by skin and soft tissue (9%), and urinary tract infections (7%). Under a third of the prescriptions were for conditions not requiring antibiotic therapy. According to Dr. Nicole M. Poole, '…ED clinicians are often worried about patient and parent satisfaction and expectations for antibiotics, which in combination with time constraints of a busy Emergency Department, may drive them to prescribe antibiotics when they aren't needed.' Dr. Poole suggested using standardized clinical pathways, clinical decision support tools, and clinical justification can improve antibiotic prescribing. It may also streamline patient work flow and decrease the length of patient visits in the ED.

NEVADA MEDICAID INITIATES ANTIBIOTICS PRIOR AUTHORIZATION CRITERIA – Nevada, along with the rest of the nation, is struggling with the antimicrobial resistance crisis. According to the Centers for Disease Control and Prevention, our state leads the country in several resistance phenotypes, including fluoroquinolones and third-generation cephalosporins. These are important antibiotic classes used to treat serious, complicated infections. Our resistance patterns over time suggest we may reach a point when these antibiotics are no longer effective, leaving us with very few options.

Nevada's Division of Health Care Financing and Policy (DHCFP) will be implementing a policy to require prior authorization in the outpatient care setting for the prescription of third-generation cephalosporins, oral fluoroquinolones, and oxazolidinones. Approval will be given if there are documented culture and sensitivity-proven susceptibilities and if resistance to other agents suggest the antibiotic is necessary. Exceptions to this prior authorization process would be if the listed antibiotics are prescribed by an infectious disease specialist or by an emergency department provider; Ceftriaxone is prescribed as a first line treatment for gonorrhea, pelvic inflammatory disease, epididymo-orchitis, and as an alternative to benzylpenicillin to treat meningitis for those with a severe penicillin allergy; if Cefixime is prescribed for gonococcal infection where Ceftriaxone is unavailable; and if the recipient resides in acute care, long-term acute care, or a skilled nursing facility. The overall goal is that together, we can preserve our ability to save lives with antibiotics and begin to turn the tide of antibiotic resistance for Medicaid recipients.

The DHCFP Pharmacy Program hosted an informational webinar in December 2018 and followed up with a public workshop on January 30, 2019. The implementation for this policy is currently scheduled for March 2019. Please see the following page for common questions from the provider community. You may check for upcoming announcements at https://www.medicaid.nv.gov/providers/rx/rxinfo.aspx. Resources can be found at http://dhcfp.nv.gov/Pgms/CPT/Pharmacy/.



Nevada Medicaid Antibiotic Policy FAQs

Question 1: Does the policy include all antibiotic classes?

Answer: No, this policy is only requiring prior authorizations for 3rd generation cephalosporins, fluoroquinolones, and oxazolidinones dispensed in outpatient settings.

Question 2: Is Nevada the first state to implement prior authorizations on antibiotics?

Answer: No, there are several other states that have prior authorization in place on antibiotics. Some of these other states include; New York, Illinois, Massachusetts, Arkansas, Texas and Ohio.

Question 3: How did you come to this decision?

Answer: This decision was based on a recommendation from the Drug Utilization Review (DUR) board. The DUR Board members agreed that there is a genuine nationwide concern that we may lose the ability to use antibiotics when we truly need them. They reviewed 4-year trends of antibiotic utilization rates for Fee for Service (FFS) and each Medicaid contracted Managed Care Organization (MCO). This policy aligns with the efforts of CDC's Core Elements of Outpatient Antibiotic Stewardship (Action for Policy and Practice) and the US National Action Plan for Combating Antibiotic Resistant Bacteria's goal of reducing inappropriate antibiotic use in the outpatient setting by 50% in 2020. This policy also falls in line with state efforts to put into place effective antimicrobial stewardship programs in outpatient settings.

Question 4: What is included in the exception criteria?

Answer: The exception criteria includes: if prescribed by an infectious disease specialist or by an emergency department provider, if ceftriaxone is prescribed as a first line treatment for gonorrhea, pelvic inflammatory disease, epididymo-orchitis and as an alternative to benzylpenicillin to treat meningitis for those with severe penicillin allergy, if cefixime is prescribed for gonococcal infection where Ceftriaxone is unavailable, or if the recipient resides in acute care, long-term acute care (LTAC) or a skilled nursing facility (SNF).

Question 5: What will be required for a provider?

Answer: A provider may be required to complete a prior authorization form and fax it into the Call Center or to call into the Call Center with the necessary information. PA forms may be found at https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

Question 6: How long does it take for a prior authorization to be approved once submitted?

Answer: The prior authorization process for FFS, Anthem and Health Plan of Nevada recipients, on average is currently less than 4 hours.

Question 7: What are the call center hours of operation?

Answer: The FFS Call Center is open 24 hours a day, 7 days a week. Each MCO Call Center is open 24 hours a day, 7 days a week and/or has electronic prior authorization system capabilities.

Question 8: What are the options to obtain a prior authorization?

Answer: A provider may call or fax to submit a prior authorization. The FFS Call Center number is (855)455-3311 and the fax number is (855)455-3303.

FDA APPROVED DRUG PRODUCTS - January 2018

APPROVAL DATE	DRUG NAME	ACTIVE INGREDIENTS	SUBMISSION CLASSIFICATION	INDICATION
12/14/2018	Herzuma	Trastuzumab-PKRB)	Type 1- new molecular entity	A biosimilar HER2/neu receptor antagonist indicated for the treatment of patients with HER2-positive breast cancer.
12/14/2018	Motegrity	Prucalopride Succinate	Type 1- new molecular entity	A once-daily, oral selective serotonin-4 (5-HT_4) receptor agonist used for the treatment of adults with chronic idiopathic constipation.
12/20/2018	Asparlas	Calaspargase Pegol-MKNL	Type 1- new molecular entity	An asparagine specific enzyme that is part of a chemotherapeutic regime for the treatment of acute lymphoblastic leukemia (ALL) in pediatric and young adults between age 1 month and 21 years.
12/21/2018	Ultomiris	Ravulizumab-CWVZ	Type 1- new molecular entity	A long-acting complement inhibitor that prevents hemolysis is the treatment of adults with paroxysmal nocturnal hemoglobinuria.
12/21/2018	Elzonris	Tagraxofusp-ERZS	Type 1- new molecular entity	The first approved therapy for the treatment of blastic plasmacytoid dendritic cell neoplasm in adults and pediatric patients, two years of age and older.
1/18/2019	Ontruzant	Trastuzumab-DTTB	Type 1- new molecular entity	A biosimilar indicated for the treatment of HER2-positive breast cancer and HER2 overexpressing gastric cancer.

UPCOMING PROGRAM EVENTS

PHARMACY

Pharmacy and Therapeutics Meeting (P&T) – Next quarterly meeting Thursday March 28, 2019

Drug Utilization Review Board (DUR) – Next quarterly meeting, Thursday

April 25, 2019

DME

Monthly DME Workgroup Meeting

February 29, 2019

PUBLIC HEARINGS

January 29, 2019 Approvals:

- Addition of Eucrisa to the existing prior authorization criteria for Topical Immunomodulators
- New prior authorization criteria for antihemophilia agents
- Revisions to the existing Hepatitis C criteria
- Amendments to the existing prior authorization criteria for Kalydeco
- Addition of new prior authorization criteria for opioid cough preparations
- Addition of Trulance to the existing Irritable Bowel Syndrome Agents
- Addition of new prior authorization criteria for Symdeko
- Existing Botulinum Toxin prior authorization criteria was relocated and revised from Chapter 600 to Chapter 1200
- Addition of new prior authorization criteria for compounded medications