DUE CARE PROGRAM NEWSLETTER

AN OVERVIEW OF THE MEDICAID PREFERRED DRUG LIST PROCESS

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The DUE CARE PROGRAM, administered by Mountain-Pacific through contract with the Medicaid 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.

The Drug Prior Authorization Unit often receives questions on the Medicaid Preferred Drug List (PDL) and the process behind drug selection for this specific list of medications. It is important to note that the PDL is only a snapshot of certain medications covered by Montana Medicaid… *Think of it as a shopping list for a starting point in drug therapy.* It is not an all-inclusive list of every medication covered by Medicaid. Unless specifically prohibited by legislation, all other medications not found on this list are also covered, but some may be subject to specific prior authorization criteria.

COMMONLY ASKED QUESTION:

Why does the Montana Medicaid Preferred Drug List (PDL) prefer some branded medications over the generic counterpart?

Preferred drug lists allow state Medicaid programs to participate in multi-state pooling initiatives and receive supplemental rebates from drug manufacturers for preferred agents. Often times, the net cost of the branded product is significantly lower than its generic counterpart due to significant supplemental rebates. Therefore, preferring the brand product ultimately produces significant cost savings to the state.

The Montana Department of Public Health and Human Services (DPHHS) has continued to expand the Medicaid Preferred Drug List (PDL) using the multi-state purchasing agreement administered by Magellan Medicaid Administration. Magellan provides the clinical evidence for the identified therapeutic classes to be included on the Preferred Drug List. Magellan also administers the supplemental rebate portion of the multi-state alliance and returns 100% of the rebates to each corresponding state. **In State Fiscal Year 2014, this amounted to $3,938,667 for the State of Montana.**

A vital component of PDL development is the review of clinical evidence by the Montana Medicaid Drug Utilization Review (DUR) Board. Under contract with DPPHS, Mountain-Pacific Quality Health is responsible for the administration of the DUR Board. The Board comprises 10 members who are actively practicing physicians and pharmacists in Montana, plus a consumer representative appointed by DPHHS. Mountain-Pacific also provides the Drug Prior Authorization call center, which is responsible for the application of the requirements of the Preferred Drug List and clinical criteria.

There are three PDL meetings held annually. During these meetings, the DUR Board reviews the evidence-based information and makes formulary recommendations to the Department for a particular drug on the PDL. Input from the Montana provider community is also considered. Clinical materials are distributed to DUR members in advance of PDL meetings to allow time for review, and the evaluations of the evidence-based literature are conducted in a public forum that allows time for public comment.

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Medicaid pharmacy information can be found on the DPHHS pharmacy page at: http://medicaidprovider.mt.gov/19

After evidence review and discussion, the DUR Board typically makes one of the following recommendations to the Department for a drug or specific class of drugs:

Class Effect: All drugs within the class have similar indications and efficacy, with no particular drug showing significant clinical advantage over another. The Department will prefer those drugs most financially advantageous to the state based off of supplemental rebates negotiated with manufacturers.

Therapeutic Alternatives: All drugs within the therapeutic class have diverse FDA-approved indications and may be considered therapeutic alternatives for the appropriate indication.

Must Have: A drug has exceptional clinical evidence as a standout within a therapeutic class, and the Board recommends the drug is added as preferred agent.

Do Not Add: The drug has clinical evidence that indicates a significant safety concern, is a new drug with an insufficient track record of safety, or insufficient clinical evidence exists to warrant first-line use. The drug is recommended as non-preferred.

The underlying goal of the PDL is to continue development of a formulary that will provide Montana Medicaid recipients with medications that have been evaluated for safety and clinical efficacy, as well as rational and cost-effective therapies that will maintain the integrity of the Medicaid pharmacy benefit.

Medicaid pharmacy information can be found on the DPHHS pharmacy page at:
http://medicaidprovider.mt.gov/19

This includes the link to the most current PDL information, meeting notices, DUR Board information, and meeting minutes.

PREFERRED DRUG LIST SNAPSHOT

ORAL ANTICOAGULANTS - HIGHLIGHTING THE NEWER AGENTS PRADAXA®, XARELTO®, ELIQUIS® AND ASSOCIATED PRIOR AUTHORIZATION CRITERIA

The Drug Prior Authorization Unit receives frequent questions regarding the oral anticoagulant category on the PDL and associated rationale for clinical criteria. Below is a snapshot of this category as listed on the PDL effective June 2015.

