Mountain Pacific DUR PROGRAM NEWS

FALL 2024

Montana Healthcare Pharmacy Programs Link
(Current Montana Healthcare Programs Preferred Drug List, Provider Notices, DUR Board/Meeting Information, Resources)
http://medicaidprovider.mt.gov/19

For current drug prior authorization criteria:
https://www.mpqhf.org/corporate/montanans-with-medicaid/pharmacy/

The Drug Utilization Review (DUR) Program, administered by Mountain Pacific through a contract with the Allied Health Services Bureau of the Montana Department of Public Health and Human Services, is the quality assurance body seeking to assure the quality of pharmaceutical care and to help provide rational, cost-effective medication therapy for Montana Healthcare Programs members.

Montana Healthcare Programs
Drug Prior Authorization Unit
1-800-395-7961

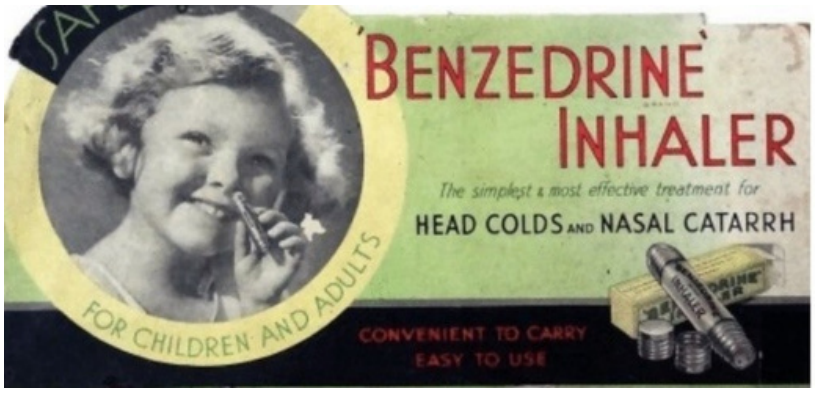
An Object Lesson on Stimulant Misuse

Stimulants are substances that raise levels of physiological or nervous activity in the body. This means that commonly used substances like nicotine and caffeine fit into this category, as well as prescription medications such as Adderall®, Vyvanse®, Ritalin® and others. Illicit stimulants also meet this definition, including cocaine, methamphetamine, methcathinone, synthetic cathinones "bath salts" and MDMA, which is a combination stimulant and psychedelic. Some of these substances trace their history back millennia, and some evolved more recently. Nicotine use in South America is believed to date back to the time before the current era.

Prescription stimulants started as the base form of amphetamine, marketed as Benzedrine nasal inhaler®, by Smith, Kline & French (SKF) in 1933. In a waxy base, it contained 325 milligrams of amphetamine in a metal tube meant to be inhaled for congestion. It did not take long before the drug was removed from the tube and melted or ingested, regardless of its wax base. Benzedrine nasal inhaler® remained on the market until 1949 when it was discontinued due to misuse.[1] By 1937 SKF had developed amphetamine in oral tablet form and named it Benzedrine® Tablets, available in five and 10 milligram doses. In 1937 the American Medical Association (AMA) approved Benzedrine® Sulfate for use in narcolepsy, postencephalitic Parkinsonism and minor depression. SKF relied heavily on Harvard psychiatrist Abraham Myerson, who was a proponent of the use of amphetamine for depression. He postulated that amphetamine adjusted the hormonal balance in the central

Continued on p. 2

This information is brought to you by:
Mountain Pacific
P.O. Box 5119 | Helena, MT 59604
www.mpqhf.org



nervous system, which he believed was the mechanism of action that treated minor depression. [2]

Meanwhile, what would become World War II was heating up in Europe. The Germans used stimulants during the Blitzkrieg in 1939. The emphasis on speed and surprise required German soldiers to be awake and alert for long periods to move far and fast enough to surprise Polish forces. The Germans' not-so-secret weapon was a popular drug manufactured by the Temmler pharmaceutical company named Pervitin®. Available first in early 1937, Pervitin® was a methamphetamine synthesized from ephedrine with a new and simpler process. The Germans were not the only military utilizing stimulants during WWII. The British, Japanese and Americans also found Benzedrine® beneficial, especially for pilots who had long distances to fly and for medical personnel who sometimes had long shifts.

By the end of the war, stimulants had gained a major foothold around the world. They became more popular, not only medically but also for non-medical purposes. The success of SKF and Benzedrine® tablets did not go unnoticed by their competition, and unbranded amphetamine, made by small companies, began to pop up. With their patent expiring in 1939 on Benzedrine®, SKF moved their focus to developing Dexedrine (dextroamphetamine) and brought it to market in 1945. Other stimulants such as methylphenidate were synthesized in 1944.

