MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Pharmacy News & Views

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Upcoming Changes Regarding Opioid Prescribing in Maryland

Maryland Medicaid Drug Utilization Review Board

The DUR Board, along with it's Corrective Managed Care advisory committee, has played an integral role in educating Maryland prescribers and pharmacists regarding the appropriate use of opioids. Recent retrospective interventions have included educational outreach regarding multiple medication-related issues, including:

- Use of opioids in participants with a history of a substance use disorder,
- Use of buprenorphine-containing products (for substance use disorder) and opioid agonists,
- Overuse of opioids based on days supply,
- Utilization of methadone,
- Overuse of narcotic based on dose per day,
- Overuse of short-acting opioids,
- Overuse of Tussionex®,
- Duplicate use of sedative/hypnotic agents,
- Concomitant use of opioids, benzodiazepines and carisoprodol-containing products,
- Use of multiple agents with additive CNS-depressant effects,
- Inappropriate long-term use of short-acting opioids,
- Non-adherence to substance use disorder medications,
- Concomitant use of opioids and muscle relaxants,
- Utilization of greater than or equal to (≥) 50 milligrams of morphine oral equivalents (excluding those with cancer, sickle cell disease or hospice care).

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More information related to the Maryland Medicaid DUR Board may be found at: https://mmcp.dhmh.maryland.gov/pap/pages/Drug-Utilization-Review.aspx

Maryland Medicaid's Opioid Prescribing Policy

As part of Maryland's effort to combat the national opioid epidemic, Maryland Medicaid is focused on improving the opioid prescribing in an effort to prevent non-medical opioid use, opioid misuse and abuse, over prescribing of opioids, overdose, dependence and opioid related substance use disorders from developing. As part of the State's comprehensive approach to combatting this epidemic, the Maryland Medicaid's Opioid Drug Utilization Review Workgroup has been working with the eight Medicaid Managed Care Organizations (MCO) in Maryland to implement minimum standards that will be applied by both the fee-for-service Program and the MCOs to ensure the State addresses this epidemic.

These new standards for use of these medications are in accordance with recommendations made by the Centers for Disease Control and Prevention (CDC), are anticipated to be implemented in July of 2017. HealthChoice MCOs may choose to implement additional requirements or limitations beyond the State's policy. These standards, among others, will include improved coverage of non-opioid medication options that are considered to be first-line treatment for chronic pain. In addition, prior authorization will be required for all long-acting opioids, methadone for pain, and any opioid prescription that results in a patient exceeding 90 morphine milligram equivalents (MME) each day, with a standard 30-day quantity limit for all opioids to be set at or below 90 MME per day. Already in place is the requirement of prior authorization for all fentanyl containing products. Specific populations will be excluded from these standards, including those with cancer, sickle cell disease and those in hospice care. However, the State encourages all patients be kept on the lowest effective dose of opioids for the shortest required duration to minimize risk.

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Providers must obtain a prior authorization every six months to prescribe long-acting opioids, fentanyl products, methadone for pain and opioids above 90 milligram equivalents per day. Prior authorization will, at a minimum, also require the following:

- Checking the Prescription Drug Monitoring Program (PDMP);
- Using urine drug screens;
- Offering naloxone;
- Signing a prescriber-patient agreement;
- Attesting to benefit outweighing risk.

More information regarding Maryland Medicaid Opioid Prescribing Guidance and Policy, including an online webinar can be found at: https://mmcp.dhmh.maryland.gov/healthchoice/opioid-dur-workgroup/Pages/opioid-response-resources.aspx

Information regarding Prior Authorization forms for the Maryland Medicaid Pharmacy program related to fentanyl-containing products can be found at: https://mmcp.dhmh.maryland.gov/pap/pages/Pharmacy-Program-Forms.aspx

A direct link to the PA form is available at: https://mmcp.dhmh.maryland.gov/pap/docs/Fentanyl%20PA%20Form.pdf

Information, including PDMP prescriber registration and available clinical resources can be found at the following links: http://bha.dhmh.maryland.gov/pdmp/Pages/-Clinical-Resources.aspx

http://crisphealth.org/services/prescription-drug-monitoring-program-pdmp/pdmp-registration

CDC recommendations can be found at: https://www.cdc.gov/drugoverdose/prescribing/guideline.html

Mobile apps, including dosage calculators, may be downloaded to your device by visiting: https://www.cdc.gov/drugoverdose/prescribing/app.html

FDA Further Restricts Codeine Use

The Food and Drug Administration (FDA) has strengthened warnings against the use of codeine and tramadol in the pediatric population (age less than 18 years) due to safety concerns regarding the increased risk of respiratory depression and death in this group. Several new warnings have been added to the product labeling of codeine and tramadol containing products, including those in the table below:

Codeine-Containing Products

Butalbital, acetaminophen, caffeine and codeine phosphate, Codeine sulfate, Fiorinal with codeine, Prometh VC with codeine, Promethazine with codeine, Soma Compound with codeine, Triacin-C, Tuxarin ER, Tuzistra XR, Tylenol with codeine
all generic products containing codeine

Tramadol-Containing Products

Conzip, Ultracet, Ultram, Ultram ER
all generic products containing tramadol

Dihydrocodeine-Containing Products

Synalgos DC

The metabolic pathway of codeine and tramadol can explain the updated warnings provided by the FDA. Both codeine and tramadol are metabolized via the cytochrome P450 2D6 enzyme to active substances with mu-opioid receptor activity (codeine → morphine, tramadol → O-desmethyltramadol glucuronide). The pharmacogenetics of the cytochrome P450 2D6 enzyme have been described in the general population as those who are one of four different types of metabolizers: poor, intermediate, extensive and ultra-rapid. It is the ultra-rapid metabolizers who are at greatest risk of adverse effects with codeine and tramadol. In these individuals, the inactive codeine and tramadol are rapidly converted to active substances, with a faster and greater onset of drug effects, including sedation, drowsiness and decreased respiratory activity. The FDA has reported 24 deaths in children less than 18 years of age who have ingested codeine containing products, and three deaths in the same group using tramadol, over the past 45 years. Further review of these reports showed that a majority of deaths occurred in those younger than 12 years of age. These reports were gathered from the FDA Adverse Event Reporting System (FAERS). While it is highly recommended to report these adverse drug events, the FDA recognizes that all instances may not be reported to the FDA and therefore is concerned this may be an issue that effects more than those that are on file.

