



Mark XXXX

DOB: 06/16/YYYY

Xarelto Case Review

Parameter	Findings	PDF Ref
First Name	Mark	9
Initial	A	9
Last Name	XXXX	9
DOB	06/16/YYYY	9
Medication Taken	Rivaroxaban (Xarelto)	83
Xarelto Start Date	05/02/YYYY	83
Dosage	15 mg, 20 mg	83
Xarelto Stop Date?	05/22/YYYY	484-486
	<i>*Reviewer's comment: Per available medical records last date of Xarelto use is noted on 05/22/YYYY after which the patient is on Coumadin.</i>	
Xarelto Adverse Events (Whether diagnosed with Uncontrolled bleeding events, Gastrointestinal Hemorrhage, Hematoma, Hemoglobin Decrease or any other major bleed)	Yes <ul style="list-style-type: none"> • Hemoptysis • Epistaxis • Pitting edema of bilateral lower extremity • Low red blood cell levels • Low hemoglobin levels • Ecchymosis 	437-443, 447, 487-489, 484-486
Date of Diagnosis of Adverse Events	05/07/YYYY: Brown productive cough - Epistaxis episode one day ago resolved on its own - Hemoptysis - Edema of bilateral lower extremity - Right greater than left - 2-3+ pitting edema - Low red blood cell and hemoglobin levels 05/12/YYYY: Right lower extremity swelling - Ecchymosis medial to incision site of right knee arthroplasty - 3 plus pitting edema 05/22/YYYY: Bilateral lower extremity edema	437-443, 447, 487-489, 484-486
Management of Bleeding?	<i>Not Available</i>	-
Other Anticoagulant Usage Before or After Xarelto	Before Xarelto: 03/09/2010-05/01/YYYY: Warfarin, Warfarin Sodium 7.5 mg After Xarelto: 06/11/YYYY-09/25/YYYY: Warfarin 7.5 mg	4, 81, 481-483, 475-477
Bleeding Caused by Previous Use Of Anti Coagulants	<i>Not Available</i>	-
INR Control Before Xarelto Intake	04/29/YYYY: INR: 0.97 04/30/YYYY: INR: 1.17 05/01/YYYY: INR: 1.35 (High)	190
Past Medical History	Medical history: Osteoarthritis, hypertension, atrial fibrillation, type 2 diabetes, gastric reflux, BPH, chronic anticoagulation with Coumadin, COPD	59-61, 511-512



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	Surgical history: Left knee arthroplasty, lumbar discectomy, hemorrhoid surgery, cholecystectomy	
History of Bleeding Disorder/Kidney Disorder/Liver Disorder	<i>Not Available</i>	-
Condition of the Patient Per Last Available Record	09/25/YYYY: Right knee tenderness - Right total knee lateral patellofemoral crepitation and Lateral Collateral Ligament (LCL) tendonitis – On Coumadin for atrial fibrillation	475-477
Patient Death?	No	

Pharmacy log: **Reviewer's comment: Pharmacy records are not available for review.*

Missing Medical Records:

What Records/Bills are Needed	Hospital/Medical Provider	Date/Time Period	Why we need the records/bills?	Is Record Missing Confirmatory or Probable?	Hint/Clue that records are missing
Pharmacy records	Unknown	04/29/YYYY-05/04/YYYY	To substantiate Xarelto usage details	Confirmatory	Placed on Xarelto 15 and 20 mg for deep vein thrombosis prophylaxis during hospitalization for right total knee arthroplasty (04/29/YYYY-05/04/YYYY)