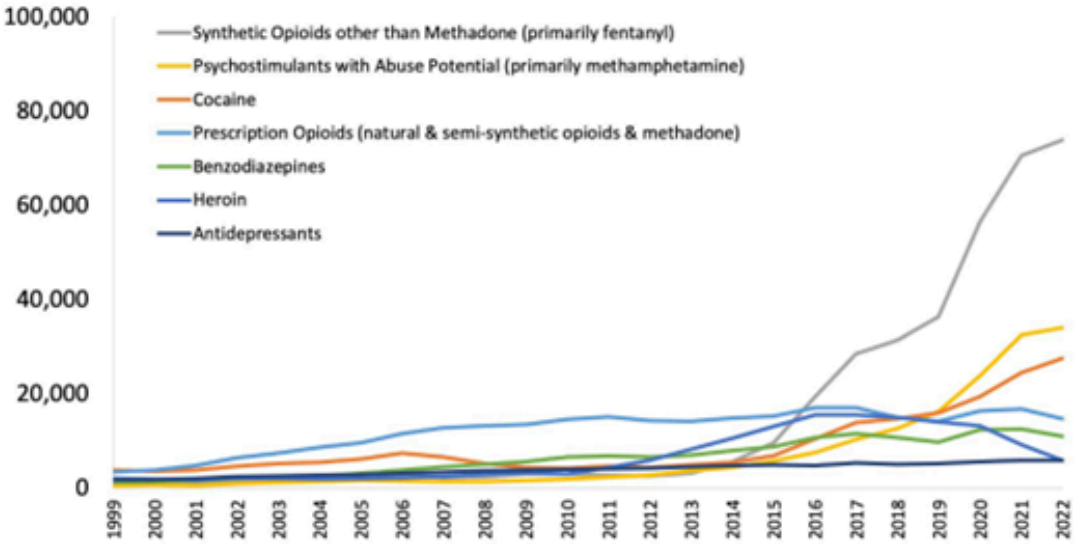
Through the 1960s, the use of prescription stimulants continued to increase, and the illicit market also skyrocketed. By the end of the 1960s the pharmaceutical use and misuse of many substances were pervasive and diverse. Vietnam War veterans returned home with drug dependence, hippie culture broadly experimented with a variety of substances, and housewives were prescribed "diet pills" to stay thin and Valium®, "Mother's Little Helper", to stay calm. Their husbands used a variety of sedatives, including Quaaludes, to relieve the stress of work. In response to America's growing drug abuse problem the Comprehensive Drug Abuse prevention and Control Act of 1970 was passed, which established the five schedules that classify controlled substances today. Stimulants were listed as Schedule II. Then, in 1973 the Drug Enforcement Agency (DEA) was established.

Though it has been couched as a modern problem, history shows prescription stimulant misuse is not new. It has escalated at various times over the years to levels of concern, such as in the post-war years of WWII and Vietnam. Perhaps the most famous example is the use and misuse of cocaine. Originally mixed in wine and soft drinks (e.g., Coca-Cola), it became popular with many high-profile personalities around the world. Soon the devastating effects of cocaine became apparent, and the federal government enacted one of the first pieces of legislation to regulate drugs, the Harrison Act of 1914. Cocaine faded into history until it came back on the scene with a crash in the 1970s and 80s. By 1989, cocaine and crack (smokable cocaine) became the prime target of the DEA. As the "crack epidemic" faded through the 1990s, both methamphetamine and cocaine continued to be used illicitly, but these substances were present in very

Continued on p. 3

few fatal drug overdoses. The U.S. had moved on from stimulants and into the prescription opioid epidemic, which was becoming deadly. By mid-2015, the death toll from the rapid rise of synthetic opioid use in the U.S. overshadowed everything else.

U.S. Overdose Deaths*
Select Drugs or Drug Categories, 1999-2022



*Includes deaths with underlying causes of unintentional drug poisoning (X40-X44), suicide drug poisoning (X60-X64), homicide drug poisoning (X85) or drug poisoning of undetermined intent (Y10-Y14), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

While the medical community was focusing their concern on drug abuse of opioids, the use of both prescription and illicit stimulants began to rise again. One CDC study on stimulant prescriptions filled among commercially insured children and adults showed "the percentage of persons receiving prescription stimulant fills increased during 2016-2021, including large increases during 2020-2021".[3] Initially this rise was attributed to the pandemic and the increase in recognition of adult attention-deficit/hyperactivity disorder (ADHD). While this was true, the use of illicit stimulants was also rising, increasing awareness of stimulant use disorder. In 2023 the FDA Center for Drug Evaluation and Research (CDER) published a Draft Guidance and Drug Safety Communication expressing concern about stimulant use disorder. On May 11, 2023, the FDA published an FDA Drug Safety Communication. It required boxed warnings and updated prescribing information for all prescription stimulants. Including the addition of information that patients should never share their prescription stimulants with anyone, the boxed warning information describes the risks of misuse, abuse, addiction and overdose consistently across all medicines in the class. The boxed warning also advises heath care professionals to monitor patients closely for signs and symptoms of misuse, abuse and addiction.[4]

