Pharmacy & Therapeutics Committee Annual Report October 2018-September 2019

Executive Summary

The 11-member Pharmacy and Therapeutics (P&T) Committee is responsible for advising the Oregon Health Authority (OHA) on the implementation of drug use review standards and interventions in the Medicaid fee-for-service (FFS) program and on the Practitioner-Managed Prescription Drug Plan. As a result of the P&T Committee's recommendations during federal fiscal year (FFY) 2019, the OHA reimbursed pharmacies \$130,657,307. The total cost avoidance for the P&T-associated programs was calculated to be \$22,760,578. Savings were garnered through drug use review (DUR) activities, preferred drug list administration, prior authorization criteria and quantity limits. Details of the P&T recommendations and these highly successful programs are discussed in detail in the following annual report. The return on the investment for P&T Committee-associated contracts was more than 26 to 1, demonstrating the value of services provided by all vendors involved.

Acronyms

CMS – Centers for Medicare & Medicaid Services

DERP – Drug Effectiveness Review Project

DUR – drug use review

DURM – Drug Use Research & Management

DXC – DXC Technology

FDB - First Databank

FFS - fee-for-service

FFY – federal fiscal year

MMIS – Medicaid Management Information Systems

OAR – Oregon Administrative Rules

OHA – Oregon Health Authority

P&T Committee – Pharmacy & Therapeutics Committee

PA – prior authorization

PDL – preferred drug list

PMPDP - Practitioner-Managed Prescription Drug Plan

POS - point of sale

ProDUR – prospective drug use review

RetroDUR – retrospective drug use review

SSDC – Sovereign States Drug Consortium

Scope and Purpose

The P&T Committee is subject to multiple reporting requirements. Pursuant to Oregon Revised Statute (ORS 414.382), the P&T Committee is directed to publish an annual report. The P&T Committee also serves as the federally mandated DUR Board and is required to report retrospective drug use review (RetroDUR) and prospective drug use review (ProDUR) activities, state prescribing habits, and cost savings generated from these programs to Centers for Medicare & Medicaid Services (CMS) annually. At various points, this report will restate, summarize and expand upon the CMS annual report.

This report covers the 2019 FFY (October 1, 2018 through September 30, 2019) and provides an overview of the programs and recommendations of the P&T Committee; an assessment of the impact of interventions, criteria and standards; and an estimate of the cost savings generated as a result of these programs. A complete list of P&T Committee activities, reports, report methodology and related resources are contained within the appendices.

Not covered in this report are programs that were initiated prior to this reporting period and continue to provide significant financial and clinical benefits. Currently there are 133 drug classes in the FFS preferred drug list affecting roughly 1,500 unique drugs that have been reviewed by the P&T Committee. Over 120 unique clinical-use criteria have been created and are being maintained. The maintenance of previous utilization controls and impact of past educational initiatives, although not detailed in this report, continue to provide quantifiable financial benefits and shape provider behavior beneficial to Medicaid members, the OHA, and the state.

Organizational Structure

The P&T Committee is responsible for advising the OHA on the development and implementation of the criteria and standards used for the Medicaid FFS RetroDUR program, ProDUR program, and the Practitioner-Managed Prescription Drug Plan (PMPDP), also known as the FFS preferred drug list (PDL).

There are several contractors involved with the P&T Committees' activities. The Oregon State University College of Pharmacy's, Drug Use Research & Management (DURM) program provides staff support for the P&T Committee. DURM develops the evidence-based reviews, drug use evaluations, policy evaluations and PDL analysis which inform the P&T Committee recommendations. All of the P&T materials are made available to the public on the DURM website where educational newsletters are also published, which were downloaded roughly

29,000 times in 2019. DURM also proposes prior authorization (PA) criteria and assists with PDL development and maintenance. DXC administers the state's electronic monitoring system called the Medicaid Management Information Systems (MMIS), staffs the call center that responds to PA requests, and invoices for rebates on behalf of the OHA. DURM assists DXC with implementing the edits and coding necessary to operationalize the P&T Committee recommendations that have been approved by the OHA. The Sovereign States Drug Consortium (SSDC) is a non-profit, multi-state, Medicaid purchasing pool that negotiates supplemental rebates with manufacturers on behalf of member states. These supplemental rebate offers are considered by the P&T Committee when making PDL recommendations. Finally, the OHA is a member of the Drug Effectiveness Review Project (DERP), which is a collaborative group of state Medicaid agencies that commission high-quality comparative effectiveness reviews. The DERP reports are summarized and presented to the P&T Committee by the DURM staff.