Detailed Chronology

DATE	PROVIDER	OCCURRENCE/TREATMENT	PDF REF
03/09/2010-04/15/YYYY	<i>Multiple Providers</i>	<p>Visits For Multiple Medical Problems:</p> <p><i>*Reviewer's comment: Multiple visits have been combined in brief to know the condition of the patient prior to Xarelto intake.</i></p> <p>03/09/2010: (PDF Ref: 4) <i>Illegible notes</i> Colon screen - Colon polyp - Atrial fibrillation - Coumadin 7.5 mg - Stop Warfarin for 3 days _____</p> <p>03/23/2010: Colonoscopy: (PDF Ref: 9-10) Postoperative diagnosis:</p> <ul style="list-style-type: none"> • Obstructive sigmoid diverticulosis • A 2.5 to 3 cm colonic polyp on a short stalk. Biopsy of polyp obtained with difficulty. Unable to resect polyp due to marked constriction of colonic lumen secondary to a very advanced diverticular disease of the colon. Unable to pass the scope proximal to 	4, 9-10, 24, 17, 33, 515, 507, 54-58, 65, 201



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		<p>that point due to marked colonic narrowing</p> <p>Current medications include Digoxin, Warfarin</p> <p>Materials forwarded to pathology: Biopsy of polyp</p> <p>Outpatient Discharge Medication List: (PDF Ref: 24) Hold Warfarin (Coumadin) today 03/23/2010. May restart tomorrow after test.</p> <p>03/24/2010: Biopsy Report: (PDF Ref: 17) Final microscopic diagnosis: Colon polyp, mid sigmoid, biopsy:</p> <ul style="list-style-type: none"> • Edematous colonic mucosa with mild superficial hyperplasia • No adenomatous features or dysplasia <p>Barium Enema: (PDF Ref: 33) Clinical information: Incomplete colonoscopy</p> <p>Impression: Diverticulosis more pronounced distally. No convincing evidence of colon cancer.</p> <p>08/23/2010, 04/01/YYYY: (PDF Ref: 515, 507) Medication Sheet: Warfarin (Coumadin) 7.5 mg</p> <p>04/07/YYYY: (PDF Ref: 54-58) On Coumadin for atrial fibrillation which greatly limits what anti-inflammatories he can take - Medications: Digoxin 125 mcg, Warfarin 7.5 mg - To discuss the need for right total knee arthroplasty</p> <p>04/15/YYYY: Pre-Operative Assessment For Right Total Knee Arthroplasty: (PDF Ref: 65) Medications: Warfarin, Digoxin Coumadin stopped.</p> <p>X-Ray Chest: (PDF Ref: 201) Impression:</p> <ul style="list-style-type: none"> • Borderline cardiomegaly • COPD with mild scarring in the lung bases. There is no acute airspace disease 	
04/29/YYYY - 05/04/YYYY	Provider/Doctor	<p>Hospitalization For Right Total Knee Arthroplasty:</p> <p>04/29/YYYY: (PDF Ref: 59-61, 64, 125-129, 131, 162-163, 185, 536-538)</p> <p>Patient with known arthritis who has failed nonoperative management.</p>	59-61, 64, 125-129, 131, 162- 163, 185, 81, 202-



