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Policy Evaluation: Prior Authorization of non-preferred oral anticoagulants

Background:

The Oregon Health Plan fee-for-service program (FFS) implemented prior authorization (PA) criteria for the use of dabigatran (Pradaxa™), rivaroxaban (Xarelto™) and apixaban (Eliquis™). The goal of the FFS PA policy was to limit use of the newer agents to patients intolerant or who had a contraindication to preferred anticoagulants and limit use to indications where there was evidence to support efficacy and safety. The dabigatran PA was implemented on April 9, 2012; the apixaban PA was implemented on January 1, 2013; and the rivaroxaban PA was implemented on April 9, 2013.

Dabigatran is an oral direct thrombin inhibitor with Food and Drug Administration (FDA) approved indications to prevent stroke in non-valvular atrial fibrillation, and to treat acute and chronic deep vein thrombosis (DVT) and pulmonary embolism (PE).[1] Rivaroxaban and apixaban are oral direct factor Xa inhibitors approved for similar FDA indications as dabigatran, with an additional indication for postoperative DVT prophylaxis following total knee or hip replacement.[2,3] Edoxaban was not included in the PA policy. It is the most recent oral anticoagulant which was approved in 2015 for patients with non-valvular atrial fibrillation and for the treatment of DVT and PE. [4]

The place in therapy for the direct-acting oral anticoagulants (DOACs) is evolving as demonstrated by the Anticoagulant Class Update and clinical guidelines.[5] The American College of Chest Physician's 9th Ed. 2012 Executive Summary recommends low molecular weight heparin (LMWH) as the preferred agent for DVT prophylaxis in orthopedic surgery but DOACs are included as alternative first line agents.[6] In patients with non-valvular atrial fibrillation at high risk for stroke, dabigatran is recommended over dose-adjusted warfarin. However, in patients with a diagnosis of acute coronary syndrome (ACS) and valvular atrial fibrillation, warfarin is still recommended first.[6]

The National Institute for Health and Care Excellence Collaborative Implementation recommends including all DOACs as first line agents for their approved indications and specifying: "The drugs must therefore be made available for prescribing within their licensed indications, and should be automatically included in local formularies. Local arrangements for use of antithrombotic therapies in atrial fibrillation should be reviewed and policies developed for integration of DOACs into the care pathway."[7]

Currently, the FFS program lists warfarin, a vitamin K antagonist, and branded Lovenox™ (enoxaparin), a LMWH, as preferred anticoagulants. The FFS PA policy approves DOACs use for patients to treat non-valvular atrial fibrillation or acute or chronic DVT/PE. It also approves up to 35 days of rivaroxaban and apixaban for patients requiring short-term (<45 days) anticoagulation for DVT prophylaxis after total knee replacement or hip replacement. Patients meeting the diagnostic criteria must also be unable to take warfarin therapy or Lovenox™ due to one of the following reasons:

- Allergy
- Contraindications to therapy
- Drug-drug interactions
- Intolerable side effects
- Unstable International Normalized Ratio (INR) (warfarin only)
- Difficulty obtaining routine INR monitoring (warfarin only)

If criteria are met, patients may be approved for up to one year of DOAC use. If the criteria are not met, PAs will be denied with DOAC allowance of 14 days (or until the patient is deemed adequately anticoagulated). Adequate anticoagulation is recommended when switching patients from DOACs. Drug labeling indicates that patients switching from rivaroxaban or apixaban to other anticoagulants are at increased risk of thrombotic events.[2,3]

State Medicaid programs have implemented similar PA criteria for DOACs with minor variations. These programs encourage warfarin or LMWH use when possible, and have developed specific inclusion criteria for prior authorization of DOACs.[8,9] Locally, CareOregon has implemented similar PA criteria for DOACs with minor variations, including more stringent criteria for use in patients with atrial fibrillation. Unlike the FFS PA criteria, CareOregon requires patients with atrial fibrillation to have additional thromboembolic risk factors in order to be approved for DOACs. Risk factors must include one or more of the following: history of stroke, TIA, or systemic embolism; age >75 years, hypertension, diabetes mellitus, moderately or severely impaired left ventricular systolic function or heart failure. CareOregon also limits dabigatran to patients with atrial fibrillation and will not approve its use in DVT.[10]

MODA Health and Providence are local commercial health plans that have taken a less restrictive approach toward DOACs. MODA Health PPO requires trial of or contraindication to rivaroxaban or apixaban before approving dabigatran.[11] However, there are no PA requirements in place for either rivaroxaban or apixaban.[12] Similarly, Providence Health Plan has neither PA nor step therapy criteria for rivaroxaban, apixaban, nor dabigatran.[13] These health plans are an example of the varying levels of restrictions placed on DOAC use. This variation reflects the current lack of literature evaluating outcomes or potential harms as a result of anticoagulation PA policies.