Evidence Reviews

Reviews of the most recent medical literature are the foundation of the P&T Committee activities. The P&T Committee met six times during this reporting period. **Table 1** summarizes the body of work that was developed by the OSU College of Pharmacy DURM program and presented to the P&T Committee during the year. A sound review of the published evidence is the starting point for developing utilization controls. The Committee's recommendations informed the implementation of the OHA's retrospective and prospective DUR programs, utilization controls, PA criteria, quantity limits and other conditions for coverage. Utilization controls such as PA criteria and quantity limits recommended by the P&T Committee are intended to promote use of safe, appropriate and cost-effective prescription drug therapy. PA criteria are designed to support access to and use of medications as approved by the FDA and are evaluated periodically to ensure they are functioning as intended and not causing any

unanticipated harms. Further details about utilization control policies and management are provided in the PDL & Utilization Management section below. Links to the agendas, reports, and recommendations to the OHA can be found in **Appendix A**.

Prospective Drug Use
Review (ProDUR) Programs
Section 1927 of the Social Security
Act requires Medicaid programs to
have a ProDUR program. Utilization

Table 1. Summary of Reports presented to the Pharmacy and Therapeutics Committee during federal fiscal year 2019.

Number of Reports Presented
27
5
3
14

controls, an important element of a ProDUR program, represent the first phase of screening for

prescription drug claims at the point of sale (POS). DXC is the OHA's pharmacy benefit administrator and is responsible for maintaining and processing Medicaid pharmacy claims through the POS system, which interfaces with MMIS. DXC, through its contract with First Databank (FDB), loads information and edits into the claims processing system on a weekly schedule. Before each prescription is filled at the pharmacy, a review of drug therapy is performed by the pharmacist and then submitted electronically to the state's MMIS. The MMIS screens prescription drug claims to identify potential problems based on the alerts detailed in **Appendix B** such as therapeutic duplication, drug interactions, incorrect dosage or duration of treatment, drug allergy, and clinical misuse or abuse. These alerts offer pharmacists additional information and the opportunity to consult with patients and prescribers to optimize care.

Early Refill and Pregnancy/Drug Interaction are the only two ProDUR alerts currently set to deny claims for FFS Medicaid pharmacy claims. Additional ProDUR alerts are sent to pharmacies when they process claims, but do not result in denial or require action by the pharmacy. These alerts are informational and provide the pharmacy with notification of potential drug therapy problems, which may improve patient care. The cost savings associated with claims that were not dispensed after the early refill or pregnancy/drug interaction alerts were triggered was \$43,773 during FFY 2019. Cost savings were calculated based on claims that were cancelled after the alert and not reprocessed again at a later date. See **Appendix B** for a detailed ProDUR program activity summary.

Retrospective Drug Use Review (RetroDUR) Programs

The RetroDUR Program is the second phase of screening prescription drug claims to identify opportunities to improve quality of care and fiscal stewardship after medications have been dispensed to patients. RetroDUR involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care. RetroDUR programs may be associated with specific drugs or groups of drugs and are designed to implement corrective action when concerning drug utilization patterns are identified. RetroDUR interventions occur after dispensing of medication and are intended to alter future behaviors. Quantification of the success of these programs is less straightforward when compared to ProDUR, Preferred Drugs List, and other utilization controls, as it is generally more difficult to tie changed behavior to the intervention.

The DURM group has developed several RetroDUR safety net programs. The Late Antipsychotic Refill Safety Net program is one example that targets members with schizophrenia who are non-adherent to routine antipsychotic therapy. This initiative was designed to notify providers when patients on routine therapy for the treatment of schizophrenia had an interruption in medication therapy of more than 15 days and missed a medication refill. Over the year, 105 providers were sent notifications alerting them to the lack of ongoing therapy. Although it is difficult to quantify the clinical impact on outcomes such as emergency department visits, the program reduces the chance a member will go without a needed medication.

