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

HHS SEEKS MAJOR CHANGE IN PART D, MEDICAID DRUG PURCHASING – A new proposal, from HHS secretary Alex Azar, outlines using revisions to exceptions of the Antikickback law to help lower total drug costs with a 2020 proposed start date. This proposal would rearrange safe-harbor exceptions that allow "relatively innocuous" business collaborations to proceed without fear of prosecution. This proposal would allow for a new carve-out for drug discounts offered directly to patients and allow for a fixed-fee service arrangement between drug makers and pharmacy benefit managers (PBM). This would exclude from safe-harbor protection the rebates on drugs paid by manufacturers to PBMs, Part D plans, and Medicaid managed care organizations.

It is hoped that this proposal would replace current drug industry protections and allow for "transparent, upfront discounts, passed on directly to patients at the pharmacy counter." HHS does concede that some costs may increase for people enrolled in Medicare and for the government. It is estimated that increases for the 2020 Part D premiums could increase to $5.64 a month per enrollee. These new costs would be offset by shared savings from reallocation of drug rebates.

Leaders of the house committees that oversee Medicare and Medicaid issued a joint statement stating that the rebate proposal will increase government spending by nearly $200 billion and Medicare beneficiaries can expect that their premiums and total out-of-pocket cost will increase.

Edwin Park, a researcher at the Center for Children and Families in Georgetown University, stated that the HHS proposals pays too little attention to the potential effects on Medicaid. Park also said that most states rely on Medicaid managed care plans and PBMs to help negotiate supplemental rebates for the enrollees. The HHS proposal could possibly increase Medicaid spending to $1.9 billion over a decade. States would need to respond quickly and start negotiating direct prices for their beneficiaries in managed care.

FDS OKs FIRST TARGETD THERAPY FOR RARE BLOOD DISORDER – The US Food and Drug Administration (FDA) has approved caplacizumab (*Cablivi*, Ablynx), as the first therapy specifically for adults with acquired thrombotic thrombocytopenic purpura (aTTP), a rare and life-threatening blood clotting disorder. According to the National Organization for Rare Disorders, 3.7 cases per million people each year of thrombotic thrombocytopenic purpura (TTP) occurs. Two thirds of those with TTP are women, and it usually affects people aged 20 to 50 years. Common side effects can include: bleeding of the nose or gums and headache. Prescribing information for caplacizumab includes a warning about the risk of severe bleeding. Providers should monitor patients closely for bleeding in patients who concurrently take an anticoagulant.

FDA PANELS ENDORSE KETAMINE NASAL SPRAY FOR RESISTANT DEPRESSION –Two panels from the US Food and Drug Administration (FDA) approved esketamine 28-mg single-use nasal spray device for treatment-resistant depression. The committees of Psychopharmacologic Drug Advisory Committee and the Drug Safety and Management voted that the benefits outweigh the risk based on research findings to date and additional risk evaluation and mitigation strategies proposed by the FDA. One cited advantage is that esketamine is fast acting, allowing patients to get symptom

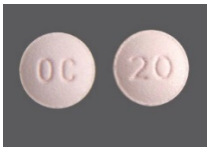
relief much more quickly and avoid self-harm activities. Adverse events of using esketamine include: sedation, dissociation, and increased blood pressure. Most events occurred within the first 2 hours of drug administration.

OXYCONTIN MAKER EXPLORED EXPANSION INTO 'ATTRACTIVE' ANTI-ADDICTION MARKET- A civil complaint was filed in Massachusetts against Purdue Pharma, eight Sackler family members, company directors, and current and former executives alleging that they created the opioid epidemic through illegal deceit. Publicly available sections contend that the Sacklers' pushed for higher doses of OxyContin, guided efforts to mislead doctors and the public about the drug's addictive capacity and pushed the blame for addiction back on patients. Unsealed court documents showed internal correspondence between Purdue Pharma executives discussing the natural link between opioid sales and treatment of opioid addiction and urged immediate attention be given to expanding across the pain and addiction spectrum.

Emails and internal company documents allege that Purdue and the Sackler family went to extreme lengths to boost OxyContin sales and continue to highlight the drug even with increased regulations and public attention on additive properties. Other allegations include Purdue paying two executives convicted of fraudulently marketing OxyContin millions of dollars to assure loyalty, concealed information about doctors suspected of inappropriate prescribing practices, and advised to burnish the image and boost the drug's sales. This also included information on how to 'counter the emotional messages' of mothers whose children overdosed. According to a redacted paragraph, the Sackler family received more than $4 billion dollars in payouts from Purdue, dating back to 2007. The compliant cited that the payments were the motivation for the Sacklers' misconduct.

Purdue responded in a statement that they were considering acquiring the rights to sells drug that combat addiction or reverse the effects of an overdose. They also pointed out that OxyContin is an approved FDA drug and that most opioid overdoses 'now result from heroin and illicit fentanyl.'

