Mountain-Pacific Quality Health

DUR PROGRAM NEWS

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The Drug Utilization Reveiw (DUR) Program, administered by Mountain-Pacific through 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's Medicaid recipients.

PHARMACOGENETIC TESTING AND CLINICAL APPLICATION OF DATA

Genetics can affect how someone responds to a medication. In some patients with polymorphisms, or genetic variants, certain drugs are not metabolized as expected, either causing lower than desired plasma concentrations at normal dosages or causing toxic levels at lower doses. The unpredictability of drug levels can cause adverse drug reactions, leading to hospitalizations, discontinuation of drug therapy, increased health care costs and even death.

Useful Provider Resources

Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines, available at www.pharmgkb.org.

The FDA lists all the FDA-approved drugs with pharmacogenomic information in the labeling, available at http://www.fda.gov/drugs/sciencereasearch/researchareas/pharmacogenetics/ucm083378.htm

Every year in the US, more than 8.6 million adverse drug events are reported. Adverse drug events are among the leading causes of deaths in the US and are annually responsible for 700,000 emergency department visits and 120,000 hospitalizations. According to a study in 2000, the cost of drug-related adverse reactions exceeded $177.4 billion.

Pharmacogenetic testing is a non-invasive test that uses a buccal or saliva specimen to detect certain genetic polymorphisms. Knowing that a patient has a certain polymorphism may help predict the patient's response to a drug or likelihood for an adverse reaction. This may have a powerful impact on patient care and quality of life, resulting in increased medication compliance, and a decrease in morbidity/mortality and health care costs.

However, routine pharmacogenetic testing is not recommended for all patients. Providers should utilize FDA-approved drug labeling and clinical guidelines for information on testing. There are currently over 100 drugs that do include information about pharmacogenetics and the effect on individual drug response.

Prescribers may also consider genetic testing on patients who:

- Take multiple medications and have experienced sub-optimal responses
- Experience adverse drug reactions to medications at lower-than-normal dosages
- Have had inadequate responses on 3+ medications in the same pharmacologic class

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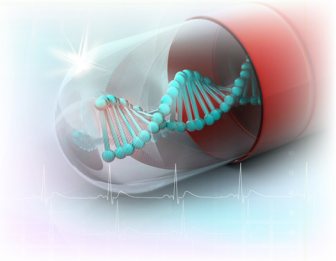

Various companies provide different versions of pharmacogenetic testing (see insert for examples). Companies can also provide specific tests for a disease state. For example, if a prescriber wants to order a test for polymorphisms related to psychiatric medications, the test may include the enzymes CYP2D6, CYP2C19, CYP1A2, HTR2A, and SLC6A4/5-HTT. Testing can also be performed to identify mutations relevant to cardiology, pain medication, ADHD medication and the MTHFR mutation.

Once the genetic test is complete, an individualized prescribing guide is provided to assist the provider, based off the patient's unique mutations and the patient's current medications. Patients typically fall into different categories regarding their metabolizing status. Knowing how a patient may respond to a drug may help providers adjust a medication dose accordingly. Typical categories include:

- Normal or extensive metabolizers-these patients have normal metabolic capacity.
- Intermediate metabolizers-these patients may require a lower-than-average drug dosage for an appropriate therapeutic response.
- Poor metabolizers-these patients may fail to produce the active form of the drug and potentially could be at risk for side effects due to decreased drug elimination.
- Ultrarapid metabolizers-these patients may require an increased dosage due to higher-than-normal rates of drug metabolism.

It is important to remember that pharmacogenetic test results are a guideline for treatment and should be used as a prescribing tool. The pharmacogenetic tests should not be used as the only means of treatment decision making, as non-genetic factors can contribute to the necessity for dose adjustments of medications that are metabolized by these enzymes. The dosage adjustment recommendations are a suggestion for the medication and dosage being prescribed.

While pharmacogenetic testing can be a helpful tool for understanding the individual patient's genetic profile, the provider must remember that pharmacogenetic testing is not recommended for all patients. As more time evolves, providers may see increased benefits that pharmacogenetics provides regarding individualized therapy and improvement of patient care.

PLEASE SEE INSERT FOR PHARMACOGENETIC TEST EXAMPLES

MONTANA MEDICAID CRITERIA UPDATES

Hetlioz®- Tasimelteon (Hetlioz®) is a melatonin receptor agonist indicated for the treatment of non-24-hour sleep-wake disorder (non-24). This is also known as free-running disorder (FRD). Non-24 is a rare circadian rhythm disorder affecting up to 100,000 individuals in the U.S. The majority of these cases occur in blind individuals who cannot perceive light. Due to significant cost (over $8400/monthly AWP) and potential for off-label uses, Montana Medicaid has implemented the following clinical criteria:

- Prescriber must be a sleep specialist or patient must have a current specialty consult (within the previous year).
- Patient must have a diagnosis of FRD
- Patient must be blind
- Patient must have documented functional impairment due to FRD
- Other therapies (timed melatonin or planned social/physical activities) must have been inadequate for improving functional impairment.
- Prior authorization will be granted for a maximum daily dose of 20 mg and an initial period of 6 months.