Dose optimization programs are RetroDUR programs with more easily quantified benefits. For a variety of reasons, Medicaid members may end up on a drug regimen with an unexpectedly large quantity of low-strength tablets that can be much more expensive and wasteful than optimal dosing. In some cases, medications are available as both tablets and capsules with significant differences in cost. Optimizing the dose or formulation can result in significant savings and can also improve patient experience of care by lowering the number of needed pills. A RetroDUR Dose Optimization program was designed to educate providers about the cost difference and allow the providers to make changes when clinically appropriate. Latuda® (lurasidone HCl) is an example of a drug identified for dose optimization. Latuda accounts for roughly 16% of the total FFS drugs costs and is generally taken once daily. Providers prescribing two or more tablets per day were informed of the potential cost savings if they prescribed higher-strength tablets. Another example of successful provider outreach and education was targeted toward fluoxetine, which is available in both tablet- and capsule-form with significant difference in cost.

During the fiscal year, DURM faxed 147 prescribers to suggest dose optimization. This resulted in an estimated savings of \$248,130. DURM faxed an additional 517 prescribers, asking them to consider prescribing fluoxetine capsules instead of tablets. This resulted in an estimated savings of an additional \$94,085. Savings from dose optimization are inherently conservative as this estimate does not include cumulative costs associated with changes in prescribing practices or ongoing use of more cost-effective regimens.

Patient safety is another focus of the RetroDUR program. Some examples include: Polypharmacy Reviews (Oregon Administrative Rule 410-121-0033), the Pharmacy Management Program (OAR 410-121-0135) and a safety net program. The Polypharmacy Reviews identify duplicative or unnecessary prescriptions filled by a member and provide an opportunity to notify prescribers with recommendations to consider discontinuing unneeded medications. Over the fiscal year, faxes were sent to 248 prescribers. The Pharmacy Management Program identifies potential fraud or misuse of drugs by a beneficiary, as indicated by members using multiple pharmacies in a short timeframe. The Pharmacy Management Program requires selected beneficiaries to use a single pharmacy to fill all their prescriptions for up to 12 months, which allows the pharmacy to monitor services being utilized and reduce unnecessary or inappropriate utilization. The safety net program notifies prescribers via fax when dangerous drug combinations have been prescribed such as opioids and sedatives and are urged to perform a risk-benefit assessment, check the PDMP, and if appropriate, prescribe naloxone to prevent overdose.

In addition to the DUR programs, DURM employed educational initiatives to inform and influence prescribing practices to ensure safety and effectiveness. DURM published and distributed educational information to prescribers and pharmacists in the form of newsletters, fax notifications and individualized lettering regarding P&T Committee activities and DUR programs. Faxes inform pharmacies when initiatives and utilization control changes are being

implemented and help avoid interruptions in therapy for their patients. Over the fiscal year, DUR faxed two informational notifications to all enrolled pharmacies and 3,370 targeted individual communications were sent to prescribers. Additionally, DURM published nine Oregon State Drug Reviews: http://pharmacy.oregonstate.edu/drug-policy/newsletters

A complete list of RetroDUR activities and number of interventions is available in **Appendix C** and on the P&T Committee website.

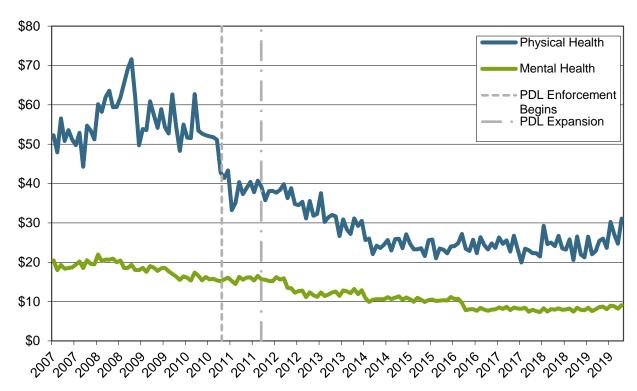
Preferred Drug List & Utilization Management