ANTICOAGULANT, ORAL

Preferred Agents	Non-Preferred Agents	Limitations
Pradaxa® % warfarin	Coumadin® Savaysa® %	% requires clinical criteria
Xarelto® %	Eliquis® % Xarelto® Dose Pack%	

Agents listed with a "%" require additional clinical criteria, even if preferred, prior to approval. This is based on:

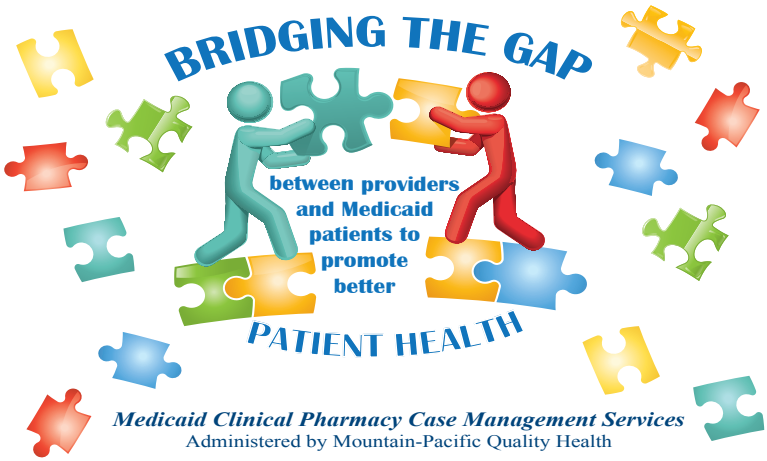
- Clinical evidence for efficacy and recommended place in therapy by published clinical trials or guidelines
  - For example, prior authorization requirements for using warfarin first-line, unless guidelines or clinical rationale supports an alternative agent instead (see insert for specific requirements).
- DUR Board and specialist input

Although these newer agents do not require INR (International Normalized Ratio) monitoring like warfarin does, patient preference for not obtaining monitoring is not considered a valid clinical rationale alone to approve a newer agent outside of established clinical criterion. Other underlying principles for warfarin first line per criteria are:

- Medicaid does not routinely consider patient preference/convenience alone a valid reason for drug approval outside of criteria.
- The cost for warfarin therapy plus monitoring is still considerably less expensive than a newer agent not requiring INR monitoring (~$80/month vs. ~$250/month with newer agents).
- These agents currently do not have an antidote like warfarin for immediate reversal and therefore still present safety risks.
- Strict adherence to dosing requirements with newer agents is imperative due to potential increased risk of stroke with missed doses.
- Montana Medicaid does reimburse transportation costs to and from medical appointments. A patient may call the **Medicaid Transportation Department at (800) 292-7114** to obtain approval prior to travel.

There are exceptions to clinical criteria, which are reviewed on a case-by-case basis. For example, in new onset atrial fibrillation when **elective cardioversion** is recommended, a newer agent may be appropriate instead of warfarin due to the ability to achieve therapeutic levels rapidly. Additionally, if there is clinical rationale in a specific patient case for requesting approval outside of criteria, the clinical staff at the Medicaid Drug PA Unit is readily available. Requests are reviewed and decisions made immediately in most cases. Decisions on requests with special circumstances that require further peer review are made within 24 hours.

Individual clinical criteria can be found on the insert - **Preferred agents: Table 1** **Non-Preferred agents: Table 2**



Medicaid Clinical Pharmacy Case Management Services
Administered by Mountain-Pacific Quality Health

The Medicaid Pharmacy Case Management clinicians are available to exchange information with providers about drug therapy and patient-specific drug usage. This may help to improve clinical outcomes and reduce patient risk by

- Providing medication and drug diagnosis history to facilitate continuity of care (i.e., Medicaid foster care recipients)
- Identifying medication noncompliance
- Preventing medication duplication
- Identifying drug-drug or drug-disease state issues
- Identifying multiple pharmacies or providers
- Providing unbiased, evidence-based disease management interventions

How we do it: This is accomplished by our access to all of the medical and pharmacy services your patients receive through Medicaid.

See what we can do for you by calling 1.800.395.7961

A reminder to pharmacies and providers

DRUG PRIOR AUTHORIZATION REQUESTS IN AN EMERGENCY, AFTER-HOURS, ON HOLIDAYS AND ON WEEKENDS

If a medication rejects for prior authorization, an emergency, 72-hour supply of medication may be dispensed by the pharmacy after-hours, on weekends, holidays and in emergency situations when the Drug Prior Authorization Unit is closed. This override is to only be used when appropriate and is auditable by the Department of Public Health and Human Services.