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Copaxone® 40 mg three times weekly - Glatiramer acetate (Copaxone®) is a self-administered, injectable medication approved for the treatment of patients with relapsing forms of multiple sclerosis (MS). The initial formulation of Copaxone®, 20 mg taken once daily, was FDA approved in 1996. Of note:

- **Copaxone® 40 mg, a three-times-weekly formulation, was FDA-approved in January of 2014, just months prior to the patent expiration of Copaxone® 20mg once daily. The pivotal trial (GALA) leading to FDA approval was a 12-month, placebo-controlled trial. The 20 mg once daily dose was not compared to the 40 mg three-times-weekly dose.**

- **In April 2015, the first generic formulation of Copaxone 20 mg® was FDA approved.**

Currently, Copaxone® 20 mg once-daily is the preferred glatiramer product for Montana Medicaid. The Montana Medicaid Drug Utilization Review board recommended implementation of the following clinical criteria in order for a patient to be considered for approval of the 40 mg three-times-weekly dose:

- Patient must have a documented trial on Copaxone® 20 mg **AND**
- Clinical rationale describing the medical necessity for Copaxone® 40 mg three-times-weekly instead of 20 mg once daily must be provided
- If approved, prior authorization will be granted for a maximum of 12 doses for a 28 day supply.

-MEDICAID DRUG PA UNIT 1.800.395.7961-

MEDICAID EXPANSION UPDATE

The Health and Economic Livelihood Partnership (HELP) Act was signed into Montana law in April 2015. The intent of this Act is to expand Medicaid health coverage in Montana to an estimated 45,000-70,000 individuals, with incomes up to 138 percent of the Federal Poverty Level (FPL). Two public meetings were held in August regarding the waiver.

Next Steps and Important Dates

- **September 15, 2015 (now completed)**

  Montana has submitted a state waiver to the Centers for Medicaid & Medicare Services (CMS) for approval. Because the Montana HELP act includes provisions not usually allowed by federal Medicaid law (premiums and co-pays), Montana is required to seek federal approval for exemptions from typical federal requirements. Montana's waiver has been posted by CMS and is located at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/waivers_faceted.html.

- **October 1, 2015**

  Montana will contract with a Third Party Administrator (TPA) to administer health care services for most new adults. The evaluation period for the TPA proposals is currently being completed, and the contract award is expected to be announced by October 1, 2015.

- **October 15, 2015**

  The federal comment period regarding the waiver is open to the public until October 15th, 2015.

- **January 1, 2016**

  Anticipated health care coverage is expected to begin January 1, 2016, pending CMS waiver approval.

For more information, access the Montana Medicaid Expansion website located at: http://dphhs.mt.gov/medicaidexpansion.

Montana Medicaid Top 20 Drugs for YTD 2015 by Generic Name*

Drug Name	By Dollars	# of Patients	Drug Name	By Rx Count
Aripiprazole	$4,815,824	1,543	Hydrocodone/Acetaminophen	20,301
Methylphenidate	$2,044,240	3,062	Albuterol	19,511
Duloxetine	$1,210,635	1,286	Amoxicillin	17,523
Dextroamphetamine/Amphet	$1,210,124	1,901	Methylphenidate	13,512
Atomoxetine	$1,201,247	933	Azithromycin	12,057
Lurasidone	$1,191,374	447	Omeprazole	10,914
Lisdexamphetamine	$1,120,585	1,424	Levothyroxine	9,654
Ledipasvir/sofosbuvir	$1,092,409	15	Fluoxetine	9,475
Insulin glargine	$1,060,398	710	Gabapentin	9,338
Albuterol	$1,041,791	10,761	Quetiapine	8,635
Insulin aspart	$984,771	680	Sertraline	8,446
Fluticasone/Salmeterol	$977,415	1,270	Montelukast	8,413
Paliperidone palmitate	$915,451	563	Clonazepam	8,055
Sofosbuvir	$912,922	11	Dextroamphetamine/Amphet	8,014
Pregabalin	$798,030	646	Lamotrigine	8,003
Quetiapine	$650,152	1,865	Clonidine	6,678
Oxycodone	$643,865	1,772	Bupropion	6,475
Dexmethylphenidate	$629,610	587	Oxycodone	6,322
Mometasone furoate	$570,778	1,740	Trazodone	6,196
Paliperidone	$558,170	140	Citalopram	6,178

*excludes injectable drugs except insulins (dollars are pre-rebate)