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		<p>Coumadin stopped one week ago.</p> <p>On the day of admission, the patient was admitted to XYZ Medical Center day surgery and was subsequently taken to the operating suite where he underwent right total knee arthroplasty under anesthesia, tolerated the procedure well, and was transferred to the post anesthesia care unit, and then to the orthopedics floor.</p> <p>While on the orthopedics floor, Statcare was consulted for medical management, and patient was started on the Coumadin protocol for deep venous thrombosis prophylaxis. On the first postoperative day, the Foley catheter, Hemovac drain and IV fluids were discontinued. The patient continued to progress well, and by the day of discharge he was ambulating, beginning to do activities of daily living, and felt to be stable for discharge to home.</p> <p>05/01/YYYY-05/03/YYYY: <i>(PDF Ref: 81, 202-203, 83, 198, 245)</i></p> <p>05/01/YYYY: Routine medication: Digoxin 125 mcg, Warfarin Sodium 7.5 mg</p> <p>CT chest: Suspicious but technically indeterminate for subsegmental pulmonary embolism with pulmonary infarction right lower lobe of the lung posterior basal segment.</p> <p>05/02/YYYY: Acute blood loss anemia –Transfuse. Transfused with 1 unit of blood.</p> <p>Changed to treatment dose Xarelto. Routine medication: Rivaroxaban 15 and 20 mg</p> <p>Labs: <i>(PDF Ref: 189-190)</i></p> <table border="1" data-bbox="475 1402 1396 1875"> <thead> <tr> <th>Parameters</th> <th>Hemoglobin</th> <th>Platelet count</th> <th>Prothrombin time</th> <th>INR</th> <th>Partial thromboplastin time</th> </tr> </thead> <tbody> <tr> <td>Reference range</td> <td>13.5-17.0 gm/dl</td> <td>140-400 1000/mm3</td> <td>11.5-15.0 seconds</td> <td>0.81-1.2</td> <td>23.5-37.5 seconds</td> </tr> <tr> <td>04/29/YYYY Y</td> <td>-</td> <td>-</td> <td>13.0</td> <td>0.97</td> <td>24.1</td> </tr> <tr> <td>04/30/YYYY Y</td> <td>10.0 (Low)</td> <td>185</td> <td>15.0</td> <td>1.17</td> <td>-</td> </tr> <tr> <td>05/01/YYYY Y</td> <td>8.8 (Low)</td> <td>172</td> <td>16.8 (High)</td> <td>1.35 (High)</td> <td>-</td> </tr> <tr> <td>05/02/YYYY Y</td> <td>7.8-9.1 (Low)</td> <td>158</td> <td>19.9 (High)</td> <td>1.69 (High)</td> <td>-</td> </tr> <tr> <td>05/03/YYYY</td> <td>8.7</td> <td>178</td> <td>-</td> <td>-</td> <td>-</td> </tr> </tbody> </table>	Parameters	Hemoglobin	Platelet count	Prothrombin time	INR	Partial thromboplastin time	Reference range	13.5-17.0 gm/dl	140-400 1000/mm3	11.5-15.0 seconds	0.81-1.2	23.5-37.5 seconds	04/29/YYYY Y	-	-	13.0	0.97	24.1	04/30/YYYY Y	10.0 (Low)	185	15.0	1.17	-	05/01/YYYY Y	8.8 (Low)	172	16.8 (High)	1.35 (High)	-	05/02/YYYY Y	7.8-9.1 (Low)	158	19.9 (High)	1.69 (High)	-	05/03/YYYY	8.7	178	-	-	-	203, 83, 245, 189-190, 198, 536-538
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Y	(Low)								
05/07/YYYY	Provider/Doctor	<p data-bbox="475 1178 862 1213">Triage Record For Knee Pain:</p> <p data-bbox="475 1245 1386 1482">Patient presents to Emergency Department (ED) complaining of right knee pain. Patient is post total knee replacement on 04/29, had a Pulmonary Embolism (PE) post operatively and was discharged 4 days ago. Patient has brown productive cough. No has redness, warmth and drainage to wound on right knee. Patient is on O2 at home. Patient states he had epistaxis episode 1 day ago resolved on its own. Patient was also placed on Xarelto while in the hospital for treatment of PE, but is no longer taking it now.</p> <p data-bbox="475 1514 1349 1650">The affected area is painful, has redness and swelling. Onset of symptoms over a period of days. Severity of symptoms is moderate. Symptoms progressed slowly. Associated symptoms: Has right knee post operative surgical incision drainage. Has hemoptysis.</p> <p data-bbox="475 1682 1365 1787">States that knee is draining more and smells bad. Patient states he went to family M.D. and he was told it was beyond him at this point and to come to Emergency Room (ER). Onset of symptoms was about 2 days ago.</p> <p data-bbox="475 1818 1354 1877">Nursing assessment: Pulmonary: Coughing up small amounts of sputum described as brownish.</p>	437-443						