The FFS Medicaid pharmacy program aims to achieve access to needed pharmaceuticals for Medicaid beneficiaries, administrative ease for providers, safety, and cost effectiveness. In order to manage FFS Medicaid prescription drug use, three primary tools are used: the PDL, PA criteria and quantity limits. The PDL contains a list of preferred drugs which have been determined by the P & T Committee to be the most efficacious. Drugs considered nonpreferred require prescribers to contact the Oregon Pharmacy Call Center to obtain an authorization. Providers can obtain an authorization by indicating they choose not to switch to the preferred option and confirming the diagnosis for which they are requesting the medication is a funded condition on the Prioritized List of Health Services. Dedicated clinical PA criteria are used for medications the OHA has determined require evaluation beyond simply being preferred or non-preferred. They ensure medications are being prescribed for funded conditions, are appropriate for the diagnosis for which they are being prescribed, or that less costly first-line therapies have been tried first. Quantity limits ensure the amounts prescribed are safe, appropriate, and not wasteful. Working together, these three utilization management tools allow the OHA to provide safe, effective, and fiscally responsible drug benefits to members.

The PDL developed by the OHA is created using comparative evidence reviews of the medical literature (See **Table 1** and **Appendix A**). The P&T Committee also considers clinician and public input, as well as appropriate standards of care in the review process. Drugs and drug classes included on the PDL are evaluated by the P&T Committee, which makes recommendations to the OHA for inclusion or removal from the PDL based on comparative safety, efficacy and cost-effectiveness. Drug cost is considered only after clinical recommendations are made, and dedicated PA criteria are often developed as new classes are reviewed for inclusion on the PDL. Since implementation of the PDL in 2009 and the expansion of the classes included on the PDL in 2011, the cost-per-member for physical health drugs has markedly decreased (See **Figure 1** below). With administration of the PDL and provider education, prescribers have become familiar with preferred medications and increasingly prescribe cost-effective medications. This is apparent in **Figure 1**, which demonstrates decreasing costs after the PDL was implemented and subsequently expanded. However, it is important to note that other factors (such as demographic changes resulting from Medicaid expansion under the Affordable Care Act) could also have played a role in lowering costs. Continued maintenance and expansion of the PDL and

development of utilization controls constitutes the bulk of the work performed and presented to the P&T Committee and generates the majority of the savings realized by the OHA.

Figure 1: Gross Per-Member-Per-Month Prescription Drug Expenditures for Physical and Mental Health Drugs Over the Last Decade



When making PDL decisions, the P&T Committee considers cost after evidence of safety and efficacy. Confidential federally mandated rebates, which are required of pharmaceutical manufacturers by Section 1927 of the Social Security Act as a condition for Medicaid coverage, are incorporated into the net cost considered by the P&T Committee. In addition, supplemental rebate offers, which manufacturers offer for some medications on top of the CMS federally mandated rebates, are negotiated on behalf of the OHA by the SSDC. Rebates can make the net cost of some brand-name drugs comparatively cost-effective to alternative drugs in some classes. Supplemental rebates are not required to be offered by manufacturers in order for their medications to be considered for PDL preferred status, but they are considered in the net price. Both supplemental and federally mandated rebates are proprietary and confidential and cannot be disclosed to the public. Over the fiscal year, supplemental rebates collected by the state as a result of implementation and maintenance of the PDL was \$22,561,965. The physical health drugs accounted for most of these supplemental rebates totaling \$18,564,654.

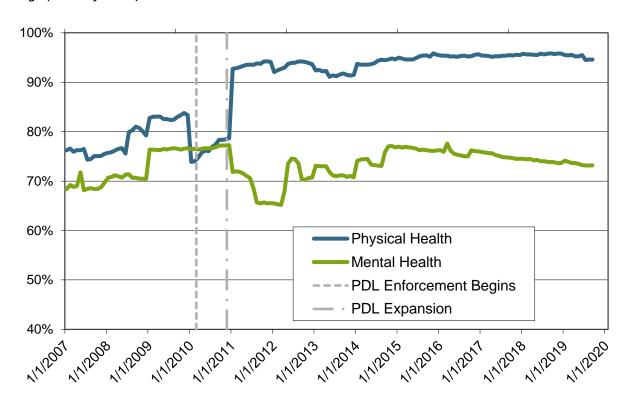
In contrast, the OHA is not permitted to enforce the mental health PDL (chapter 544, Oregon Laws 2019); as a result, the voluntary mental health PDL supplemental rebates accounted for a smaller total at \$3,997,311.