This same issue prompted the FDA to create a Boxed Warning in 2013 for all codeine products warning against the use in children

FDA Further Restricts Codeine Use Cont'd

of any age to treat pain after surgery to remove tonsils or adenoids. The FDA again intervened by issuing Drug Safety Communications regarding both codeine and tramadol in 2015 due to safety concerns and a recent movement in Europe to restrict access of these products in pediatric patients. The updated labeling will include:

• A new ***Contraindication*** alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years,

• A new ***Contraindication*** for tramadol warning against use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids,

• A new ***Warning*** for codeine and tramadol to recommend against their use in adolescents between 12-18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems,

• A strengthened ***Warning*** to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

These effects include excess sleepiness, difficulty breastfeeding or serious breathing problems that could result in death.

<< Reference: US Food and Drug Administration (FDA): FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. US Food and Drug Administration (FDA). Silver Spring, MD. 2017. Available from URL: https://www.fda.gov/downloads/Drugs/DrugSafety/UCM553814.pdf. As accessed 2017-04-20.

Conversion to National Average Drug Acquisition Cost (NADAC)

The Covered Outpatient Drugs Final Rule (CMS-2345-FC), published on February 1, 2016, is designed to ensure pharmacy reimbursement is aligned with the acquisition cost of drugs and the states pay a professional dispensing fee. The final rule establishes Actual Acquisition Cost (AAC) as the basis by which states should determine their ingredient cost reimbursement, so payments are based on an accurate average of the prices available in the marketplace, while still ensuring sufficient participant access. Furthermore, the rule implements the use of the term "professional dispensing fee" to ensure the dispensing fee paid to pharmacies reflects the cost of the pharmacist's professional services and cost to dispense the drug product to a Medicaid participant.

After reviewing various methodologies, the Maryland Medicaid Pharmacy Program (MMPP) made the determination to utilize the National Average Drug Acquisition Cost (NADAC), calculated by CMS, as the primary basis for AAC ingredient reimbursement. MMPP has contracted with Myers and Stauffer, LC, a national accounting and consulting firm, to assist in developing and maintaining an up-to-date State Actual Acquisition Cost (SAAC) list for items not contained on the NADAC pricing benchmark.

Effective April 1, 2017, as required by the CMS Final Rule, the Department changed the pharmacy provider reimbursement methodology from an Estimated Acquisition Cost (EAC) to an AAC. The new reimbursement methodology was shared at the Pharmacy Stakeholder meeting on January 9, 2017, and is available on the Department of Health and Mental Hygiene, Medicaid Pharmacy Program website at: https://mmcp.dhmh.maryland.gov/pap/docs/Presentation%20Slides%20from%20January%209th%20Pharmacy%20Stakeholders%20Meeting.pdf

Further information may be found online through the Maryland Department of Health and Mental Hygiene Pharmacy page, under Provider Advisories. Direct links to this information are listed below:

• Change in Pharmacy Reimbursement Methodology (Provider Advisory #172): https://mmcp.dhmh.maryland.gov/pap/docs/Advisory%20172%20Change%20in%20Pharmacy%20Reimbursement%20Methodology.pdf

• FSS and Nominal Price Update (Provider Advisory #173): https://mmcp.dhmh.maryland.gov/pap/docs/Advisory%20173%20%20FSS%20and%20Nominal%20Price%20Update%20(1).pdf

• Current Maryland Pharmacy Reimbursement Rates and other information can be found at: http://www.mslc.com/Maryland/Pharmacy.aspx

• Myers and Stauffer, LC Help Desk: (800) 591-1183

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Pharmacy News & Views

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TELEPHONE NUMBERS

Xerox Technical Assistance and Preauthorizations

1-800-932-3918

24 hours a day, 7 days a week

Maryland Medicaid Pharmacy Access Hotline

1-800-492-5231 (select option three)
Monday-Friday, 8:00 am to 5:00 pm

Kidney Disease Program
1-410-767-5000 or 5002
Monday-Friday, 8:00 am to 5:00 pm

Breast & Cervical Cancer Diagnosis and Treatment

1-410-767-6787
Monday-Friday, 8:00 am to 4:30 pm

Maryland AIDS Drug Assistance Program
1-410-767-6535
Monday-Friday, 8:30 am to 4:30 pm

Peer Review Program
1-855-283-0876
Monday-Friday, 8:00 am to 6:00 pm
with exception of State Holidays

Advisory Keeps You in the Know

Get the latest updates regarding pharmacy issues through the Maryland Medicaid Pharmacy Program (MMPP) e-mail notification service. Called the Advisory, these communications provide the pharmacy community with the most up to date information. Advisories can be found at this link: https://mmcp.dhmh.maryland.gov/pap/Pages/Provider-Advisories.aspx

Please contact the MMPP representative at 410-767-1455 if you are currently not receiving e-mail Advisories through a pharmacy organization to which you belong.

You can sign up to receive Advisories and the MMPP News & Views via e-mail by going to the website: http://www.maryland-medicaidpharmacyinformation.com Follow the links to enter your e-mail address.