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		<p>Review of systems: Circulatory: Irregular rhythm. Controlled rate. Musculoskeletal: Edema of bilateral lower extremities. Right greater than left. Right knee dressing has sanguinous fluid present. 2-3+ pitting edema. No cellulitis or lymphangitis.</p> <p>Has right knee post operative incisional drainage. Has brown sputum productive cough.</p> <p>Current medications:</p> <ul style="list-style-type: none"> • Digoxin 125 mcg • Rivaroxaban 15 mg tablet: Special instructions: Take 1 tablet oral twice a day • Rivaroxaban 20 mg tablet: Indication: Continue per SCIM; Special instructions: Take 1 tablet oral once a day <p>Primary diagnosis:</p> <ul style="list-style-type: none"> • Post-operative knee pain • Bilateral lower extremity edema • Chronic atrial fibrillation • Chronic anticoagulation therapy <p>Disposition: Discharge to home Condition at discharge: Stable</p> <p><i>*Reviewer's comment: In this visit it is mentioned that "Patient was placed on Xarelto for treatment of PE but is no longer taking it now". On contrary we note Rivaroxaban 15 and 20 mg in current medication list.</i></p>																			
05/07/YYYY	Provider/Doctor	<p>Labs:</p> <table border="1" data-bbox="548 1352 1325 1696"> <thead> <tr> <th>Parameter</th> <th>Value</th> <th>Reference range</th> </tr> </thead> <tbody> <tr> <td>Red Blood Cell (RBC)</td> <td>2.79 (Low)</td> <td>4.00-5.90 mill/cu mm</td> </tr> <tr> <td>Hemoglobin</td> <td>8.5 (Low)</td> <td>13.5-17.0 gm/dl</td> </tr> <tr> <td>Platelet count</td> <td>295</td> <td>140-400 1000/mm3</td> </tr> <tr> <td>Prothrombin time</td> <td>16.2 (High)</td> <td>11.5-15.0</td> </tr> <tr> <td>International Normalized Ratio (INR)</td> <td>1.29 (High)</td> <td>0.81-1.20</td> </tr> </tbody> </table>	Parameter	Value	Reference range	Red Blood Cell (RBC)	2.79 (Low)	4.00-5.90 mill/cu mm	Hemoglobin	8.5 (Low)	13.5-17.0 gm/dl	Platelet count	295	140-400 1000/mm3	Prothrombin time	16.2 (High)	11.5-15.0	International Normalized Ratio (INR)	1.29 (High)	0.81-1.20	447-448
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05/07/YYYY	Provider/Doctor	<p>X-Ray Chest:</p> <p>Indication: Cough, brown sputum</p> <p>Impression:</p> <ul style="list-style-type: none"> • New small right pleural effusion and mild right basilar atelectasis 	450																		



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DATE	PROVIDER	OCCURRENCE/TREATMENT	PDF REF
05/12/YYYY	Provider/Doctor	<ul style="list-style-type: none"> • Cardiomegaly, unchanged <p>Lower Extremity Ultrasound:</p> <p>Indication: Edema</p> <p>Impression: No evidence for right lower extremity deep venous thrombosis identified.</p>	467
05/12/YYYY	Provider/Doctor	<p>Visit For Right Knee Evaluation:</p> <p>Patient had a right total knee arthroplasty on April 29, YYYY. He suffered a pulmonary embolism postoperatively, which has slowed his recovery. He is currently doing Physical Therapy three days a week. He is here for staple removal.</p> <p>He is extremely frustrated with his situation today. He states he is having a lot of swelling into his right lower extremity. He states he has had some drainage coming from his incision, but describes it as bloody. He denies fevers or chills. He is on Xarelto, which his Primary Care Physician is managing that currently for the postoperative Deep Vein Thrombosis (DVT). He is also out of his pain medicine and is requesting additional pain medicine at this time. He is using a walker to ambulate.</p> <p>Physical exam: Right knee has a midline longitudinal incision that is well approximated and well healed without erythema or drainage. He does have evidence of ecchymosis medial to the incision site. Neurovascularly he is intact. He does have 3 plus pitting edema to his right lower extremity. There is no erythema. Homans is negative.</p> <p>Impression:</p> <ul style="list-style-type: none"> • Status post right total knee arthroplasty April 29, YYYY • Right lower extremity pitting edema <p>Plan: I discussed options with him and his wife in detail today. They are very worried about his condition given his postoperative pulmonary embolism. I think at this point it is best to send him for a Doppler of his right lower extremity to rule out DVT. We offered to take out his staples today and he did decline. We will plan on home health removing them the next time they see him.</p> <p>He is very upset and frustrated today. He wants to see Dr. XXXX to discuss his situation with him before we do anything else. He does request a prescription for Percocet so I did write him a prescription for Percocet 5 mg tablets and to dispense 60 of those with pain. He will follow-up this afternoon at 1 to see Dr. XXXX. No radiographs would be necessary. He will also be following up in Dr. XXXX' clinic in two weeks and that will be his four week follow-up and radiographs will be necessary at that time.</p>	487-489
05/20/YYYY	Unknown	Medication Sheets:	499