As illustrated in **Figure 2**, the ability to require PA for non-preferred physical health drugs resulted in a dramatic increase in the use of preferred agents (from 75% to 95%) - after implementation of the PA for non-preferred agents. This was the driver of the significant savings illustrated in **Figure 1**. In contrast, the use of preferred mental health drugs has remained relatively flat (see **Figure 2**) due to a lack of a PA process for non-preferred agents.

Over the fiscal year, the Committee's recommendations regarding drugs to be included on the PDL required changes to the PDL status of 68 drug products in the MMIS. Links to the current and historical versions of the PDL that were updated as a result of P&T Committee recommendations can be found in **Appendix D**.

Developing, revising, or removing existing PA criteria is an important role of the Committee. Over the fiscal year, the P&T Committee recommended implementing, making substantive changes to, or retiring PA criteria 50 times and made clerical changes to another 21 criteria. Many additional PA criteria were reviewed to ensure they remain reflective of current best evidence although no changes were made.

Figure 2: Percent Use of Preferred Drugs for Physical Health Drugs (Enforced) and Mental Health Drugs (Not Enforced)



The enforcement of quantity limits improves safety and patient outcomes by encouraging appropriate care and minimizing waste. They can be used to help prevent overuse and dependence that can occur with sedative hypnotics, narcotic analgesics, benzodiazepines and certain migraine treatments. They are also used to ensure durations of therapy meet accepted standards of care, such as with certain antibiotics and proton pump inhibitors. Quantity limits can also be used to assure doses do not exceed maximum safe levels. Initiatives to manage use of opioids with quantity limits and help address the ongoing prescription opioid epidemic has been a priority for the OHA and the Committee.

In select cases when brand name medications lose patent protection and generic alternatives are introduced into the market, the generic alternatives remain much more expensive than the net cost of the brand equivalent. In these cases, there is an opportunity to mandate continued use of the brand-name drug until the cost of the generic alternatives drop. Careful analysis of the federally mandated rebates and comparative net cost of the alternatives is necessary to take advantage of this scenario. Since the selection of the medication being dispensed falls to the pharmacy (and they generally dispense the generic version if available), targeted communication is necessary to ensure pharmacies have adequate stock on hand and understand the departure from the general requirement to dispense generics. Pharmacies also need to have sufficient notice to know when this requirement will end so they can stock and begin to dispense the generic alternatives. Over the 2019 fiscal year, four medications lost patent protection where this opportunity presented, resulting in \$1,393,370 in cost avoidance. In the past, these scenarios have resulted in savings exceeding \$15 million for one drug in a single year.

Cost Avoidance Associated with the Utilization Management

Development and implementation of PA criteria and administration of the PDL encourages use of cost-effective therapies and limits costs due to inappropriate prescribing, waste, or abuse. The DURM group created a methodology to estimate cost avoidance attributable to PAs and the PDL. The methodology calculates savings by considering the ultimate therapy received by the member and the duration of cost avoidance. When payment for a claim is denied (e.g., denial due to a PA requirement or non-preferred status), all subsequent claims (paid and denied) for the member within the drug class are monitored. Cost avoidance is then calculated based on the initial claim (index event) and the final disposition of therapy within the drug class for a member.

Cost avoidance is categorized into one of several types based on the specific treatment recommendation and scenario. The cost-avoidance categories are deferred, therapeutic duplication, switched, add-on, discontinued, and other. A description of these types of cost avoidance can be found in **Appendix E**. Each cost avoidance type has a distinctive calculation for the duration of cost avoidance and the amount saved, based on the most likely clinical treatment pathway. Factors considered for each cost avoidance type include: duration of

eligibility for the FFS program, enrollment into CCOs; maintenance drug indicator; cost of alternative therapy; and the number of paid and denied claims in the drug class.

The estimate of cost avoided over the fiscal year was \$20,888,976 in total drug expenditures by administration of PA criteria, PDL enforcement and quantity limits.

Cost Benefit, Outcomes & Impact Assessment

The cost related to OHA's pharmacy contracts to support the P&T Committee must be accounted for when measuring the cost-benefit analysis of both the ProDUR and RetroDUR programs as well as PDL management.