Other court documents included information about a secret project that was started in 2014 that would join their efforts and addiction treatment medication. It was code-named Project Tango. Team members included Purdue executives, staff, and Dr. Kathe Sackler. Dr. Sackler is the daughter of the company co-founder. A presentation by this team noted, 'It is an attractive market…. Large unmet need for vulnerable, underserved, and stigmatized patient population suffering from substance abuse, dependence, and addiction.' The internal team at Purdue touted that the addiction treatment marketplace was expanding even if OxyContin sales were declining.



CMS PROPOSES RULES ON INFORMATION BLOCKING, PATIENT EHR ACCESS –The Centers for Medicare and Medicaid (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) proposed a plan to improve the interoperability of health IT systems, increase the access of patients to their electronic health information (EHI), and prevent information blocking. Information blocking is when a person or entity knowingly and unreasonably interferes with the exchange and use of electronic health information.

Under this proposal the healthcare providers and Electronic Health Record (EHR) vendors will not be able to charge consumers for using their data in third-party apps. This will not stop app providers from charging consumers for their services. Fees may vary and will be based on the provider's costs to provide access to or to exchange/use the data.

The implementation date would begin in 2020 and will require hospitals to inform physicians, and other providers when their patients are admitted, discharged, or transferred via electronic notifications. The goal of this is to improve transitions of care between medical settings to improve patient safety, coordination, and overall care.

EHR developers will also be required to program the capability to electronically export all the health information that they produce and electronically manage. In doing so, patients will have access to their electronic records and will allow physicians to automatically export their current EHR data when they switch EHR systems. Another advantage to this proposal is the efficiency of producing clinical summaries. Certified EHRs will use the new US Core Data for Interoperability to expand the data types available. The data indicators include various kinds of clinical notes, pediatric vital signs, patient contact information, and information on the provenance of clinical data.

The ONC has also developed 10 recommendations for the voluntary certification of health IT for pediatric care. This includes: growth charts, weight-based computation of drug doses, age- and weight-specific single dose range checking, and the ability to document all guardians and caregivers.

This proposed rule will also increase patients' access to claims data and provide them with a way to use their health data. Under this rule, private insurers who operate Medicare Advantage plans, Medicaid plans, Children's Health Insurance Program plans, and federal marketplace plans will also have to develop FHIR-based programming interfaces for their members. It is the hope of CMS that patients will take their information with them as they move from one provider to another. Patients can also aggregate their clinical summaries from multiple patient portals and enable them to share it with providers.

CMS PROPOSES COVERAGE WITH EVIDENCE DEVELOPMENT FOR CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY- The Centers for Medicare and Medicaid (CMS) proposed coverage FDA-approved CAR T-cell therapy under 'Coverage with Evidence Development.' This is a new form of cancer therapy that uses a patient's own immune system to fight the disease. Currently there is no national policy for coverage and it is up to local Medicare Administrative Contractors to decide to pay for it.

The proposed coverage would require Medicaid to pay for the therapy nationwide when it is offered in a CMS-approved registry or clinical study, in which patients are monitored for at least two years post-treatment. Evidence from these registries and studies would help CMS determine the types of patients that benefit from CAR T-cell therapy and inform future decisions regarding the types of cases in which Medicare would cover the treatment with no registry or trial. CMS is seeking public comments on the proposed therapy currently.

CMS LAUNCHES 'WHAT'S COVERED' APP- The 'What's Covered' app allows beneficiaries to easily access accurate, consistent information on specific medical items or services that are covered by Medicare. CMS administrator Seema Verma stated, 'The new app is the next in a suite of products designed to give consumers more access and control over their Medicare information.' The 'What's Covered' app is available for free in both Google Play and the Apple App Store.

CMS's eMedicare initiative also includes online decision support to help beneficiaries understand and evaluate coverage options and costs between Medicare and Medicare Advantage. This initiative shows how their choices will impact their estimated out-of-pocket costs; price transparency tools allows for the comparison of national average costs of certain procedures; a webchat option in the Medicare Plan Finder; and surveys across Medicare.gov so beneficiaries can provide feedback and input.

FDA APPROVED DRUG PRODUCTS - January 2018

APPROVAL DATE	DRUG NAME	ACTIVE INGREDIENTS	SUBMISSION CLASSIFICATION	INDICATION
2/1/2019	Jeuveau	Prabotulinumtoxina-XVFS		Indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults.
2/6/2019	Cablivi	Caplacizumab-YHDP		First therapy specifically indicated, in combination with plasma exchange and immunosuppressive therapy, for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), a rare and life-threatening disorder that causes blood clotting.
2/13/2019	Egaten	Triclabendazole	Type 1- New Molecular Entity	Indicated treatment for liver flukes, specifically fascioliasis and paragonimiasis.
2/27/2019	Herceptin Hylecta	Trastuzumab; Hyluronidase-oysk		Indicated treatment for certain people with HER2-positive early breast cancer (node-positive, or node-negative and ER/PR-negative or with one high-risk feature) in combination with chemotherapy, HER2-positive metastatic breast cancer in combination with paclitaxel, or alone in people who have received one or more chemotherapy regimens for metastatic disease.

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 26, 2019

PUBLIC HEARINGS

February 26, 2019: Prior Authorization on Fluoroquinolones, third generation Cephalosporins, and Oxazolidines.