

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY:</b>	Clotting Disorders, Arrhythmias, Stroke	<b>P&amp;T DATE:</b>	9/15/2020
<b>THERAPEUTIC CLASS:</b>	Cardiovascular	<b>REVIEW HISTORY:</b> (MONTH/YEAR)	9/19, 9/18, 5/17, 2/16, 5/15, 2/15, 11/14, 7/14, 2/13, 11/12, 9/12, 4/12, 5/11, 2/10, 1/10
<b>LOB AFFECTED:</b>	Medi-Cal		

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.*

## OVERVIEW

The below criteria, limits, and requirements for certain agents are in place to ensure appropriate use of those agents using standards of care as set by clinical practice guidelines, including but not limited to the Chest Guidelines. Areas include VTE/DVT, and other coagulopathies as well as anti-arrhythmic agents.

### Anticoagulant/Antiplatelet agents (Current as of 6/2019)

Therapeutic Class	Generic (Brand)	Strength	Form Limits	Avg Cost per month	Indication			Notes	
					Afib	VTE	PPX		
<b>Oral Anticoagulants</b>									
Target Specific Oral Anti-coagulants (TSOACs)	Rivaroxaban (Xarelto)	<b>Tablets:</b>							
		2.5 mg	PA	--				x	Reserved for patients with <b>stable</b> CAD or patients with symptomatic PAD with high risk of cardiovascular events. Mandatory Bleeding Risk assessment, and documentation of inadequate response/intolerance to dual antiplatelet therapy are required unless not indicated. Must be prescribed by a cardiologist.
		10 mg	QL, PA*	\$196.37	x	x	x		Max 35 tablets per 365 days
		15 mg	QL, PA*	\$462.19	x	x	x		Max 42 tablets per 3 months
		20 mg	QL, PA*	\$428.18	x	x	x		Max 30 tablets per 30 days
		<b>Starter Pack:</b>							
	15/20 mg	NF	--	x	x	x			
	Apixaban (Eliquis)	<b>Tablets:</b>							
		2.5 mg	QL; PA*	\$358.40	x	x	x		Max 70 tablets per 365 days
		5mg	QL; PA*	\$410.99	x	x	x		Max 74 tablets per 30 days
		<b>Starter Pack:</b>							
	5 mg	NF	--	x	x	x			
	Dabigatran (Pradaxa)	<b>Capsules:</b>							
		75 mg	NF	--	x				
110 mg		NF	--				x		
150 mg		QL	\$407.53	x	x	x		Max 60 capsules per 30 days	
<b>Tablets:</b>									

	Edoxaban (Savaysa)	15 mg	NF	--	x	x		
		30 mg	NF	--		x		
		60 mg	NF	\$370.87	x	x		
	Betrixaban (Bevyxxa)	<b>Capsules:</b>						
		40 mg	NF	--		x		
80 mg		NF	--		x			
Vitamin K Antagonists (VKA)	Warfarin	<b>Tablets:</b>						
		1 mg	--	\$6.94	x	x	x	--
		2 mg	--	\$6.11	x	x	x	--
		2.5 mg	--	\$7.92	x	x	x	--
		3 mg	--	\$5.14	x	x	x	--
		4 mg	--	\$5.56	x	x	x	--
		5 mg	--	\$5.47	x	x	x	--
		6 mg	--	\$5.66	x	x	x	--
	7.5 mg	--	\$5.57	x	x	x	--	
	10 mg	--	\$6.10	x	x	x	--	
	JANTOVEN	1 mg	NF	--	x	x	x	
		2 mg	NF	\$9.13	x	x	x	
		2.5 mg	NF	\$6.62	x	x	x	
		3 mg	NF	\$5.07	x	x	x	
		4 mg	NF	\$3.88	x	x	x	
	5 mg	NF	\$4.19	x	x	x		
	6 mg	NF	\$6.36	x	x	x		
	7.5 mg	NF	\$13.84	x	x	x		
	10 mg	NF	\$0.24	x	x	x		

\*\*Atrial Fibrillation (A. fib), Venous thromboembolism (VTE), Prophylaxis (PPX)