In May of 2024, the provisional data from the CDC's National Center for Health Statistics indicated an estimated 107,543 drug overdose deaths in the U.S., a 3% decrease over the 2022 estimate of 111,029. This was the first annual decrease in drug overdose deaths since 2018. The chart on the following page shows the breakout of drugs involved. However, multiple drugs may be involved, so the totals do not add up to the numbers listed above.[5]

Continued on p. 4

Stimulants (cont.)

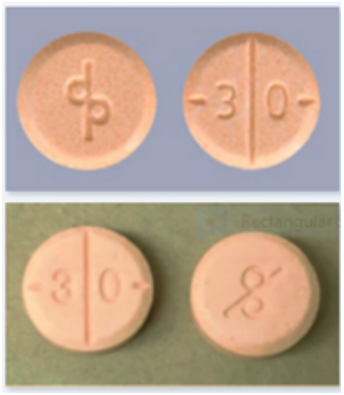
Drug Type*	Estimated Deaths 2023	Estimated Deaths 2022
Synthetic opioids (fentanyl)	74,702	76,226
Psychostimulants (including methamphetamine)	36,251	35,550
Cocaine	29,918	28,441
Natural/semi-synthetic	10,171	12,135

*Deaths may involve multiple drugs, while others might not specify any specific drug. As a result, the sum of deaths attributed to specific drugs may not equal the total number of overdose deaths.

Though the overall drug overdose deaths decreased, cocaine and psychostimulant involvement in overdose deaths increased. The warning is clear. It is time to find improved treatment for stimulant use disorder, as cocaine and methamphetamine use continues to rise.

In June of 2024, the CDC Health Alert Network declared misuse of prescription stimulants, particularly among young adults, as a growing public health concern, with 14.5% of college students reporting misusing prescription stimulants.[6] Diversion of legitimate prescription stimulants feeds the growing abuse. The most common source of prescription stimulants for nonmedical use come from friends or family members, with estimates generally ranging from 56 to 80%.[7]

Diversion of prescription stimulants has offered a new opportunity for drug cartels. They now ship counterfeit Adderall into the U.S. In the 2024 National Drug Threat Assessment, the FDA reported confiscating and testing the counterfeits. The chemical assay from the fake Adderall was methamphetamine,[8] but cocaine, fentanyl and xylazine have shown up in the past. This unknown cocktail is being sold in the U.S. and is taking its toll on Americans. It is time to learn from history and make moves to again turn down the trend of stimulant abuse.



Prescription Adderall (top) and fake Adderall pill containing methamphetamine (bottom). Source: DEA

1 Jackson C. O., The Amphetamine Inhaler: A Case Study of Medical Abuse," *Journal of the History of Medicine* 26 (1971): 187–196.

2 Rasmussen, "Making the First Anti-Depressant;" A. Myerson, "Effect of Benzedrine Sulfate on Mood and Fatigue in Normal and Neurotic Persons," *Archives of Neurology and Psychiatry* 36 (1936): 816–822.

3 Danielson ML, Bohm MK, Newsome K, et al. "Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults-United States, 2016-2021." *The Morbidity and Mortality Weekly Report (MMWR)* 2023:72:327-332. DOI https://www.cdc.gov/mmwr/volumes/72/wr/mm7213a1.htm

4 *FDA Drug Safety Communication: FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions.* (2023, May 11). U.S. Food & Drug Administration. https://www.fda.gov/media/168066/download?attachment

5 CDC Newsroom. (2024, May 15). Statement from CDC Chief Medical Officer Dr. Deb Houry on 2023 Overdose Death Data. Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. https://www.cdc.gov/media/releases/2024/s-overdose-data.html

6 CDC Health Alert Network (HAN). Disrupted access to prescription stimulant medications could increase risk of injury and overdose. (2024, June 13). https://emergency.cdc.gov/han/2024/han00510.asp

7 *FDA Drug Safety Communication: FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions.* (2023, May 5). U.S. Food & Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions

8 Drug Enforcement Administration; National Drug Threat Assessment 2024. https://www.dea.gov/sites/default/files/2024-07/2024%20NDTA-updated%207.5.2024.pdf

CDC Vaccination Recommendations for School-Age Children

Important reminder: Pharmacist-administered vaccines, including COVID-19 vaccines beginning October 1, 2024,[1] are not covered for Medicaid-enrolled children as these members are eligible under the Vaccines for Children (VFC) program. Pharmacist-administered vaccines and vaccine administration are covered for members enrolled in Medicaid and Medicaid Expansion who are 19 years of age and older and for all members enrolled in Healthy Montana Kids (HMK). Find a Montana Vaccines for Children (VFC) provider: https://dphhs.mt.gov/publichealth/Immunization/VaccinesforChildreninMontana.