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		<ul style="list-style-type: none"> • Digoxin (Lanoxin) 125 mg • Xarelto 15 mg 	
05/21/YYYY	Provider/Doctor	<p>Telephone Conversation Regarding Swelling In Thigh:</p> <p>Problem: Patient has been discharged from ABC Physical Therapy (HH PT). They are concerned about the amount of swelling he has which extends to the thigh area. Lower leg is very tight. Possible cellulitis?</p> <p>Physician response: Worked patient in to see Harold E. XXXX, M.D. (HEC) on 05/22/YYYY.</p>	520
05/22/YYYY	Provider/Doctor	<p>Visit For Leg Swelling:</p> <p>Patient has some leg swelling. He has gained at least 20-30 pounds he feels like which is fluid retention. He has had his Hydrochlorothiazide increased.</p> <p>He remains on Xarelto. He has a little serous exudate from the knee. It does not appear to be true drainage. There is incomplete superficial wound healing. There are some uneven edges from the staples.</p> <p>His pain is lessening. He has some stiffness. He has trouble flexing the knee much past about 95 degrees today. He has gotten to 106 in Physical Therapy at home. He has finished Physical Therapy and is here considering outpatient therapy.</p> <p>Medications: He has a PE and is on Xarelto. Other medications are unchanged.</p> <p>Physical exam: The right knee is as described. The sutures are removed today as well as Steri-strip reapplied after cleansing the area with Peroxide. He will do outpatient therapy twice a week for four weeks. Return in four weeks for repeat clinical exam.</p> <p>Impression:</p> <ul style="list-style-type: none"> • Right total knee 04/29/YYYY complicated by post-operative pulmonary embolus • Bilateral lower extremity edema • Current use of Xarelto for recent PE <p>Recommendations: He is finishing home therapy. I recommend outpatient therapy. He will do local wound care three times a day with Peroxide. Return in three weeks for a wound check. Return early of course if unexpected problems arise.</p>	484-486
06/11/YYYY	Provider/Doctor	<p>Visit For Bilateral Lower Extremity Edema:</p> <p><i>History reviewed.</i></p>	481-483