DXC's and DURM's contracts are not solely devoted to the work of the P&T Committee as they provide additional services to assist the OHA. It is impossible to calculate the cost of DXC's services that were directly associated with the functions of the P&T Committee, due to the nature of their contract and activities associated with MMIS. However, the portion of the DURM contract that was dedicated to supporting the P&T Committee work and assisting DXC with PDL and PA coding was tracked and estimated to be roughly 61% of their effort.

Since the DURM staff is almost exclusively staffed by pharmacists who provide clinical expertise to the OHA, the cost for their services is paid by 75% federal matching funds and 25% from state funds. Over the fiscal year, approximately \$741,538 was billed by DURM to the OHA for those clinical services, of which \$185,385 would have been state funds, with the remainder being federally funded.

The OHA also contracts with OHSU and is a member of DERP. DERP is a collaborative group of state Medicaid agencies and other organizations that commission high-quality, evidence-based, comparative effectiveness reviews which are also presented to the P&T Committee. The cost to Oregon to participate in DERP for the fiscal year was \$95,500 which is paid with 50% state and 50% matching federal funds.

The OHA is a member of the SSDC, a CMS approved, state-administered, multi-state Medicaid supplemental drug rebate pool which negotiates supplemental rebate offers that are considered for PDL placement. Oregon paid \$12,436 total funds over the fiscal year to be a member of the SSDC and to take advantage of the supplemental rebates negotiated.

The cost benefit analysis of the ProDUR and RetroDUR programs should consider the total cost of the program, potential cost savings and avoidance, and the total cost of pharmacy benefits. The OHA reimbursed pharmacies \$130,657,307 over the fiscal year. Various vendor contracts (with specific calculations for DXC's contributions as described above) cost the state \$849,474 over the same period to provide services associated with the P&T Committee. These contract costs were approximately 0.65% of the total pharmacy expenditures. The total cost avoidance for the P&T Committee-associated programs was calculated to be \$22,760,578, representing slightly more than 17% of total outpatient pharmacy expenditures. The return on the

investment for P&T Committee-associated contracts was more than 26 to 1, demonstrating the value of services provided by all vendors involved.

Appendices

Appendix A – Materials Presented to the Pharmacy and Therapeutics Committee

Documents from October 2018 - September 2019

P &T Meetings

- 1. November 29, 2018 P&T Packet Recommendations
- 2. January 24, 2019 P&T Packet Recommendations
- 3. March 21, 2019 P&T Packet Recommendations
- 4. May 23, 2019 P&T Packet Recommendations
- 5. July 25, 2019 P&T Packet Recommendations
- 6. September 26, 2019 P&T Packet Recommendations

Class Reviews and Class Updates (may also include a New Drug Evaluation)

- 1. Hidradenitis Suppurativa
- 2. Long-acting insulins DERP Summary
- 3. Severe Acne
- 4. Antiepileptics Class Update
- 5. Antivirals for Influenza
- **6.** Biologics for Autoimmune Conditions
- 7. Colony Stimulating Factors
- 8. Fibromyalgia Indication Review
- 9. Substance Use Disorder
- 10. Thrombocytopenia Drugs
- 11. Endometriosis Class Update
- 12. Hereditary Angioedema
- 13. Tetracyclines
- 14. Asthma and COPD Maintenance Medications
- **15. CGRP Inhibitors DERP Summary**
- **16.** Migraine Treatment and Prevention
- 17. Non-statin Lipid Lowering Agents
- 18. Potassium Exchangers
- 19. Antidepressants
- **20.** Atopic Dermatitis
- 21. Off-label Modafinil and Armodafinil
- 22. Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis
- 23. Bone Metabolism Drugs
- 24. Diabetes, Insulins
- 25. Fabry Disease
- 26. Opioids
- 27. Spinal Muscular Atrophy

Drug Use & Policy Evaluations

- 1. Hepatitis C, Direct-acting Antivirals
- 2. Substance Use Disorder
- 3. Schizophrenia Drug Use Evaluation
- 4. ADHD Drug Use Evaluation
- 5. Combination Biologic Therapy