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Form Limits	Avg Cost per month	Notes/Restriction Language
<b>Injectable Agents</b>					
Unfractionated Heparin	Heparin Flush/ Heparin Vials	10 Unit/ml	--	--	--
		100 Unit/mL	--	--	--
		1,000 Unit/mL	--	--	--
		5,000 Unit/mL	--	\$26.45	--
		10,000 Unit/mL	--	\$2.90	--
		20,000 Unit/mL	--	--	--
Fractionated Heparin	Enoxaparin (Lovenox)	<b>Prefilled Syringes:</b>			No prior authorization is required if less than 10 days' supply as bridge therapy. Maximum of 2 syringes per day and 3 courses per 180 days. Submit PA for larger quantities.
		30 mg/0.3 mL	QL	\$52.32	
		40 mg/0.4 mL	QL	\$59.01	
		60 mg/0.6mL	QL	\$187.24	
		80 mg/0.8 mL	QL	\$202.08	
		100 mg/mL	QL	\$178.10	
		120 mg/0.8 mL	QL	\$366.03	
150 mg/mL	QL	\$370.95			

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Form Limits	Avg Cost per month	Notes/Restriction Language
Antiplatelet Agents	Aspirin	<b>Tablets:</b>			
		81 mg	--	--	--
		325 mg	--	--	--
		75 mg	--	\$2.13	--

	Clopidogrel (Plavix)	300mg	NF	--		
	Dipyridamole (Persantine)	<b>Tablets:</b>				
		25 mg	--		\$8.41	--
		50 mg	--		--	--
		75 mg	--		\$21.50	--
		<b>Solution:</b>				
		5 mg/ml (10 ml)	NF	--		
	Prasugrel (Effient)	<b>Tablets:</b>				
		5 mg	PA	--		Reserved for patients with weight <60kg. Reserved for patients status-post stent placement or medical management of ACS for patients intolerant of Clopidogrel or Ticagrelor, or who have concomitant Diabetes.
		10 mg	PA	\$25.80		Reserved for status post stent placement or medical management of acute coronary syndrome for patients intolerant to Clopidogrel or Ticagrelor
	Ticagrelor (Brilinta)	60mg	PA	--		Step therapy to 12 months of Dual Oral Antiplatelet Therapy (DAPT) with Clopidogrel, Ticagrelor, or Prasugrel.
		90 mg	PA, QL	\$360.20		Restricted to 60 tablets per month. Total concurrent Aspirin dose should not exceed 100 mg per day.
	Dipyridamole/ Aspirin (Aggrenox)	<b>Tablets:</b>				
		25mg-200 mg	PA	--		Restricted to secondary CVA prevention.
	Cilostazol (Pletal)	<b>Tablets:</b>				
		50 mg	--	--		--
		100 mg	--	--		--
	Vorapaxar (Zontivity)	<b>Tablets:</b>				
		2.08 mg	NF			

ANTI-ARRHYTHMIC AGENTS					
Generic Name (Brand Name)	Available Strengths	Form Limits	Avg Cost per month	Notes/Restriction Language	
<b>CLASS 0</b>					
Ivabradine (Corlanor)	<b>Tablets:</b>				
	5 mg	PA	\$365.99	Reserved for patients with LVEF<35%, NYHA Stage II-IV, resting HR greater than 70 bpm, and compliant use or contraindication to use of dose-optimized beta-blocker, ACE-I/ARB, and Aldosterone Antagonist.	
	7.5 mg	PA	\$422.65		
<b>CLASS I</b>					
Quinidine Sulfate	<b>Tablets:</b>				
	200 mg IR	--	\$4.43	--	
	300 mg IR	--	--	--	
	300 mg ER	--	--	--	
Quinidine Gluconate	<b>ER tablet</b>				
	324mg	--	\$248.49	--	
	<b>Injection:</b>				