The aims of this policy evaluation are to: 1) describe anticoagulation utilization after the FFS PA policy was implemented to determine if DOACs are prescribed only for FDA indications, 2) quantify the number of patients switched from one anticoagulant to another, and 3) quantify number of patients encountering a PA for a DOACs that do not continue on any anticoagulant therapy.

Methods:

Patients were included if they had a paid FFS drug claim for any drug in Table 1 or a denied FFS drug claim for any drug in Table 1 with Explanation of Benefit (EOB) code 1056 (i.e. "PA Required") and simultaneously no EOB of 2017 (i.e. "Patient enrolled in MCO") from April 9, 2012 and through December 31, 2014. Patients were excluded if they had Medicare Part D coverage as indicated by benefit packages of BMM or BMD. Using only FFS claims, the *first anticoagulant paid or denied claim* per patient during the study period was designated the *index event*. Patients were excluded if they had less than 75% days of combined FFS or coordinated care organization eligibility from 4 months prior to the index month to 2 months after the index month (for a total of 7 months).

Table 1. Anticoagulant Drugs

HSN code	Route	Brand	Generic
007878	SUB-Q	ENOXAPARIN SODIUM	ENOXAPARIN SODIUM
007878	SUB-Q	LOVENOX	ENOXAPARIN SODIUM
002812	ORAL	COUMADIN	WARFARIN SODIUM
002812	ORAL	JANTOVEN	WARFARIN SODIUM
002812	ORAL	WARFARIN SODIUM	WARFARIN SODIUM
035604	ORAL	PRADAXA	DABIGATRAN ETEXILATE MESYLATE
035915	ORAL	XARELTO	RIVAROXABAN
037792	ORAL	ELIQUIS	APIXABAN

HSN = hierarchical ingredient code list (HICL) sequence number as reported by First DataBank™

Patients were categorized by whether the index event was a paid or denied claim. Patients were also categorized by the generic drug name of index event. Patients with a paid FFS or encounter claim at any time from January 1, 2012 through December 31, 2014 with an International Classification of Diseases (ICD-9) diagnosis code for each of the diagnostic groups (e.g. atrial dysfunction or thromboembolic events) from Table 2 or Table 3 were flagged.

Patients with paid index events were categorized in the following groups in order to describe drug switching.

1) New Anticoagulant start - no paid FFS or encounter anticoagulant claims within 102 days prior to *index event.*
2) Continuation Therapy - Patients where the *index event* is for the same generic drug as a paid FFS or encounter anticoagulant claim within 102 days prior.
3) Switch Preferred to DOAC - Patient where the *index event* is a DOAC and there is a previous warfarin or enoxaparin claim within 102 days prior.
5) Switch DOAC to Preferred – Patients where the *index event* is warfarin or enoxaparin and there is a previous paid FFS or encounter DOAC claim within 102 days.
6) Other - *Index event* does not fit in prior categories.

Patients with denied index events were categorized in the following groups to describe drug therapy disruption.

1) Anticoagulant > 90 days or no anticoagulant claims
2) Anticoagulant ≤ 14 days
3) Anticoagulant > 14 and < 90 days

The PA data was queried for all patients with denied index events. If a PA was requested for any anticoagulant within 5 days prior or ≤14 days after the index event they were counted as requesting a PA. The PA request could be for a different anticoagulant than the index event.

De-identified patient claim profiles were created for the following three patient groups: patients with paid DOAC claims; patients with denied DOAC claims who later received an anticoagulant within 14-90 days; patients with denied DOAC claims who received an anticoagulant >90 days or not at all. The de-identified patient profiles were reviewed for presence of diagnoses matching FDA labeled indications for anticoagulation and DOAC contraindications, precautions, or adverse events. Patients were labeled as having DOAC claim for FDA labeled indications if any diagnosis from Table 2 was found within the patient profile at any time, regardless of whether pre- or post-index date. Patients were labeled as having contraindications or precautions to DOAC use if any diagnosis from Table 3 was found within the patient profile at any time, regardless of whether pre- or post-index date. For patients denied a DOAC, adverse events were defined as any major clotting event (venous embolism, pulmonary embolism, or deep vein thrombosis) that occurred post-index date. For patients with paid DOAC claims, adverse events were defined as any major bleeding event (intracerebral hemorrhage or any major hemorrhage) that occurred post-index date.