DATE	PROVIDER	OCCURRENCE/TREATMENT	PDF REF
		<p>Patient is currently taking Coumadin.</p> <p>Medication: Digoxin 125 mcg, Warfarin 7.5 mg</p> <p>Impression:</p> <ul style="list-style-type: none"> • Status post right total knee April 29, YYYY complicated by a postoperative pulmonary embolus and currently on Coumadin • Bilateral lower extremity edema <p>Recommendations:</p> <ul style="list-style-type: none"> • Will continue doing Physical Therapy on his own at home • Electronically prescribed Amoxicillin to take for dental prophylaxis • Follow-up in seven to eight weeks per his request with Dr. XXXX 	
08/04/YYYY	Provider/Doctor	<p>Visit For Right Knee Sore:</p> <p>On Coumadin for Atrial Fibrillation (A. fib). His calf swells and his knee is sore posteriorly. He has great range of motion and the knee does not hurt. He is doing his Physical Therapy at home. He did not want to go to outpatient Physical Therapy.</p> <p>Current medications: On Coumadin, Digoxin</p> <p>Impression:</p> <ul style="list-style-type: none"> • Successful right total knee, 04/29/YYYY, with an intermittent ache • Post-operative PE - The patient is currently on Coumadin although he has previously been on Coumadin for atrial fibrillation <p>Recommendations: He is doing well overall. His pain should go away. He has good mobility. He will work on knee flexion. He will return here in three months for a range of motion check. He was given Lortab 5, #60, with no refills. I have encouraged him to make these the last pain pills necessary. He is to start to wean off these for night-time pain. I have urged him to use Tylenol for pain and Benadryl for sleep going forward after his Lortab is diminished. No X-rays are needed upon his return.</p>	478-480
09/25/YYYY	Provider/Doctor	<p>Visit For Right Knee Tenderness:</p> <p>This patient returns with tenderness in several areas of his right knee.</p> <p><i>History reviewed.</i></p> <p>He has calf soreness. He is still sore. He is doing Physical Therapy at home at this time. He has patellofemoral crepitation on the lateral side of the right knee. He hurts on the lateral side. He hurts in the medial epicondyle and medial pes. He is neurovascularly intact.</p> <p>He has been on Coumadin amongst other medicines.</p>	475-477



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		<p>Medications: Warfarin 7.5 mg tablet</p> <p>Physical exam: Gait today is cautious favoring the right lower extremity.</p> <p>Diagnostics:</p> <p>Radiographs: No radiographs today. Prior radiographs have shown a Smith and Nephew BCR knee on the right. The left knee shows a Zimmer knee.</p> <p>Impression:</p> <ul style="list-style-type: none"> • Right total knee lateral patella crepitation and Lateral Collateral Ligament (LCL) tendonitis • Smith and Nephew BCR right total knee 04/29/YYYY • Post-operative PE currently on Coumadin and placed on Coumadin for atrial fibrillation <p>Recommendations: He will work on quad strengthening exercises to minimize scar of the patella. He will be placed on a 14 day Medrol Dose Pack of Prednisone 4 mg and this is six days for two days, five pills for two days, and four pills for two days, etc until he uses the 42 pills up. No refills are given. Return in about six weeks for clinical exam and sunrise view. If still symptomatic, he may require arthroscopic intervention.</p>	
03/09/2010-09/25/YYYY	Multiple Providers	<p>Miscellaneous Records: Admission Record, Anesthesia Record, Assessment, Authorization, Checklist/Verification List, Consent, Discharge Instructions, Discharge Plan, Exercise Stress Test, Fax Sheets, Flow Sheet, Input / Output Record, Labs, Medical Bills, Medical Questionnaire, Medication Sheets, Myocardial Perfusion, Nursing Notes/Records, Orders, Others, Patient Education, Patient's Information, Prescription Record, Endoscopy, Progress Notes, RCA Stress Test With Stress Electrocardiogram (EKG), Referral Report, Rhythm Strips, Telephone Conversation, Ultrasound, Visit For Knee Sprain, X-Ray Reports</p> <p>PDF Ref: 1-3, 5-8, 11-16, 19, 20-23, 25-32, 34-50, 62-63, 66-80, 82, 84-124, 130, 132-161, 164-184, 186-188, 191-197, 199-200, 204-244, 246-436, 444-446, 449, 451-466, 468-474, 493-498, 500-506, 508-514, 516-519, 521-524, 528-529, 532-535, 543-547, 549, 555, 559-561, 564, 566-570, 572-575, 577-594</p> <p><i>*Reviewer's comment: The above records do not contain any significant details related to Xarelto Case Review hence combined and not elaborated.</i></p>	