	80 mg/mL	--	--	--
<b>Disopyramide Phosphate (Norpace, Norpace CR)</b>	<b>ER Capsule:</b>			
	100 mg	--	--	--
	150 mg	--	--	--
	<b>IR Capsule:</b>			
	100 mg	--	\$149.38	--
	150 mg	--	\$89.69	--
<b>Mexiletine</b>	<b>Capsule:</b>			
	150 mg	--	\$75.80	--
	200 mg	--	\$80.36	--
	250 mg	--	\$135.42	--
<b>Flecainide</b>	<b>Tablet:</b>			
	50 mg	--	\$15.30	--
	100 mg	--	\$24.29	--
	150 mg	--	\$15.62	--
<b>Propafenone (Rythmol, Rythmol SR)</b>	<b>IR Tablet:</b>			
	150 mg	--	\$14.74	--
	225 mg	--	\$21.41	--
	300 mg	--	\$68.96	--
	<b>ER Capsules:</b>			
	225 mg	--	\$193.56	--
	325 mg	--	\$290.37	--
<b>Ranolazine ER (Ranexa)</b>	<b>ER Tablet:</b>			
	500 mg	PA	\$302.36	Reserved for treatment failure or intolerance to 3 formulary alternatives including a beta-blocker, calcium channel blocker and long-acting nitrate.
	1000 mg	PA	\$582.44	
<b>CLASS II- (Beta Blockers): Seehypertension coverage policy</b>				
<b>CLASS III</b>				
<b>Amiodarone (Cordarone, Pacerone)</b>	<b>Tablet:</b>			
	100 mg	NF	\$57.55	
	200 mg	--	\$5.42	--
	400 mg	NF	\$218.94	
<b>Dofetilide (Tikosyn)</b>	<b>Capsules:</b>			
	125 mcg	NF	\$219.56	
	250 mcg	NF	\$205.58	
	500 mcg	NF	--	
<b>Dronedaron (Multaq)</b>	<b>Tablet:</b>			
	400 mg	PA	\$539.29	Reserved for patients 55 and younger or with treatment failure of Amiodarone and high risk of pulmonary fibrosis or optic neuropathy without NYHA class II-III heart failure with recent exacerbation, NYHA Class IV heart failure, or LVEF ≤ 35%
<b>Sotalol (Betapace, Betapace AF, Sotylize)</b>	<b>Tablet:</b>			
	80 mg Af	--	--	--
	80 mg	--	\$6.62	--
	160 mg Af	--	--	--
	160 mg	--	\$13.55	--
	120 mg Af	--	--	--
	120 mg	--	\$11.60	--
	240 mg	--	--	--
<b>Oral Solution:</b>				

	5 mg/ ml	NF	--	
<b>CLASS IV (Calcium Channel Blockers)- See hypertension coverage</b>				
<b>CARDIAC GLYCOSIDES</b>				
<b>Digoxin (Digitek, Digox, Lanoxin)</b>	<b>Oral Solution (60 ml):</b>			
	50 mcg/ ml	--	\$215.69	--
	<b>Tablet:</b>			
	125 mcg	--	\$13.62	--
	250 mcg	--	\$13.97	--
	<b>Lanoxin Tablets:</b>			
	62.5 mcg	NF	--	
	125 mcg	NF	--	
187.5 mcg	NF	--		
250 mcg	NF	--		

NF = Non-formulary

## ⊞ **CLINICAL JUSTIFICATION:**

Overall, Target Specific Oral Anti-coagulants (TSOACs) have similar treatment efficacy to Vitamin K Antagonists (VKAs), with lower risk of major bleeding. Patient specific treatment regimen is emphasized. CHEST Guideline recommends use of CHA2DS2-VASC to assess and identify the low risk patients to avoid antithrombotic treatment. NOACs are recommended over VKAs in patients with high risk of bleeding, except in patients with moderate to severe mitral stenosis or a mechanical heart valve. Current CHEST Guideline updates on the emphasis on weighing bleeding risks versus benefits of using anticoagulant agents have been considered in HPSJ formulary.

For Acute Coronary Syndrome (ACS), Clopidogrel and Prasugrel showed equal efficacy with the exception of the diabetic subgroup. These patients fared better on Prasugrel than Clopidogrel. Prasugrel is a more potent anti-platelet drug, and as a result, had more bleeding risk in studies, so much so, that it carries a black box warning for increased risk of intracranial bleed in patients with previous history of stroke or TIA. Therefore, Clopidogrel is the preferred agent.