Table 2. FDA Labeled Indications for warfarin, enoxaparin, dabigatran, rivaroxaban, or apixaban

	ICD-9 Code
Atrial Dysfunction	
Atrial fibrillation & atrial flutter	427.3x
Supraventricular premature beats	427.61
Thromboembolic Events	
Phlebitis & thrombophlebitis	451.xx
Other venous embolism & thrombosis	453.xx
Acute venous embolism & thrombosis of deep vessels of lower extremity	453.4x
Chronic venous embolism & thrombosis of deep vessels of lower extremity	453.5x
Personal history of venous thrombosis & embolism	V12.51
Pulmonary embolism & infarction	415.1x
Personal history of pulmonary embolism	V12.55
Orthopedic Procedures	
Total knee arthroplasty	81.54-81.55; V43.65
Total hip arthroplasty	81.51-81.53; V43.64, 820xx
Acute Coronary Syndrome	
Cardiac device in situ	V45.0x
Postsurgical aortocoronary bypass status	V45.81
Percutaneous transluminal coronary angioplasty status	V45.82
Angina pectoris	413.x
Acute myocardial infarction	410.xx

Table 3. Contraindications or precautions for DOACs

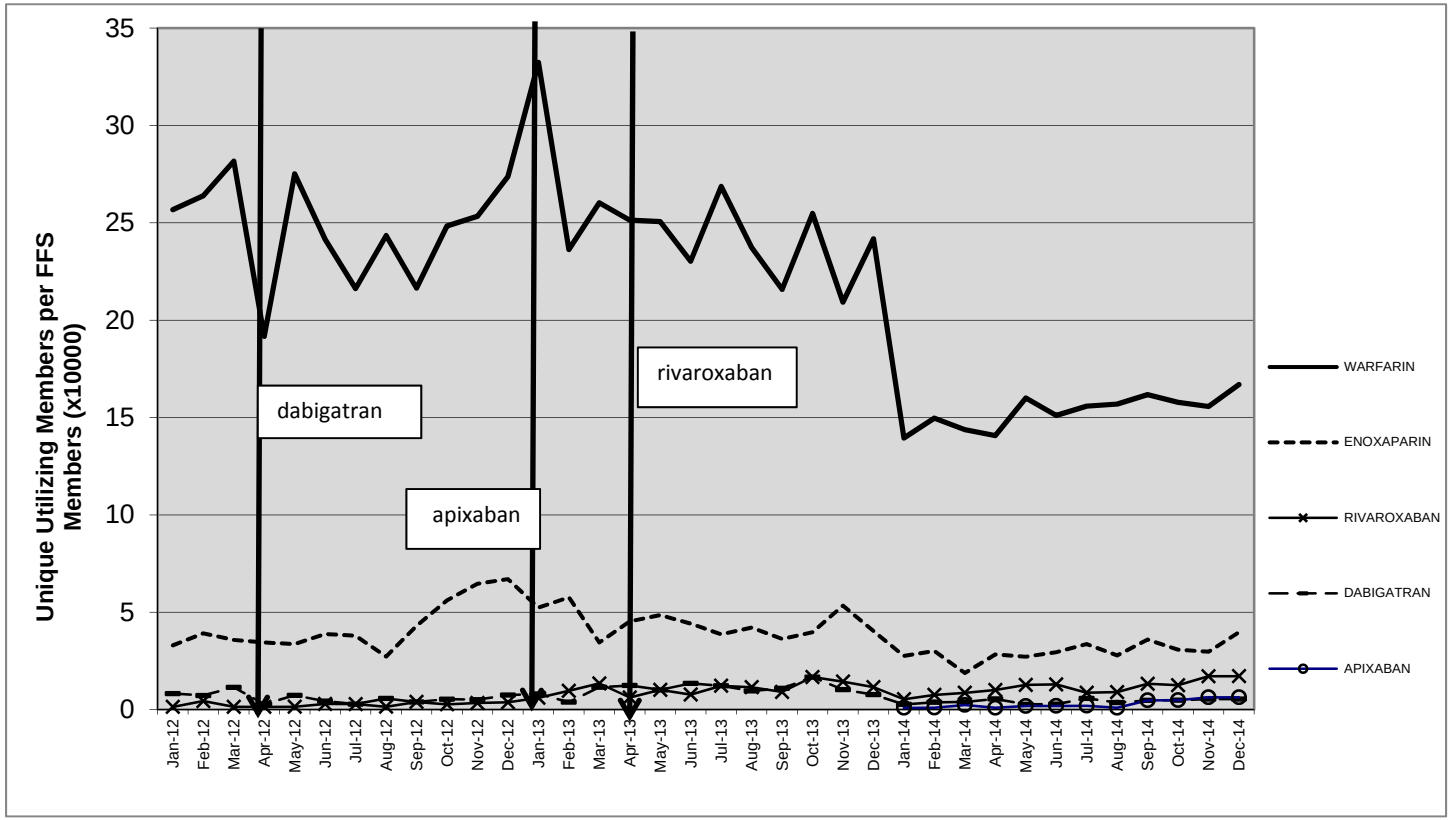
	ICD-9 Code
Valve Replacement	
Heart valve replaced by transplant	V42.2
Heart valve replaced by other means	V43.3
Valvular Disease/Dysfunction	
Other congenital anomalies of heart	746.xx
Anomalies of pulmonary valve congenital	746.0x
Diseases of mitral valve	394.x
Diseases of aortic valve	395.x
Disease of mitral & aortic valves	396.x
Disease of other endocardial structures	397.x
Diseases of tricuspid valve	397.0
Rheumatic diseases of pulmonary valve	397.1
Rheumatic diseases of endocardium valve unspecified	397.9
Cardiac	
Acute & subacute endocarditis	421.x
Aortic aneurysm & dissection	441.xx
Cranial Bleeding	
Subarachnoid hemorrhage	430
Intracerebral hemorrhage	431
Other & unspecified intracranial hemorrhage	432.x
Gastrointestinal	
Esophageal varices with bleeding	456.0
Esophageal varices in diseases classified elsewhere with bleeding	456.20
Hemorrhage unspecified	459.0
Ulcer of esophagus with bleeding	530.21
Gastric ulcer	531.xx
Duodenal ulcer	532.xx
Peptic ulcer	533.xx