- Payment is authorized by the pharmacy inputting a "3" in the Days Supply field and a Medical Certification Code of "8" in the PA/MC Code field.

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TABLE 1: PREFERRED AGENTS and additional clinical criteria requirements (as of June 2015)

Drug	Covered Indication	Limitations
Pradaxa® (dabigatran)	Non-valvular atrial fibrillation	• *Patient must have had an inadequate response to warfarin OR have a contraindication to warfarin OR if warfarin naïve, must have the presence of at least one additional risk factor for stroke (i.e., CHF, HTN, DM, previous stroke/TIA) AND* • *Renal function assessment (CrCl) has been performed* • Max dose allowed is 150 mg twice daily in patients with CrCl>30 ml/min. • Max 75 mg twice daily if estimated CrCl 15-30 ml/min. • Approval will not be granted for CrCl <15 ml/min.
	Treatment of PE/DVT/Reduction in risk or recurrence of PE/DVT	• *Patient must have an ADR/contraindication to warfarin* (pt will have already been anticoagulated with 5-10 days of a parenteral anticoagulant such as LMWH) • Max dose allowed is 150 mg twice daily in patients with CrCl > 30 ml/min. • No approval if CrCl< 30 ml/min or patient on dialysis. • No approval if CrCl< 50 ml/min with concomitant P-GP inhibitors (e.g., ketoconazole, amiodarone, verapamil, quinidine).
Xarelto® (rivaroxaban)	Non-valvular atrial fibrillation	• *Pt must have had an inadequate response to warfarin OR have a contraindication to warfarin OR if warfarin naïve , patient must be at moderate-to-high risk of stroke (prior history of TIA, stroke, or systemic embolism or ≥2 additional risk factors for stroke) AND* • *Renal function assessment (CrCl) has been performed* • Max dose allowed is 20 mg once daily • Max dose allowed is 15 mg daily if CrCl 15-50 ml/min.
	DVT Prophylaxis post hip or knee replacement surgery	• *No alternate therapy required* • Max dose allowed is 10 mg once daily • Hip replacement-max 39 days duration • Knee replacement-max 15 days duration
	DVT/PE treatment/reduction in risk or recurrence of DVT/PE	• *Patient must have a contraindication to warfarin or LMWH* • Max dose allowed is 15 mg twice daily x 21 days, then 20 mg once daily thereafter

Abbreviations:

PE-Pulmonary Embolism
DVT-Deep Venous Thrombosis
TIA-Transient Ischemic Attack
ADR-Adverse Drug Reaction
CHF-Congestive Heart Failure
HTN-Hypertension
DM-Diabetes Mellitus
LMWH-Low Molecular Weight Heparin
CrCl-Creatinine Clearance
P-gp-P-Glycoprotein 1

TABLE 2: NON-PREFERRED AGENTS and additional clinical criteria requirements (as of June 2015)

- ***Note:*** *In addition to the following clinical criteria,* ***authorization for one of these agents requires a trial on a preferred agent in table 1,*** *or clinical rationale provided why a preferred agent cannot be utilized.*

Drug	Covered Indication	Limitations
Eliquis® (apixaban)	Non-valvular atrial fibrillation	• *Patient must have had an inadequate response to warfarin OR have a contraindication to warfarin OR if warfarin naïve, must have the presence of at least one additional risk factor for stroke (i.e., CHF, HTN, DM, previous stroke/TIA) AND* • *Renal function assessment (CrCl) has been performed* • Max dose allowed is 5 mg twice daily, or 2.5 mg twice daily if two of the following: SrCr >1.5 mg/dL, weight <60 kg, age >80 years
	DVT prophylaxis post hip or knee replacement surgery	• *No alternate therapy required* • Max dose allowed is 2.5 mg twice daily • Hip replacement-Max 35 days • Knee replacement-Max 12 days
	Treatment of PE/DVT	• *Patient must have ADR/contraindication to warfarin or LMWH* • Max dose allowed is 10 mg twice daily x 7 days, then 5 mg twice daily thereafter
	Reduction in risk or recurrence of PE/DVT	• *Patient must have ADR/contraindication to warfarin or LMWH* • Max dose allowed is 2.5 mg twice daily after 6 months of treatment for PE/DVT
Savaysa® (edoxaban)		Clinical criteria currently under development

The Medicaid Drug Prior Authorization Unit can be reached at
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