HPSJ formulary is open and includes all classes of antiarrhythmic agents. One exception exists with respect to dronedarone. HPSJ restricts this to members with a trial history of amiodarone due to the heart failure risks that dronedarone might pose.

## ⊞ **EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION**

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

### **Vitamin K Antagonists**

#### **Warfarin (Coumadin, Jantoven)**

##### **Warfarin (Coumadin)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** Warfarin is the gold standard for anticoagulation management. It is the preferred agent for DVT treatment

### **Target Specific Oral Anticoagulants**

#### **Rivaroxaban (Xarelto), Apixaban (Eliquis), Dabigatran (Pradaxa), Edoxaban (Savaysa)**

##### **Rivaroxaban (Xarelto)**

- Coverage Criteria:**
  - Xarelto 2.5 mg:
    - σ Must be prescribed by a cardiologist.
    - σ Mandatory bleeding risk assessment.

- Reserved for patients with **stable** CAD or patients with symptomatic PAD with high risk of cardiovascular events.
  - No recent stroke or previous hemorrhagic or lacunar stroke
  - No severe heart failure
  - No advanced kidney disease
- Documentation of inadequate response/intolerance to dual antiplatelet therapy unless not indicated.
  - Refer to the 2016 ACC/AHA Guideline Update on Duration of Dual Antiplatelet Therapy in CAD Patients to check if patient is indicated
- Expected benefit must outweigh the bleeding and associated risks.
- Xarelto 20mg or 15mg: None (Quantity limits apply).
- Xarelto 10mg: Reserved for post-TKA/THA DVT Prophylaxis
- Limits:**
  - Xarelto 20mg: 30 tablets/month,
  - Xarelto 15mg: 42 tablets per 90 days
  - Xarelto 10mg: PA required
- Required Information for Approval:** For 10mg strength, submit documentation of eminent THA/TKA procedure.
- Other Notes:** none
- Non-Formulary: Xarelto Starter Pack**

**Apixaban (Eliquis)**

- Coverage Criteria:**
  - 5mg: None,
  - 2.5mg: Reserved for secondary prevention of DVT/PE post treatment, or as renally adjusted Atrial Fibrillation Treatment.
- Limits:**
  - 5mg: 74 per 30 days,
  - 2.5mg: PA required
- Required Information for Approval:** For renally adjusted Eliquis, Age, body weight, and Serum Creatinine are required for review.
- Other Notes:** Renally dose-adjusted Apixaban appropriate for members having any two of the following: Age ≥80 years, body weight ≤60 kg, or serum creatinine ≥1.5 mg/dL.
- Non-Formulary: Eliquis Starter Pack**

**Dabigatran (Pradaxa)**

- Coverage Criteria:** None
- Limits:** 150mg: 60 capsules/month
- Required Information for Approval:** N/A
- Other Notes:** Patients with poor renal function, use warfarin instead.
- Non-Formulary:** Pradaxa 75 mg and 110 mg, Savaysa

<b>Injectable Agents</b>
<b><i>Unfractionated Heparin, Enoxaparin (Lovenox)</i></b>

**Unfractionated Heparin**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

**Enoxaparin (Lovenox)**

- Coverage Criteria:** No prior authorization is required if < 10 days supply as bridge therapy. Maximum of 2 syringes per day and 3 courses per 180 days.
- Limits:** 2 syringes per day for 10 day supply, 3 courses per 180 days.
- Required Information for Approval:** N/A
- Other Notes:** Please submit PA if used for any other indication than bridge to warfarin, if total days' supply exceeds 10. Include chart notes with diagnosis and treatment course.