Gastrojejunal ulcer	534.xx
Gastritis & duodenitis	535.xx
Gastrointestinal hemorrhage	578.x
Hematologic and Circulatory	
Hemorrhagic disorder due to intrinsic circulating anticoagulants	286.5x
Abnormality of red blood cells	790.0x
Abnormal coagulation profile	790.92
Coagulation defects	286.xx
Hepatic	
Chronic liver disease & cirrhosis	571.xx
Kidney Disease	
Acute kidney failure	584.x
Chronic kidney disease	585.x
Chronic kidney disease, stage IV	585.4
Chronic kidney disease, stage V	585.5
End stage renal disease	585.6
Other	
Purpura & other hemorrhagic conditions	287.xx
Other aneurysm	442.xx

Results:

Figure 1 depicts the trend of anticoagulant usage per individual agent for the unique FFS patients with paid claims only. Warfarin was the most utilized anticoagulant; ranging from 14 patients per 10,000 FFS members to 34 patients per 10,000 FFS members per month). Enoxaparin was the second most utilized anticoagulant. There are no discernable trends at the implementation points for each PA but the warfarin use spiked down coincident of the dabigatran PA and spiked up coincident to the apixaban PA. Of the DOACs, rivaroxaban was prescribed most frequently; however, overall there was very low utilization of any DOAC. The seemingly decreased use seen in December 2013 corresponded with an increase in total number of patients enrolled due to the Affordable Care Act, rather than a true decrease in anticoagulant usage.

Figure 1. FFS Trend Line of Unique Patients per 10,000 members per Month for each Anticoagulant (January 1, 2012 – December 31, 2014)



There were 1,626 unique non-Medicare patients with FFS paid or denied anticoagulant claims identified between April 9, 2012 and December 31, 2014. After excluding patients with <75% of days of combined FFS and coordinated care organization eligibility from 4 months prior to the index month to 2 months after the index month (for a total of 7 months), 1,007 patients were included in the study. Of these patients, only 96 (9.5%) had a denied claim. Table 4 displays the patient demographics. The majority of patients (n= 961, 95.4%) fell in the age group of 19-64 years old. The mean age of patients included in the study was 47.3 years old, which was similar in patients with DOAC paid claims (47 years old) and denied claims (49.2 years old). There was a lower female rate for those with denied claims (39.6%), but the absolute numbers are very small. The study population was primarily self-identified as White (80.3%), with DOAC paid claims being slightly more diverse (70% White).

Table 4. Demographics of Study Population

	Total	Index = Denied
	1,007	**96**
Mean age (range)	47.3 (0-88)	49.2 (15-68)
<19 19-64 >64	28 (2.8%) 961 (95.4%) 18 (1.8%)	3 (3.1%) 91 (94.8%) 2 (2.1%)
Female	525 (52.1%)	38 (39.6%)
White	809 (80.3%)	74 (77.1%)

Tables 5 represents the distribution of paid (n=911, 90.5%) and denied (n=96, 9.5%) index claims by drug. The majority of paid index claims were for enoxaparin and warfarin, with only 20 (2.2%) for DOACs. There were 10 patients (10.4%) with denied claims for the non-preferred generic enoxaparin and the remaining balance of patients with denied index claims were for DOACs (n=86, 89.6%). It appears only 5 DOAC claims were subsequently paid for one of the preferred agents; 1 for enoxaparin and 4 for warfarin.

Table 5 also displays potential anticoagulation therapy disruptions after encountering a denied claim. Only 55 of the 96 (57.3%) denied patients received an anticoagulant within 14 days of the original denied claim. There were a total of 41 patients who did not receive an anticoagulant within 14 days. Twelve of these patients had a claim paid between 14 and 90 days after the denied index claim, while 29 patients received an anticoagulant after 90 days or not at all prior to December 31, 2014. Among the patients who received an anticoagulant between 14 and 90 days, the average number of days from the denied claim was 38.5 (15-89 days). No claims for enoxaparin were paid beyond 14 days, and all of the DOACs had similar percentages of subsequent paid claims within the 14-90 day period.

Table 5. Drug Distribution

Total n=1007	**Index Drug Paid Claims**	**Total Index Drug Denied Claims**	*Index denied by **subsequent** paid anticoagulant claim*		
			≤ 14 days Mean = 4.7 (1-14)	*Between 14-90 days Mean= 38.5 (15 – 89.5)*	*>90 days or never*
Generic Name	**n=911**	**n=96**	*55*	*12*	*29*
ENOXAPARN	233 (25.6%)	10 (10.4%)	*11 (20.0%)*	*0 (0%)*	*NA*
WARFARIN	658 (72.2%)	0 (0%)	*4 (7.3%)*	*2 (16.7%)*	*NA*
DABIGATRAN	7 (0.8%)	24 (25.0%)	*12 (21.8%)*	*3 (25.0%)*	*NA*
RIVAROXABAN	12 (1.3%)	52 (54.2%)	*26 (47.3%)*	*3 (25.0%)*	*NA*
APIXABAN	1 (0.1%)	10 (10.4%)	*2 (3.6%)*	*4 (33.3%)*	*NA*

Table 6 shows the PA status for patients with a denied index claim by the drug requested, not by the originally denied index drug. A total of 56 PAs were requested for 54 patients, with 100% approval. Of the 56 total PA requests, 87.5% (n=49) were for one of the DOACs, and only 12.5% (n=7) for generic enoxaparin.

Table 6. Prior authorization status for patients with denied index claim, by *drug requested (not index drug)*

		PA Requested*	PA Approved	PA Denied
HSN	Generic	**54 (56.3%)**	**54 (100%)**	**0**
007878	ENOXAPARN	7	7	-
002812	WARFARIN	0	0	-
035604	DABIGATRAN	13	13	-
035915	RIVAROXABAN	33	33	-
037792	APIXABAN	3	3	-

**Requests made 5 days prior or ≤14 days after index claim*

Table 7 displays the diagnoses for the 20 patients with paid DOAC index claims. All 20 patients had claims with ICD-9 codes for FDA labeled indications. FDA indicated diagnoses found among the DOAC patients included atrial dysfunction, thromboembolic events, orthopedic procedures, and ACS. However, among the 20 patients with paid DOAC claims, a cumulative of 14 contraindications or precautions were found. These primarily included valvular dysfunction, hepatic impairment, and kidney disease. Table 7 also shows that there was 1 adverse event post-index date among the 20 paid DOAC claims.

Table 7. Associated diagnoses for patients with paid DOAC index claims (n=20)

	DABIGATRAN	RIVAROXABAN	APIXABAN
	7	12	1
FDA Indications			
Atrial Dysfunction	3 (42.9%)	2 (16.7%)	-
Thromboembolic Events	-	5 (41.7%)	1 (100%)
Orthopedic Procedures	-	5 (41.7%)	-
Acute Coronary Syndrome	4 (57.1%)	-	-
Contraindications or Precautions			
Valve Replacement	-	-	-
Valvular Disease/Dysfunction	-	1 (8.3%)	1 (100%)
Cardiac	-	-	-
Cranial Bleeding	-	-	-
Gastrointestinal	1 (14.3%)	1 (8.3%)	-
Hematologic and Circulatory	-	2 (16.7%)	-
Hepatic	1 (14.3%)	1 (8.3%)	-
Kidney Disease	2 (28.6%)	2 (16.7%)	1 (100%)
Other	1 (14.3%)	-	-
Adverse Events			
Unspecified Hemorrhage	-	1 (8.3%)	-

Table 8 displays additional details about the patients with denied DOAC index claims who did not have a subsequent paid anticoagulant within 14 days (n=41). The numbers listed in Table 8 are cumulative counts. Thirty-two patients (78.0%) had FDA labeled indications for anticoagulation. However, 18 of these 41 patients (43.9%) had contraindications or precautions to DOAC therapy and 6 of the 41 patients (17.1%) had an adverse event post-index date.

Table 8. Associated diagnoses for patients with denied DOAC index claims and no anticoagulant within 14 days (n=41)

	Denied DOAC with subsequent claim between 14-90 days after denial	Denied DOAC with subsequent paid anticoagulant claim >90 days or never
	12	**29**
FDA Indications		
Atrial Dysfunction	9 (75.0%)	7 (24.1%)
Thromboembolic Events	3 (25%)	10 (34.4%)
Orthopedic Procedures	-	4 (13.8%)
Acute Coronary Syndrome	2 (16.7%)	-
Contraindications or Precautions		
Valve Replacement	2 (16.7%)	1 (3.4%)
Valvular Disease/Dysfunction	2 (16.7%)	1 (3.4%)
Cardiac	1 (8.3%)	1 (3.4%)
Cranial Bleeding	1 (8.3%)	-
Gastrointestinal	-	1 (3.4%)
Hematologic and Circulatory	3 (25%)	2 (6.9%)
Hepatic	2 (16.7%)	7 (24.1%)
Kidney Disease	4 (33.3%)	4 (13.8%)
Other	-	-
Adverse Events		
Thrombophlebitis of deep veins of upper extremities	1 (8.3%)	-
Acute Myocardial Infarction	1 (8.3%)	-
Cerebral artery occlusion with cerebral infarction	-	4 (13.8%)

Table 9 quantifies the amount of anticoagulant switching among patients with paid claims (n=911). Most patients were new anticoagulant starts (n=574, 63%) or continuation of previous therapy (n=312, 34.2%). Anticoagulant switches were rare overall (n=35, 3.8%) and the majority of therapy switching occurred from one preferred agent to a different preferred agent (n=34, 97.1%). Only 1 patient was switched from a preferred agent to a DOAC. No patients were switched between DOACs or from one DOAC to a preferred agent.

Table 9. Anticoagulation Therapy Switching

Total Paid Claims (n = 911)	
New start	574 (63.0%)
Continuation of same therapy	312 (34.2%)
Continuation therapy switches	35 (3.8%)
Preferred to different preferred	34 (97.1%)
Preferred to DOAC	1 (2.9%)
DOAC to preferred	0 (0%)
DOAC to different DOAC	0 (0%)

Discussion:

The study demonstrated higher utilization of preferred agents, warfarin and enoxaparin. The vast majority of patient had index events that were initially paid. DOACs made up nearly 90% of the patients with denied index claims. In total, the number of patients with index events for DOACs accounted for only 9.5% of the total anticoagulant prescribing. Several reasons may be attributable to the overall low rate of DOAC prescribing, including lack of reversal agents, concerns with adherence, and cost issues.