Vaccine and Other Immunizing Agent	4-6 Years	7-10 Years	11-12 Years	13-15 Years	16 Years	17-18 Years
Diphtheria, tetanus and acellular pertussis (DTaP<7 yrs)	5th dose					
Tetanus, diphtheria and acellular pertussis (Tdap≥7 yrs)			1 dose			
Inactivated poliovirus (IPV)	4th dose					
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)	1 or more doses of updated (2024-25) vaccine					
Influenza	Annual vaccination 1 or 2 doses	Annual vaccination - 1 dose only				
Measles, mumps, rubella (MMR)	2nd dose					
Varicella (VAR)	2nd dose					
Human papillomavirus (HPV)			Recommended age; 2 or 3 doses depending on age at initial vaccination			
Meningococcal (MenACWY-TT ≥2 years)			1st dose		2nd dose	

For those who fall behind or start late, catch-up vaccination is recommended at the earliest opportunity. Additional vaccinations may be recommended depending on special circumstances. To determine minimum intervals between doses or special recommendations, visit https://www.cdc.gov/vaccines/.

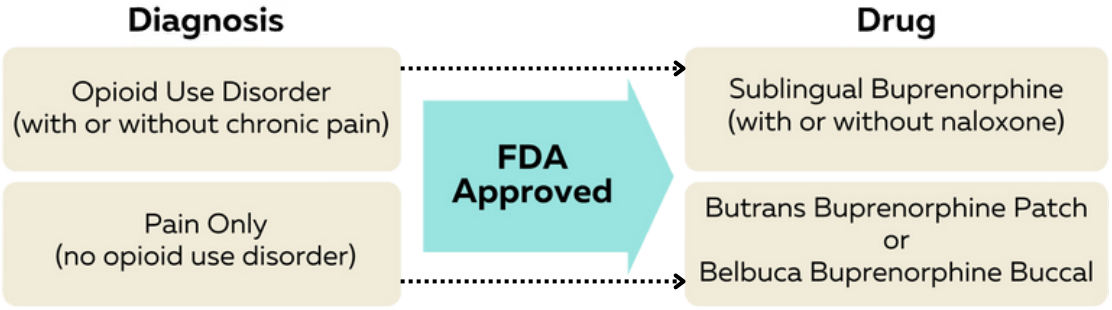
[1] Montana Healthcare Programs Provider Notice, September 4, 2024, Effective October 1, 2024; COVID At-Home Tests and Vaccine Coverage Changes. https://medicaidprovider.mt.gov/docs/providernotices/2024PN/COVIDAt-HomeTestsandVaccineCoverageChanges.pdf

Are You Treating Opioid Use Disorder or Pain Only?

With the goal of reducing barriers to care, the Montana Healthcare Programs and the Drug Utilization Review (DUR) Board have reduced prior authorization (PA) criteria for sublingual medications for opioid use disorder (OUD). Changes have also been made to the Preferred Drug List with additional forms of buprenorphine sublingual products joining Suboxone® film on the preferred side.

These changes were made to improve access to care for members with OUD. The sublingual tablets and films that contain buprenorphine, either alone or with naloxone, are only FDA-indicated for a diagnosis of OUD. This means they will not be covered by the Montana Healthcare Programs for pain management alone. If a member has a diagnosis of OUD and pain, then the sublingual forms are appropriate for coverage because of the diagnosis of OUD, not the pain diagnosis.

When a Montana Healthcare Programs member has pain without a diagnosis of OUD, and the provider wishes to use buprenorphine, FDA-approved options, which are available and covered for pain only, include Butrans® patch and Belbuca® buccal film. Butrans® patch is a preferred drug in the analgesic category of the PDL. It does not require PA. Belbuca® is non-preferred and does require a PA. Information for dosing initiation and titration or transition from full agonist opioids is available on each product's website. Butrans® is not recommended as a transition product for patients on greater than 80 milligrams oral morphine equivalents. Belbuca® has recommendations for patients on up to 160 milligrams oral morphine equivalents. Butrans® and Belbuca® do not have FDA approval for OUD.



SUBOXONE® sublingual film and generics are indicated for treatment of opioid dependence.

BUTRANS® and generic are indicated for severe and persistent pain.

BELBUCA® is indicated for severe and persistent pain.