<b>Antiplatelet Agents</b>
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***Aspirin, Clopidogrel (Plavix), Cilostazol (Pletal), Ticagrelor (Brilinta), Prasugrel (Effient), Dipyridamole (Persantine), Dipyridamole/Aspirin (Aggrenox), Vorapaxar (Zontivity)***

***Aspirin, Clopidogrel (Plavix), Cilostazol (Pletal), Dipyridamole (Persantine)***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Dipyridamole 5 mg/ ml solution, Vorapaxar (Zontivity)

***Ticagrelor (Brilinta)***

- Coverage Criteria:** None (Quantity limits apply)
- Limits:**
  - o 90mg: 60 tablets/month,
  - o 60mg: Step therapy to 12 months of DAPT Therapy.
- Required Information for Approval:** N/A
- Other Notes:** none

***Prasugrel (Effient)***

- Coverage Criteria:** Reserved for patients status post stent placement or medical management of acute coronary syndrome for patients intolerant to Clopidogrel (Plavix)
- Limits:** Prasugrel 5 mg is reserved for patients with weight <60kg.
- Required Information for Approval:** Prior Authorization form with chart notes documenting treatment failure or intolerance to Clopidogrel (Plavix)
- Other Notes:** Prasugrel should not be used in patients with a previous history of CVA, due to increased risk of bleed. Patients on Ticagrelor should not use more than 100mg aspirin daily.

***Dipyridamole/Aspirin (Aggrenox)***

- Coverage Criteria:** Restricted to secondary CVA prevention.
- Limits:** None
- Required Information for Approval:** Prior Authorization form and chart notes documenting a history of previous CVA.
- Other Notes:** None

***Antiarrhythmic Agents***

***Quinidine Sulfate/Gluconate, Disopyramide Phosphate, Mexiletine, Flecainide, Propafenone (Rythmol), Amiodarone (Cordarone, Pacerone), Sotalol, Dofetilide (Tikosyn), Dronedarone (Multaq), Digoxin***

***Quinidine Sulfate/Gluconate, Disopyramide Phosphate, Mexiletine, Flecainide, Propafenone, Sotalol***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

***Amiodarone***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Amiodarone 100 mg and 400 mg, Tikosyn

***Dronedarone***

- Coverage Criteria:** It is reserved for patients younger than 55 years of age or treatment failure or intolerant to amiodarone or for patients with high risk of pulmonary fibrosis or high risk of optic neuropathy, AND without NYHA Class II or III heart failure with exacerbation/hospitalization within the previous 4 weeks, NYHA Class IV HF, or LVEF ≤ 35%.
- Limits:** None

- Required Information for Approval:** Documented treatment failure of amiodarone, chart notes documenting current ejection fraction (if applicable), and no recent hospitalization within the past 4 weeks as evidenced by HPSJ records.
- Other Notes:** Claims for members older than 55 will pass through; no prior authorization is required.

### **Digoxin**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

## **REFERENCES**

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## # REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Plavix_PVD and Stent Rvw w TC 1-15-08_2.doc	1/2010	Allen Shek PharmD BCPS
Update to Policy	Plavix study 2-8-10.docx	2/2010	Allen Shek PharmD BCPS
Update to Policy	Multaq 5-4-11.doc	5/2011	Allen Shek PharmD BCPS
Update to Policy	Antiplatelet Class Review 2-12-10.docx	4/2012	Allen Shek PharmD BCPS
Update to Policy	Rivaroxaban Monograph V6.doc	9/2012	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment 9-18-12.xlsx	9/2012	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment PT 11-20-12.xlsx	11/2012	Allen Shek PharmD BCPS
Update to Policy	Xarelto revisit 2013-2-19.docx	2/2013	Allen Shek PharmD BCPS
Update to Policy	Ticagrelor Drug Monograph 204-05-29.docx	7/2014	Jonathan Szkotak, PharmD BCACP
Update to Policy	Apixaban Monograph 11-2014.docx	11/2014	Jonathan Szkotak, PharmD BCACP
Update to Policy	Anti-coagulants 2-17-2015.docx	2/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Clotting Disorders 2015-05.docx	5/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Clotting Disorders, Arrhythmias, Stroke 2016-05.docx	2/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Clotting Disorders, Arrhythmias, Stroke 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Clotting Disorders, Arrhythmias, Stroke 2018-09.docx	9/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Clotting Disorders, Arrhythmias, Stroke 2019-09.docx	9/2019	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Clotting Disorders, Arrhythmias, Stroke 2020-09.docx	9/2020	Matthew Garrett, PharmD

*Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy*