Florida Medicaid Retrospective Drug Utilization Review Program Quarterly Report

10/2015 – 12/2015

January 16, 2016

Pl. Trial Ex. 246

Contents

Follow Up/Updates

Topic	Description	Action	Status as of 12/29/15
Skeletal Muscle Relaxants Utilization	Skeletal muscle relaxants may increase the risk of drowsiness, dizziness, and impaired coordination. In addition, certain muscle relaxants may increase the risk of liver injury when used for extended periods of time and/or in excessive dosages and may interact with other medications that primarily affect central nervous system function when taken concomitantly.	Implement maximum daily dose limits (excluding baclofen and tizanidine in patients with qualifying diagnosis)- complete -Implement duration of therapy edit for more than six consecutive months of therapy within the last 12 months; excluding baclofen and tizanidine in patients with qualifying diagnoses	An edit to limit the duration of therapy with skeletal muscle relaxants (excluding baclofen and tizanidine in recipients with qualifying diagnoses) deployed on March 25, 2015. -A problem was noted post-implementation where pharmacies were resubmitting denied claims for less than a 30-day supply to circumvent the edit; an analysis was conducted to determine how frequently this was occurring-see page 9 -Post implementation analysis of duration of therapy edit-see page 9
Duplicate Angiotensin Blockade	FDA Alert issued a safety alert in November 2012 regarding dual angiotensin blockade; DUR examined the use of overlapping prescriptions for dual angiotensin converting enzyme inhibitors (ACEs) or dual angiotensin receptor blockers (ARBs) or a combination of an ACE and an ARB; later clarified to include direct renin inhibitors (aliskiren and combinations)	Implement edit that denies first duplicate claim using ProDUR; allow pharmacist to enter appropriate intervention/ professional service code and outcome/result of service code once per six months; if another occurrence is encountered within the same six months, the claim denies for PA required	-Pre implementation analysis reviewed at Sept 2014 meeting -Edit went into production on 8/7/15 - post impact analysis will be presented at March 2016 DUR Board meeting to allow for the 6-month window to have elapsed after edit deployment
September 2014 P&T Top Therapeutic Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee's consideration, if deemed necessary.	*Antipsychotics*- maximum daily dose limits for atypical antipsychotics in adults-	-Pre-implementation analysis reviewed at September 2014 meeting -Antipsychotic maximum daily dose limits in adults deployed on May 8, 2015 -post impact analysis was reviewed at September 2015 meeting -F/U regarding 381 recipients who exceeded MDD: Requests are sent back to provider by Call Center for justification of dosing

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January 2015 P & T Top Therapeutic Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee's consideration, if deemed necessary.	*Insulins*-DUR Board approved a change in monthly quantity limits of 10 insulin vials to a quantity limit of seven insulin vials (7,000 units of insulin) DUR Board approved a change in monthly quantity limits of insulin pens, down to a maximum of 2 boxes. All pens come in boxes of 5 pens per box and all pens are 3mL each so 15 mL/box times two boxes = 30 mL(3,000 units)	The new quantity limits on the insulin vials deployed on 1/22/15 and the new quantity limits on the insulin pens deployed on 4/1/2015 - Overall post implementation analysis of insulin utilization was presented at September 2015 meeting -F/U regarding detail data on recipients receiving > 100 units/day and/or ≥ 5 vials per claim- see page 11
June 2015 P & T Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee's consideration, if deemed necessary.	*ranolazine (Ranexa®)*- Implement diagnosis look back for chronic angina as a management strategy	Implementation pending
September 2015 P & T Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee's consideration, if deemed necessary.	DUR Board voted in March to recommend to the P & T committee to make oral erythromycin products as non-preferred based on escalating costs and available alternatives such as azithromycin and clarithromycin.	P & T committee accepted recommendation but requested the DUR Board develop prior authorization criteria for oral erythromycin products. Proposed criteria will be presented at Spring DUR meeting
January 2016 P & T review classes	-Recommendation to institute a quantity limit of 30 capsules/ 30 days for Spiriva Handihaler (preferred) -Create AutoPA for roflumilast (Daliresp) to include diagnosis of COPD and concomitant therapy with a LABA and/or a LAMA -Add age limits of ≥ 12 years for all topical acne products	DUR Board requested further information regarding the number of Spiriva claims > 30 capsules/30 days	Spiriva follow-up information: There were 1,506 claims for 697 recipients ($454,401) from 3/1/15-6/30/15; of these there were 11 claims for 6 recipients ($6,304) that exceeded 30 capsules/30 days AutoPA for roflumilast is being coded and will deploy 1Q16 Age limits on acne products will deploy 1Q16

Topic	Description	Action	Status as of 12/29/15
Rheumatoid Arthritis Utilization Review	Review aspects of utilization regarding treatments for rheumatoid arthritis; break up the initiatives into three categories Concomitant use of more than one biologic agent Utilization without an appropriate diagnosis on file Use of a nonbiologic DMARD prior to use of a biologic	-Identified number of claims/recipients utilizing RA agents for off-label use -DUR Board approved an edit requiring FDA approved indication within the last two years prior to claim adjudication -Analysis of appropriate step therapy with a non-biologic DMARD conducted for recipients with TNF-inhibitor claim	An AutoPA combining all these elements is currently being drafted; a post implementation analysis will be presented approximately 3 months post deployment
Polypharmacy with PPIs	Proton pump inhibitors (PPIs) are a widely utilized class of drugs; omeprazole was the 4th most commonly filled prescription by number of claims for the Florida Medicaid FFS population during the 2nd quarter of 2014 (74,856 claims)	Implement edit for maximum daily dose limits for this class of medications; implement ProDUR edit to deny claim resulting in overlapping therapy with two PPIs; allow pharmacist to override first instance using service intervention/outcome codes	-Edits are currently being coded and will deploy 1Q16
Polypharmacy with Opioids	Opioids are a widely used class of medications and have the potential for abuse. There has been a rise in prescription drug overdose deaths in the U.S. in recent years and inappropriate use of opioids can lead to physical dependence as well as opiate addiction.	Analysis revealed recipients (excluding those with diagnoses of cancer or sickle cell disease) receiving overlapping opioid therapy; some overlap may be clinically appropriate such as utilization of a long-acting opioid and a short-acting opioid	-Educational banner message approved by DUR Board was posted on 3/2/15 -Edit to deny overlapping long-acting opioids: pre-implementation analysis presented at March 2015 DUR Board meeting; edit is being coded
Codeine Use in Pediatrics	Codeine is contraindicated in children following tonsillectomy and/or adenoidectomy. Other national guidelines recommend against the use of codeine as a cough suppressant in pediatric patients	Following a review of literature and the Medicaid FFS usage of codeine in pediatric patients at the January 2015 DUR Board meeting, the Board voted to restrict codeine to children below the age of six	AHCA has determined there are Rx-only ibuprofen suspension options that could serve as alternate therapy in these children; in addition acetaminophen solution products were added to the PDL for children under the age of six; banner message posted 12/3/15; edit deployed 12/17/15-see page 9

Topic	Description	Action	Status as of 12/29/15
Overlapping use of benzodiazepines and stimulants	Benzodiazepines and stimulants have opposing pharmacologic actions	Review utilization of recipients who received overlapping claims for a benzodiazepine and a stimulant medication to define patient population and to determine if the two medications were prescribed by the same prescriber	-Letters and patient profiles sent to affected prescribers -Create edit to deny stimulant claim only after two ProDUR pharmacist interventions when the two drugs are from different prescribers; this edit is being coded
Long acting stimulants (plus Strattera®) in children under the age of six	No long acting stimulants on the market for the treatment of ADHD are FDA approved for use in children under the age of six	Implement a prior authorization procedure for all long acting stimulant preparations as well as Strattera for children less than six years of age	Edit deployed 7/1/15: All long acting stimulants and Strattera require the provider to submit a prior authorization form for review before one of these products can be dispensed to a child under the age of six. Post implementation analysis- see page 14
High dose stimulants in children under the age of six	The Florida Medicaid Drug Therapy Management Program for Behavioral Health expert panel advised there is a concern with the use of high dose stimulants in preschoolers and suggested an appropriate prior authorization review be implemented	Any child under the age of six who is exceeding the expert panel's recommended dose limitations will require prior authorization review by the USF behavioral health program prior to dispensing.	Will deploy January 2016
Methadone Clinically Significant Drug Interactions	Methadone is a drug with a narrow therapeutic window between efficacy and toxicity; the pharmacokinetics and drug interaction associated with methadone can impact safety and efficacy	Due to the risk associated with severe and/or major methadone drug interactions and the fact that methadone is overrepresented in opioid related overdoses, the ProDUR edit for these interactions will be changed so that dispensing requires a pharmacist to review the interaction before the claim will pay	The P & T committee voted to make methadone products nonpreferred and will require a prior authorization effective November 2015; therefore no further edits will be initiated
Topical testosterone products utilization	There is increasing utilization of these products and the FDA has recently released a safety announcement regarding risks associated with these products as well as a lack of established evidence for use beyond the labeled indications	Implement prior authorization procedure for these products	Proposed PA criteria – see page 11 below
Synagis® utilization	The August, 2014 updated guidance for the use of palivizumab (Synagis) by the American Academy of Pediatrics recommended a maximum of 5 doses for all qualifying infants	For the 2015/2016 RSV season, AHCA reduced the maximum number of doses per qualifying infant to five per season (providers will still be able to	Banner message posted regarding the decreased number of maximum doses. DUR Board requested information regarding how many children received a

Topic	Description	Action	Status as of 12/29/15
		request further doses through the PA process if necessary)	complete course of therapy for the 2014/2015 RSV season- see page 12
Morphine equivalent daily doses ≥ 100 mg	Determine the number of FFS recipients who are receiving ≥ 100 mg MEDD	Follow up requested on number of prescribers for excepted recipients as well as total APAP dosage in excepted recipients who were receiving combination products	See page 14 for follow up
Novel Oral Anticoagulants	Describe utilization patterns and length of use for the NOAC class	Utilize a longer window (6 months) to examine length of therapy and possible correlation with treatment indication	See page 14 for follow up
Maximum Daily Dose of Antidepressants in ≥ 6 years of age	DUR Board approved recommended maximum daily doses of antidepressants in recipients age six or older	Implement edit to deny claims exceeding recommended maximum daily dose on affected claims	Edit in process

Follow Up: Hepatitis C Virus (HCV) Treatment Management

Developments this quarter regarding the treatment of Hepatitis C:

- Simeprevir (Olysio®) indication expanded to include HCV genotype 4 (previously only G1)
- Ombitasvir, paritaprevir, ritonavir with dasabuvir (Viekira Pak®) and ombitasvir, paritaprevir, ritonavir (Technivie®) have been changed from "not recommended" in patients with Child-Pugh B liver dysfunction to contraindicated in patients with Child Pugh B cirrhosis.
- CMS issued a Medicaid Drug Rebate Program Notice regarding Medicaid beneficiary access to HCV drugs. Highlights include clarification of requirements for excluded drugs; a concern regarding limiting HCV drugs based on Metavir scores, specialist prescribing, or drug/alcohol abstinence; and CMS agreement with AASLD/IDSA/IAS guidelines. CMS acknowledges cost of newer HCV drugs may cause concern but states market competition may decrease costs and encourages states to negotiate pricing and supplemental rebates. Link: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf
- FDA approved expanded use of ledipasvir/sofosbuvir (Harvoni®) :
    - HCV genotypes 4, 5 and 6
    - Patients with HIV co-infection
    - Harvoni + ribavirin (RBV) for 12 weeks as an alternative to Harvoni monotherapy for 24 weeks for treatment experienced, cirrhotic patients with genotype 1 infection, who have failed prior therapy with a Peg-IFN + RBV regimen followed by a treatment failure with a Peg-IFN + RBV + HCV protease inhibitor regimen.
    - Wyden-Grassley investigation releases report regarding Gilead's pricing strategy for Sovaldi. Findings state "marketing strategy was designed to maximize revenue with minimal concern for

impact on access or affordability". Link: http://www.finance.senate.gov/newsroom/ranking/release/?id=3f693c73-0fc2-4a4c-ba92-562723ba5255

Current Utilization:

Hepatitis C Treatment Utilization- FFS Medicaid Recipients 1/1/15 to 12/1/15			
	Claims	**Recipients**	**Total Paid**
ledipasvir/sofosbuvir (Harvoni)	70	23	$2,141,452
simeprevir (Olysio®)	2	1	$44,911
sofosbuvir (Sovaldi®)	25	9	$710,593
Viekira Pak®	39	22	$1,099,539
Technivie®	-	-	-
Daklinza®	-	-	-
peginterferon	8	3	$24,762
ribavirin	63	34	$33,269

*Note: Viekira Pak was voted as the preferred agent at the March 2015 P & T meeting and was effective April 1, 2015

Follow Up: Skeletal Muscle Relaxants- Duration of Therapy

The DUR Board voted at the June 2014 meeting to implement a duration of therapy edit for the skeletal muscle relaxants. The Board was interested in reducing inappropriate chronic daily use of these medications which are generally intended for short-term treatment of acute musculoskeletal pain. This edit looks back for claims filled for at least a 30-day supply within a rolling one-year period. Once the patient has received six claims (≥ 30 day supply) within a rolling 365 day period, future claims for ≥ 30 day supply will deny. This edit excludes all claims for baclofen and tizanidine for any patient with a qualifying diagnosis on file within the past two years.

Skeletal Muscle Relaxants- Qualifying Diagnoses	
ICD-9	**Description**
335.2	Upper motor neuron syndrome
343*	Infantile cerebral palsy
342*	Hemiplegia and hemiparesis
334*	Spinocerebellar disease
438.2	Late effects of cerebrovascular (CVA) disease, hemiplegia/hemiparesis
438.3	Late effects of CVA disease, monoplegia of upper limb
438.4	Late effects of CVA disease, monoplegia of lower limb
438.5	Late effects of CVA disease, other paralytic syndrome
438.9	Late effects of CVA disease, unspecified

340*	Multiple Sclerosis
341*	Other demyelinating disorders of the CNS
781.7	Tetany
952*	Spinal cord injury

The duration of therapy edit deployed on March 25, 2015. Therefore, impacted claims would have begun in late September 2015 (6 months post edit deployment).

Post Edit Impact Analysis: Skeletal Muscle Relaxants

Time Frame	Claims Count	Recipient Count	Quantity	Amount Paid
Pre-Edit (12/24/14-3/24/15)	12,464	7,264	823,779	$222,796
Post-Edit (9/25/15-12/15/15)	7,288 *(41%↓)*	5,085 *(30 % ↓)*	469,739 *(43% ↓)*	$139,611 *(37%↓)*

Follow Up: Codeine Use in Pediatric Patients

- On July 1, 2015 the FDA published a Drug Safety Communication stating they were evaluating the potential risks of codeine cough-and-cold medicines in children http://www.fda.gov/Drugs/DrugSafety/ucm453125.htm
- On December 12, 2015 the FDA's Pulmonary-Allergy and Drug-Safety and Risk Management advisory committee voted to expand codeine contraindication for pain management in anyone under the age of 18 years and also voted to recommend contraindication of codeine for the treatment of cough in anyone under the age of 18 years. FDA action regarding these recommendations is pending.
- DUR review of FFS Medicaid revealed 740 claims for 675 children ages 12 or under during time frame 8/1/14 to 10/31/14; all of these claims were for codeine combination products (acetaminophen, guaifenesin) rather than single agent codeine
- DUR Board voted to implement an edit restricting the use of codeine to children ages six and older
- DUR Board was concerned about Rx versus OTC availability of alternative agents such as ibuprofen suspension
- Ibuprofen suspension 100 mg/5mL is available on the Florida Medicaid PDL as an Rx product; APAP liquid product alternatives are now available for children less than 6 years on PDL
- Educational banner message was posted on December 3, 2015
- Edit deployed December 17, 2015

Follow Up: Insulin Quantity Limits

Due to the wide range of dosing requirements, quantity limits for insulin products are difficult to establish. Effective 1/22/15 the quantity limit for insulin vials was reduced to 7 vials (70 mL) per month and effective 4/1/15; the quantity limit for insulin pens was reduced to 30 mL (2 boxes of 5 pens each) per month. Prior to these edits, quantity limits were 100 mL of insulin across all products.

Despite these new quantity limits, the quantities of insulin being dispensed still remains quite high.

Insulin- New Quantity Limits (4/1/15 to 6/30/15)						
Insulin Dosage Form	**Claims**	**Recipients**	**Total Paid**	**Total Days Supply**	**Total Quantity Dispensed**	**Dispensed Per Recipient**
Cartridges	218	103	$78,195	6,251	3,066	29.8
Insulin Pens	6,229	2,320	$2,338,772	175,426	94,425	40.7
Vials	7,001	2,694	$2,343,189	194,749	119,652	44.4

The DUR Board requested further analysis of the data, specifically looking into how many recipients were receiving 5 or more vials per claim and also how many recipients had claims indicating they were using > 100 units of insulin per day.

(4/1/15-6/30/15)	**Claims count**	**Recipients**	**Amount Paid**
>100 units/day AND/OR ≥ 5 vials/day	5,931 (45%)	2,367 (47 %)	$2,666,137 (57%)
Totals	13,230	5,014	$4,681,961

Of the 2,367 recipients who received > 100 units/day of insulin (based on quantity dispensed and days supply), or received 5 or more vials of insulin per Rx, 1,620 (68.4%) of those patients had a diagnosis of "Type 1 diabetes" on file.

Follow Up: Topical Testosterone Product Utilization

In the U.S., androgen prescriptions among men 40 years of age or older increased more than 3-fold from 2001 to 2011. Of the four formulations available (injectable, oral, transdermal, topical gel), topical gel demonstrated the highest rate of overall use and highest rate of increase- more than 5-fold.

In March 2015, the FDA released a Safety Announcement concerning the use of prescription testosterone products. The FDA noted that testosterone is FDA-approved as replacement therapy only for men who have low testosterone levels due disorders of the testicles, pituitary gland or brain that result in medical hypogonadism. However, the FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging. The benefits and safety of this use have not been established. The FDA has concluded there is a possible increased cardiovascular risk associated with testosterone use. Based on these findings, the FDA is requiring labeling changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use.

Topical testosterone is currently on the Florida Medicaid PDL with only age and gender restrictions. A recent review determined approximately 75% of Florida Medicaid FFS recipients had a history of a serum testosterone level measurement while 70% had a diagnosis of testicular hypofunction on file.

DUR Board recommended that the P & T committee consider moving all topical testosterone products to non-preferred and to institute prior authorization criteria for topical testosterone products. Further, the DUR Board recommends requiring a baseline PSA concentration as well as serum testosterone concentration (measured in the morning on at least two separate days) indicating a serum testosterone value below the normal range for all diagnoses except gender identity disorder.

The following are the proposed ICD-10 codes that would satisfy the prior authorization diagnosis criteria:

- ICD-10-CM-E89.5- postprocedural testicular hypofunction
- ICD-10-CM-E29.1- testicular hypofunction
- ICD-10-CM-29.8-Other testicular dysfunction
- ICD-10-CM Code Q98.0-Klinefelter syndrome karyotype 47, XXY
- ICD-10-CM Code Q98.1-Klinefelter syndrome, male with more than 2 X chromosomes
- ICD-10-CM Code 98.4-Klinefelter syndrome, unspecified
- ICD-10-CM Code E23-Hypofunction and other disorders of the pituitary gland
- ICD-10-CM Code F64-Gender identity disorders

Follow Up: Synagis Utilization

According to the most recent update of the American Academy of Pediatrics guidelines regarding the use of palivizumab (Synagis®), which were published in August, 2014, “the benefit resulting from this drug is limited; palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality and a minimal effect on subsequent wheezing.” Current guidelines recommend the use of a maximum of 3 to 5 doses depending on the infant’s age and risk factors. There is geographic variability in the onset and offset of RSV season. Generally it runs from November through April in the continental United States; however Florida has variations within different regions of the state. According to the AAP guidelines, “despite the varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons in Florida”.

After reviewing the Synagis utilization data for the 2014-2015 Florida RSV season, The DUR Board voted at the June 2015 meeting to decrease the maximum number of monthly doses from seven to five for Florida Medicaid recipients during the 2015-2016 Florida RSV season.

The DUR Board requested further information regarding the total number of doses recipients were receiving:

Synagis DOS Count	Recipient Count
1	445
2	341
3	299
4	273
5	269
6	240
7	278

During the review of the Synagis utilization, it appears there are some recipients who received Synagis only AFTER an RSV-related hospitalization. There were 40 recipients identified who had a Synagis claim as well as an RSV-related inpatient admission during the 2014-2015 Florida RSV season. Of those 40 recipients, there were 15 recipients with only post-admission Synagis claims on file. The patient's ages may have been a contributing factor as the medical claims capture is likely incomplete in the analysis.

Recipients with RSV-related admission and only post-admission Synagis claims

Date of Birth	Hospital Admit Date (Age at time of admission)	First DOS Synagis claim	Last DOS Synagis Claim
2/6/13	7/24/14 (17 months)	9/11/14	10/13/14
1/2/14	10/17/14 (9 months)	10/28/14	2/10/15
12/9/13	7/27/14 (7 months)	10/8/14	2/10/15
3/4/14	9/14/14 (6 months)	10/8/14	3/23/15
5/20/14	8/30/14 (3 months)	10/7/14	4/8/15

7/3/14	11/13/14 (4 months)	1/12/15	1/12/15
12/28/13	8/6/14 (7 months)	9/29/14	4/6/15
8/7/14	11/15/14 (3 months)	12/9/14	3/9/15
9/2/14	11/16/14 (2 months)	3/23/15	4/22/15
8/26/14	10/7/14 (1 month)	10/29/14	1/7/15
9/9/14	11/24/14 (2 months)	1/5/15	4/7/15
9/9/14	11/23/14 (2 months)	1/5/15	4/7/15
9/6/14	11/27/14 (2 months)	12/15/14	1/12/15
9/6/14	11/26/14 (2 months)	12/15/14	1/12/15
9/19/14	11/11/14 (1 month)	12/3/14	3/23/15

Follow Up: Long-Acting Stimulants (and Strattera) in Children Under 6 Years of Age:

Prior to the implementation of this edit (7/1/15), there were no age restrictions on any long acting stimulant or atomoxetine (Strattera). None of the long-acting stimulants are FDA-approved for use in children under the age of six years. In consultation with the USF Behavioral Health program, a prior authorization form for children under the age of six was developed and is now required prior to approval of one of these agents in these children.

Long Acting Stimulants and Strattera in Children Under 6 Years of Age (FFS):

Time Period	Claims Count	Recipient Count	Amount Paid
Pre edit (4/1/15 to 6/30/15)	477	253	$109,384
Post edit (7/1/15 to 9/30/15)	95 *(80% ↓)*	55 *(78% ↓)*	$21,362 *(80% ↓)*

Follow Up: Morphine Equivalent Daily Dose (MEDD)

A total of 1,510 recipients were identified during the time frame April 1, 2015 through June 30, 2015 who received opiate doses that were greater than or equal to a 100 mg MEDD. The DUR committee requested further information regarding the identified recipients including the number of prescribers associated with these opioid claims and the acetaminophen daily dose for those recipients who were receiving opioid/acetaminophen combination products.

Prescriber Count	Recipient Count
1	1,007
2	347
3	109
4	30
5	9
6	7
9	1
Total	1,510

Acetaminophen Dose:

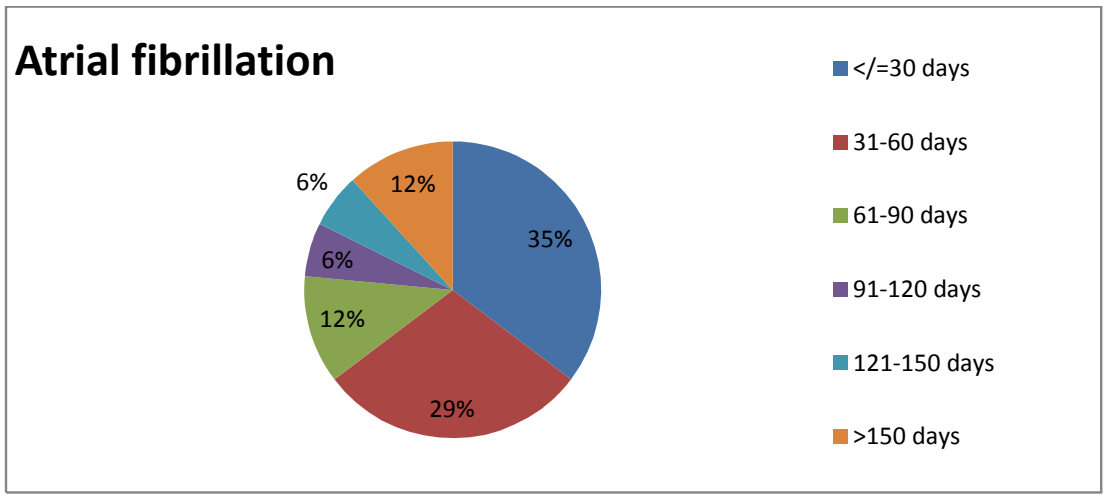
There were a total of 686 recipients who received a combination opioid/acetaminophen product in the same time frame. Based on quantity dispensed and days supply submitted on the claim, 230 recipients may have received greater than 4 grams of acetaminophen on at least one day of the examined period.

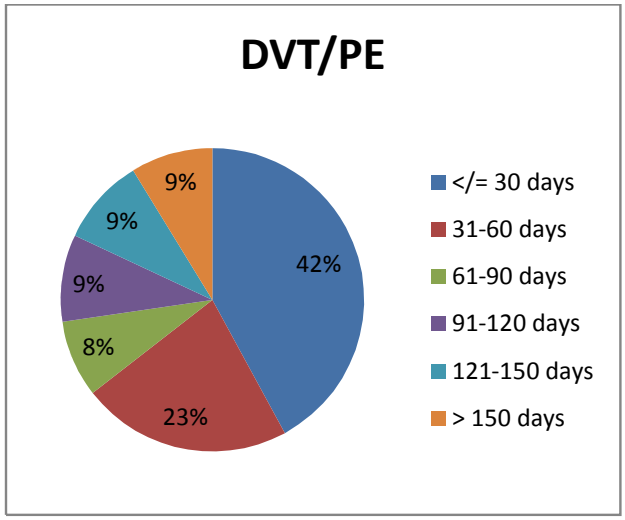
Follow Up: Novel Oral Anticoagulant Utilization

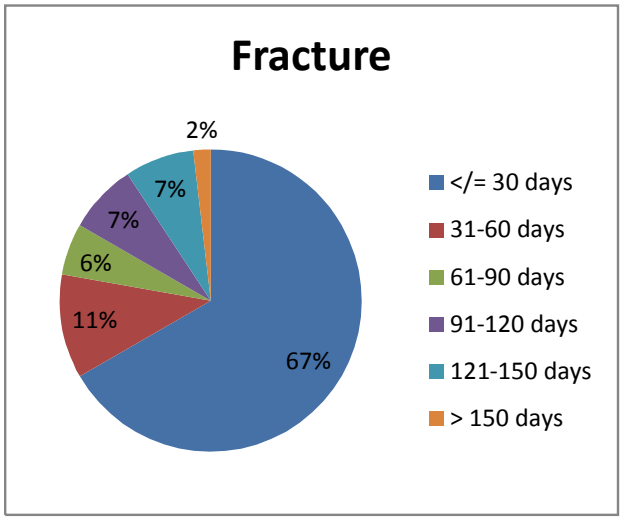
Preferred novel oral anticoagulants include dabigatran (Pradaxa), apixaban (Eliquis), edoxaban (Savaysa) and rivaroxaban (Xarelto). The indications for these products vary slightly from one another but generally include deep vein thrombosis (DVT) prophylaxis following orthopedic surgery, the treatment of DVT, prophylaxis for patients at risk for venous thromboembolic (VTE) complications due to a transient cause, prophylaxis or treatment of various types of myocardial infarction and to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). The length of therapy may vary according to indication. VTE prophylaxis is generally short term, 10-14 days postoperatively or until the reversal of a transient risk factor such as immobility. For the treatment of VTE, the American College of Chest Physicians guidelines recommend anticoagulation for a minimum of three months. Adherence with NOAC therapy may be a concern for long term

treatment or prophylaxis and these agents are not routinely monitored with blood levels in the same way that INR is utilized in patients receiving warfarin for these same indications.

During a six month time frame (June 1, 2015 through December 1, 2015); there were a total of 689 unique FFS recipients who received a claim for one of the preferred novel oral anticoagulants. The majority of these recipients (62 %) did not have an indicated diagnosis on file; some of these may represent short-term DVT prophylaxis indications. For those patients with a diagnosis on file, the most common diagnosis was DVT (169) followed by fracture (54), pulmonary embolism (25) and atrial fibrillation (17).







New Business

June 2016 Pharmacy and Therapeutics Committee Therapeutic Classes

June Therapeutic Classes

Antibiotics, vaginal
Antidepressants, other
Antidepressants, SSRIs
Antiemetics/Antivertigo agents
Beta-blockers
Cephalosporins and related antibiotics
Cytokine and CAM antagonists
Epinephrine, self injected
Erythropoiesis stimulating proteins
Hepatitis B agents
Hypoglycemics, TZDs
Immunosuppressants, oral
Intranasal rhinitis agents
Lipotropics, other
Otic antibiotics
Pancreatic enzymes
Platelet aggregation inhibitors
Stimulants and related agents
June Mass Review
Acne agents, oral
Analgesics, non-sal/1st gen antihistamines
Analgesics, non-sal/barbiturate
Analgesics, non-sal/barbiturate/xanthine
Analgesics, sal/barbiturate/xanthine
Analgesics, salicylates
Anti-alcoholic preparations
Antifungals, vaginal
Antihypertensives, sympatholytics
Anxiolytics
Estrogen agents, combinations
Estrogen agents, injectable
Estrogen agents, oral/transdermal
Glucocorticoids, injectable
Glucocorticoids, oral
Histamine II receptor blockers
Iron, parenteral
PAH agents, injectable
Rosacea agents, topical

Mucolytics

Drug	Claims	Recipients	Total Paid	PDL Status
Acetylcysteine nebulizer soln 10%	10	6	$680.66	preferred
Acetylcysteine nebulizer soln 20%	10	6	$724.92	preferred
Pulmozyme (dornase alfa) 1 mg/mL	839	357	$2,737,599	preferred

The only FDA-approved indication for Pulmozyme is mucolysis in patients with cystic fibrosis, given in conjunction with standard therapies to improve pulmonary function.
Recommendation: Establish AutoPA with diagnosis look back for cystic fibrosis

Glucocorticoids, Oral

Label Name	Users	Claims Count	Total Amt Paid
BUDESONIDE EC 3 MG CAPSULE	46	66	$49,134.55
METHYLPREDNISOLONE 4 MG DOSEPK	1,462	1,551	$40,431.94
PREDNISOLONE 15 MG/5 ML SOLN	2,501	2,817	$24,391.29
PREDNISONE 20 MG TABLET	2,383	2,647	$17,311.35
PREDNISONE 10 MG TABLET	1,029	1,260	$11,772.53
PREDNISOLONE 15 MG/5 ML SOLN	1,693	1,883	$11,639.00
HYDROCORTISONE 5 MG TABLET	175	368	$9,726.32
PREDNISONE 5 MG TABLET	424	640	$6,798.85
METHYLPREDNISOLONE 4 MG TABLET	52	79	$5,060.16
HYDROCORTISONE 10 MG TABLET	60	123	$4,786.55
PREDNISOLONE 5 MG/5 ML SOLN	67	77	$3,639.50
ORAPRED ODT 10 MG TABLET	8	9	$2,604.89
DEXAMETHASONE 4 MG TABLET	294	374	$2,548.36
ORAPRED ODT 15 MG TABLET	8	10	$1,909.00
PREDNISONE 50 MG TABLET	285	302	$1,810.72
DEXAMETHASONE INTENSOL 1MG/1ML	19	27	$1,583.31
DEXAMETHASONE 2 MG TABLET	58	72	$1,366.13
PREDNISONE 1 MG TABLET	47	94	$1,342.82
PREDNISONE 5 MG/5 ML SOLUTION	39	48	$1,310.11

Budesonide EC tablets are indicated for the treatment of mild to moderate Crohn's disease dosed at 9 mg once daily for up to 8 weeks. Repeated 8 week courses can be given for recurring episodes of active disease. Budesonide EC tablets are also indicated for the maintenance of clinical remission of mild to moderate Crohn's disease at a dose of 6 mg for up to 3 months. Continued treatment with budesonide EC tablets for more than 3 months has not been shown to provide substantial clinical benefit.
Recommendation: Require clinical prior authorization of budesonide 6 mg for any patient who has exceeded 3 months of consecutive therapy.

Quarterly Activities

Metoclopramide Dosing /Risk of Tardive Dyskinesia

Purpose:	To determine the number of Medicaid FFS recipients who are receiving doses exceeding the recommended maximum daily dose of metoclopramide (60 mg/day for adults and 40 mg/day for patients < 18 years old) or who are receiving more than 12 weeks of continuous therapy	
Why Issue was Selected:	Metoclopramide carries a black box warning stating the risk of developing tardive dyskinesia is directly related to the length of therapy and recommends against use for durations lon ger than 3 months. Extrapyramidal reactions are dose dependent and also occur more frequently in younger patients.	
Program Specific Information:	Performance Indicators	Exceptions
	FFS adult recipients receiving > 60 mg/day	16
	FFS recipients < 18 years old receiving > 40 mg/day	2
	Any recipient receiving more than 84 days (12 weeks) of therapy	255
Setting and Population:	All FFS recipients who received a claim for metoclopramide between July 1, 2015 through October 31, 2015	
Main Outcome Measures:	Determine the number of recipients exceeding recommended dose limits	
Anticipated Results:	Consider implementing dosing limits	

There were a total of 1,813 claims for 1,178 recipients ($12,363) for metoclopramide in the studied date range. There were only 18 patients (1.5% of recipients) who exceeded the recommended daily dose. However, there were 255 recipients (22%) who received 84 or more days supply of metoclopramide. Of the 1,178 recipients examined, one patient had a diagnosis of tardive dyskinesia on file.

Recommendation: Consider implementation of duration of therapy edit to ensure therapy does not exceed recommended maximum of 12 weeks.