Single New Drug Evaluations

- 1. Elagolix
- 2. Solriamfetol
- 3. Tafamidis

Scans

- 1. Growth Hormone
- 2. <u>Testosterone Replacement</u>
- 3. Erythropoietic Stimulating Agents
- 4. Antipsychotics Literature Scan
- 5. Benzodiazepine PA Update
- 6. Calcium and Vitamin D PA Update
- 7. GLP-1 Receptor Agonists Scan
- 8. Short-Acting Beta Agonists
- 9. Antivirals for Herpes Simplex
- **10. Cystic Fibrosis**
- 11. <u>Duchenne Muscular Dystrophy</u>
- 12. Hepatitis C, DAAs
- 13. Skeletal Muscle Relaxants
- 14. **Smoking Cessation**

Newsletters

- 1. Oct 2018 Updates on Testosterone Therapy
- 2. Dec 2018 Basal Insulin Update
- 3. Jan 2019 2017-18 Year in Review: Important Safety Updates
- 4. Feb 2019 Benzodiazepine Safety and Tapering
- 5. Mar 2019 Non-statin Low-Density Lipoprotein Cholesterol (LDL-C) Lowering Therapy and Cardiovascular Outcomes
- 6. May 2019 Update on Medications Used to Manage Opioid Use Disorder and Opioid Withdrawal
- 7. <u>Jul 2019</u> Oregon Health Authority Mental Health Clinical Advisory Group (MHCAG) Recommendations for the Treatment of Schizophrenia
- 8. Aug 2019 Stimulant Use in Excessive Somnolence Disorders
- 9. Sep 2019 Pearls and Pitfalls of Clinical Practice Guidelines

Appendix B – ProDUR Summary

The ProDUR review includes screening for potential drug therapy problems based on the following alerts:

- DA <u>Drug/Allergy Interaction:</u> Triggers if there is an association between an ingredient and an allergy recorded in the recipient profile.
- DC <u>Inferred Disease Interaction:</u> Triggers if there is a drug on the recipient's profile that is indicated for a disease state that interacts with the drug being filled.
- DD <u>Drug to Drug Interaction</u>: Triggers if there is an interaction between the drug being filled and another drug on the recipient's profile.
- **ER** <u>Early Refill (Overutilization):</u> Triggers if the drug being billed is too early based on previous billing and day supply. Allow filling when 80% of previous fill has been used.
- HD <u>High Dose:</u> Triggers if the drug being billed, based on billed day supply, exceeds the maximum recommended daily quantity limit
- ID <u>Ingredient Duplication:</u> Triggers if the drug being filled has a matching ingredient to another recently filled drug on the recipient's profile.
- LD <u>Low Dose:</u> Triggers if the drug being billed, based on billed day supply, is below the minimum recommended daily quantity limit.
- LR <u>Late Refill (Underutilization):</u> Triggers if the drug being filled is late in being refilled for the recipient.
- MC <u>Drug to Disease Interaction:</u> Triggers if there is a disease Diagnosis (ICD-10) on the recipients claim profile that interacts with the drug being filled.
- MX <u>Maximum Duration of Therapy:</u> Triggers if the day supply on the claim is greater than the maximum days value.
- PA <u>Pediatric and Geriatric Age Limits:</u> Triggers if the age of the recipient is less than the minimum (pediatric) or greater than the maximum (geriatric) age for the drug being billed.
- **PG** Pregnancy/Drug Interaction: Triggers if the drug being filled is contraindicated for use in pregnancy and the patient profile indicates that the patient may be pregnant.
- TD <u>Therapeutic Duplication:</u> Triggers if the class of drug being billed matches the drug class of another recently filled medication on the recipient's profile.

Early Refill and Pregnancy/Drug Interaction are the only two ProDUR alerts set to deny claims for FFS Medicaid pharmacy claims.

Cost Savings Estimates

The Pro-DUR program currently relies on the following alerts for monitoring claims triggered by these alerts and controlling associated claim costs:

- Early Refill
- Pregnancy/Drug Interaction

Early Refill Cost Savings Estimates

Starting January 13, 2013, a system enhancement went into production that required pharmacies to enter a Submission Clarification Code each time they were overriding an early refill ProDUR rejection. The accepted codes would help OHA and the P&T Committee to identify the reasons for the early refill. Accepted values in this field were as follows:

3= Vacation supply - The pharmacist is indicating that the cardholder has requested a vacation supply of the medication.