Currently there are no direct reversal agents on the market for any of the DOACs. While one reversal agent was recently granted Fast Track designation by the FDA, with several more agents in phase II and III clinical trials, bleeding complications remain a large fear among providers.[14-17] Other concerns regarding DOAC use is the potential for poor adherence due to more frequent medication administration, fewer monitoring requirements, shorter half-lives and higher patient drug costs as compared with warfarin or enoxaparin.[16,17] As prescribers become more familiar with DOACs and guidelines evolve, there may be an increase in total number of DOAC prescriptions. Additionally, the increase in newly enrolled patients due to the Affordable Care Act may impact the number of DOAC prescriptions beyond what was shown in this study.

The PA policy was successful at limiting use of DOACs to FDA approved indications. However, DOAC claims were approved in patients with possible contraindications or precautions to use. The only absolute contraindications to DOACs are mechanical prosthetic heart valve, serious hypersensitivity reactions, and active pathological bleeding.[1-3] The findings are limited by the inability to determine whether the diagnoses from Table 3 ("Contraindications & Precautions for DOACs") found in the patient profiles occurred before or after the paid DOAC claim. Additionally, some conditions such as dosing for renal impairment , only require dose adjustments or temporarily holding a drug for an acute situation (i.e. acute kidney failure).[1] In some situations the severity of the condition from patient profiles were unclear (i.e. "chronic kidney disease, unspecified") and could affect the determination of appropriateness of using DOACs. Overall, the

identification of contraindications to DOACs among patients with paid claims indicates potential risk and a gap in the policy that should be considered to ensure that these agents are used appropriately.

The policy did not lead to frequent switching from one anticoagulant to another, which was a concern upon implementation. This data is particularly important since the switch from DOACs to other anticoagulants has been shown to increase risk of thrombosis.[1-3]

Overall, if requested, 100% of anticoagulation PAs were approved. However, only 54 (56.3%) patients who were originally denied an anticoagulant had a PA later requested. This number is alarmingly low, but is consistent with trends from previous PA policy evaluations.[18] Additionally, it was discovered that only 57.3% of the patients with originally denied claims received subsequent anticoagulation therapy within 14 days of the denied claim. Furthermore, 12.5% of the denied patients didn't receive an anticoagulant until 14-90 days later and nearly one-third of patients did not receive an anticoagulant within 90 days or at all after having a denied claim. This signifies that many patients with an indication for anticoagulation therapy were potentially at risk for thrombotic events. The high number of patients not receiving anticoagulation within an appropriate time period was not due to PA denial, but rather due to PAs not having been requested at all by providers. This may be a consequence of the burdens associated with submitting a PA request, including time and administrative costs.[19]

Thrombotic risk is increased in patients who are not properly anticoagulated within an appropriate amount of time.[6] Among the 41 patients not receiving anticoagulation within 14 days of the denied claim, profile reviews discovered a cumulative of 6 adverse clotting events that occurred post-index date. Adverse events included 1 patient with thrombophlebitis of deep veins of the upper extremities, 1 patient with an acute myocardial infarction, and 4 patients with cerebral artery occlusions with infarction. While the adverse event dates recorded did occur post-index claim and denial, it cannot be determined that lack of anticoagulation therapy directly contributed to these events since the event dates were compiled from claims data and not patient medical records. Some patients may have already had a high baseline risk for clotting events regardless of the presence or absence of anticoagulation therapy.

The FFS program originally implemented prior authorization criteria for DOACs to promote safe and effective anticoagulation therapy, while also directing prescribing toward lower cost agents. This study showed that the policy successfully approved claims for DOACs in patients with FDA labeled indications. However, findings from this study also suggest that the presence of a PA policy may be a concern in itself. The low rate of PA requests submitted by providers after having encountered a PA, along with the many patients who did not subsequently receive anticoagulation therapy within an appropriate time period are both factors potentially leading to increased risk of thrombotic events. The risk posed by the patients not receiving anticoagulation is high enough to consider making changes to the current PA policy.

Recommendation:

1. Given the high risk to patients from anticoagulation disruption, the high incidence of disruption among patients encountering the prior authorization requirement and the apparent low use of the DOACs it is recommended the clinical PA for DOACs be discontinued.
2. It is recommended that a Retrospective DUR program be developed to monitor appropriate dosing and use in the presence of contraindications, as these remain a concern.
3. It is recommended the class utilization be reviewed again in one year given the evolving evidence and new drugs in the class.

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