Budesonide Suspension for Inhalation/Brand versus Generic

Purpose:	To determine if denials of generic budesonide suspension for inhalation prescriptions are being appropriately redirected to preferred brand name Pulmicort Respules	
Why Issue was Selected:	The DUR Board is concerned that asthma patients are not receiving optimal therapy due to rejected claims for generic budesonide suspension for inhalation not being appropriately redirected to preferred Pulmicort Respules	
Program Specific Information:	Performance Indicators	Exceptions
	Percent of recipients with rejected claims for generic budesonide suspension for inhalation who subsequently had a paid claim for Pulmicort Respules within 7 days of the denied generic claim	49%
Setting and Population:	All Medicaid FFS recipients between August 1, 2015 and October 31, 2015	
Main Outcome Measures:	Determine the relative percentage of recipients that are appropriately redirected to the preferred drug	
Anticipated Results:	Patients are being appropriately redirected to preferred agent	

Recommendation: Consider educational letter campaign or other means of contacting pharmacy providers to educate regarding preferred status of Pulmicort Respules.

Celecoxib (Celebrex) Quantity Limits

Purpose:	To determine the incidence of recipients who are receiving celecoxib (Celebrex) doses of 800 mg/day	
Why Issue was Selected:	The P & T committee requested at the November 2015 meeting that the DUR Board review and consider implementing quantity limits for celecoxib	
Program Specific Information:	**Performance Indicators**	**Exceptions**
	Number of recipients who are receiving celecoxib doses greater than or equal to 800 mg/day	3
Setting and Population:	All celecoxib claims for FFS recipients between DOS 5/1/2015 to 10/31/2015	
Main Outcome Measures:	Describe the incidence of celecoxib use equal to exceeding 800 mg/day	
Anticipated Results:	Determine need for maximum daily dosing and quantity limits for celecoxib	

Current FDA approved indications for the use of celecoxib include:

- Osteoarthritis
- Rheumatoid Arthritis
- Juvenile Rheumatoid Arthritis
- Ankylosing Spondylitis
- Acute Pain
- Primary Dysmenorrhea

The normal dose of celecoxib for these currently FDA-approved indications ranges from 100 mg/day to 200 mg twice daily. In December 1999, the FDA approved celecoxib as an adjuvant treatment for patients with familial adenomatous polyposis (FAP). This approval was based on data showing that 200 mg BID or 400 mg BID for up to 3 years led to fewer patients with an adenoma at years one and three compared to placebo recipients. However, in February 2011, the FDA withdrew the approval of celecoxib for FAP following analysis of two long-term safety studies which revealed an increased incidence of serious cardiovascular events in patients with long-term celecoxib as compared to placebo, the risks associated with this therapy were determined to outweigh the potential benefits for patients with FAP. Therefore, there are no current FDA approved indications with a recommended dose of 800 mg/day.

Recommendation: Implement celecoxib 400 mg/day maximum daily dose limitation.

Further Information Requested by the DUR Board:

Daraprim Utilization:

On August 11, 2015, Turing Pharmaceuticals increased the price of Daraprim 25 mg from $13.55/tablet to $750/tablet (based on Wholesale Acquisition Cost). On October 8, 2015 AHCA implemented clinical prior authorization criteria for the use of pyrimethamine (Daraprim).

Daraprim Utilization:

Date Range	Claims	Recipients	Total Paid
4/10/15 to 8/10/15	26	15	$21,548
8/11/15 to 12/11/15	12	6	$335,574

Top Therapeutic Classes by Claims Count (9/1/15 to 11/30/15)

Therapeutic Class	Claim Count	Total Amount Paid	Paid/Claim
Anticonvulsants	36,986	$4,961,574	$134.15
Antipsychotics, Atypical, Dopamine & Serotonin Antagonists	14,725	$2,545,818	$172.89
Analgesics, Narcotics	12,646	$341,281	$26.99
SSRIs	11,034	$73,352	$6.65
Beta-Adrenergic Agents	9,626	$413,335	$42.94
NSAIDS, Cyclooxygenase Inhibitor	8,900	$75,522	$8.49
Penicillins	8,568	$108,023	$12.61
Anti- Anxiety	7,235	$53,552	$7.40
Antihistamines-Second generation	6,204	$36,239	$5.84

Top Therapeutic Classes by Total Paid (9/1/15 to 11/30/15):

Therapeutic Class	Claim Count	Total Paid	Paid/Claim
Antihemophilic Factors	529	$11,236,394	$21,241
Anticonvulsants	36,986	$4,961,574	$134.15
Antipsychotics, Atypical, D2 Partial Agonist/Serotonin Mixed	2, 896	$2,744,831	$947.80
Antipsychotics, Atypical, Dopamine & Serotonin Antagonist	14,725	$2,545,818	$172.89
Insulins	3,202	$923,485	$288.41
Glucocorticoids, Orally Inhaled	2,458	$705,341	$286.96
Adrenergic, Aromatic, Non-Catecholamine	4,651	$631,008	$135.67
Attention Deficit-Hyperactivity Disorder/Narcolepsy	3,408	$504,030	$147.90
Antineoplastic Systemic Enzyme Inhibitors	56	$479,088	$8,555.15

Prior Authorization Requests/Outcome Statistics for the following drugs will be presented at the January 16, 2016 DUR Board Meeting:

- Alirocumab (Praluent)
- Evolocumab (Repatha)
- Ivacaftor (Kalydeco)
- Lumacaftor/Ivacaftor (Orkambi)