4= Lost prescription - The pharmacist is indicating that the cardholder has requested a replacement of medication that has been lost.

5= Therapy change - The pharmacist is indicating that the physician has determined that a change in therapy was required; either the medication was used faster than expected or a different dosage form is needed, etc.

6= Starter dose - The pharmacist is indicating that the previous medication was a starter dose and now additional medication is needed to continue treatment.

7= Medically necessary - The pharmacist is indicating that this medication has been determined by the physician to be medically necessary.

13=Payer-Recognized Emergency/Disaster Assistance Request-The pharmacist is indicating that an override is needed based on an emergency/disaster situation recognized by the payer.

14=Long Term Care Leave of Absence_- The pharmacist is indicating that the cardholder requires a short-fill of a prescription due to a leave of absence from the Long-Term Care (LTC) facility.

The cost savings due to claims that were not dispensed because of this alert, defined as being cancelled and then not being reprocessed again at a later date, are outlined in the table below.

Early Refill Cost Saving				
	ER Claims Cancelled	ER Cost Savings		
October-18	12	\$1,518.04		
November-18	18	\$3,482.25		
December-18	25	\$5,422.97		
January-19	39	\$6,752.12		
February-19	5	\$1,674.28		
March-19	17	\$2,750.05		
April-19	28	\$10,997.07		

May-19	7	\$1,140.09
June-19	13	\$2,205.42
July-19	28	\$2,019.30
August-19	21	\$2,896.71
September-19	19	\$2,620.92
Total	232	\$43,479.22

Pregnancy/Drug Cost Savings Estimates

The cost savings due to claims that were not dispensed because of this alert, defined as being cancelled and then not being reprocessed again at a later date, are outlined in the table below.

Pregnancy/Drug Interaction Cost Saving				
	PG Claims cancelled	PG Cost Savings		
September-19	1	\$293.40		
Total	1	\$293.40		

Appendix C - RetroDUR Summary



Appendix D – PDL Changes

PDLs from October 2018 - September 2019

Oregon Medicaid Preferred Drug List - October 1, 2018

Oregon Medicaid Preferred Drug List - January 1, 2019

Oregon Medicaid Preferred Drug List - April 1, 2019

Oregon Medicaid Preferred Drug List - July 1, 2019

Appendix E – Cost Avoidance Methodology Details

Cost avoidance is calculated based on the initial claim (index event) and the final disposition of therapy within the drug class for a member. The types of cost avoidance are: deferred, therapeutic duplication, switched, add-on, discontinued, and other. Each cost avoidance type has a distinctive calculation for the duration of cost avoidance and the amount saved, based on the most likely clinical treatment pathway.

Deferred cost avoidance includes claims for which the requested therapy is eventually approved and savings are calculated based on the time from the initial request to the first paid claim.

Therapeutic duplication cost avoidance is calculated when a drug is denied when there are already paid claims for an alternative in the same drug class.

Switch cost avoidance covers situations when a restricted access drug (PA required or non-preferred) is denied, but an alternative within the PDL class is subsequently paid. The difference in cost between the initial drug requested and the actual drug dispensed is the cost avoided.

Add-on therapy is calculated when a drug is denied when there are already paid claims for an alternative that treats the same condition.

There are limitations to the cost avoidance methodology. The method is dependent upon detecting a denied claim. Members new to the Medicaid program or newly marketed medications are examples of situations that make it more difficult to adequately track and model potential savings. However, providers who have learned the FFS Medicaid PDL (or have learned to consult it) will prescribe preferred and unrestricted medications without first generating a denied claim for a drug requiring prior authorization. These types of long-term behavior modifications represent significant cost saving for the FFS program but are difficult to reliably quantify. Another limitation of the methodology occurs at the beginning and end of the reporting periods. Only costs avoided due to an initial denied claim during the reporting period are included. When an index event occurs immediately before the reporting period, there are savings associated with that event which are not summarized in the report. Likewise, when the initial denied claim occurs immediately before the end of the reporting period, the costs avoided after the end of the reporting period are not included. Significant savings go undetected with the methodology in the interest of conservative reporting. The methodology may also potentially inflate savings. For example, assuming a denied claim for a chronic medication would have continued to be filled throughout the reporting period, or until the member dis-enrolled could overestimate savings resulting from the intervention.