

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Colchicine Agents

Clinical Criteria Information Included in this Document

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

Initial publication and presentation to DUR Board



Colchicine Agents

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
LODOCO 0.5 MG TABLET	54457



Colchicine Agents

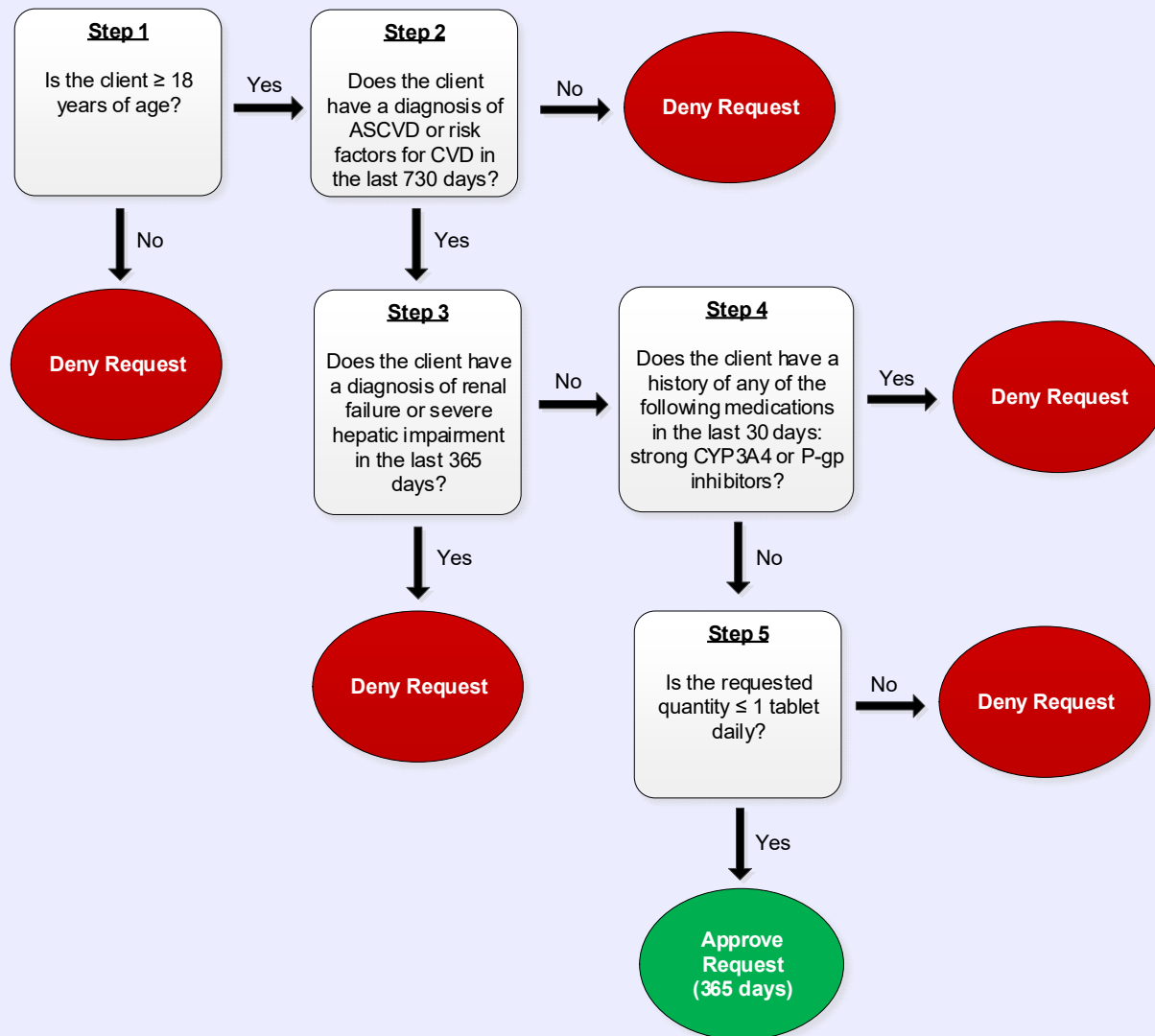
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of **ASCVD or risk factors for cardiovascular disease** in the last 730 days?
 Yes (Go to #3)
 No (Deny)
3. Does the client have a diagnosis of **renal failure or severe hepatic impairment** in the last 365 days?
 Yes (Deny)
 No (Go to #4)
4. Does the client have a history of the following medications in the last 30 days:
strong CYP3A4 or P-gp inhibitors?
 Yes (Deny)
 No (Go to #5)
5. Is the quantity requested less than or equal (\leq) to 1 tablet daily?
 Yes (Approve – 365 days)
 No (Deny)



Colchicine Agents

Clinical Criteria Logic Diagram





Colchicine Agents

Clinical Criteria Supporting Tables

Step 2 (diagnosis of ASCVD or risk factors for CVD)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
E7801	FAMILIAL HYPERCHOLESTEROLEMIA
E782	MIXED HYPERLIPIDEMIA
E785	HYPERLIPIDEMIA, UNSPECIFIED
I10	ESSENTIAL (PRIMARY) HYPERTENSION
I2101	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT MAIN CORONARY ARTERY
I2102	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT ANTERIOR DESCENDING CORONARY ARTERY
I2109	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF ANTERIOR WALL
I2111	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING RIGHT CORONARY ARTERY
I2119	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF INFERIOR WALL
I2121	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT CIRCUMFLEX CORONARY ARTERY
I2129	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER SITES
I213	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF UNSPECIFIED SITE
I214	NON-ST ELEVATION (NSTEMI) MYOCARDIAL INFARCTION
I240	ACUTE CORONARY THROMBOSIS NOT RESULTING IN MYOCARDIAL INFARCTION
I248	OTHER FORMS OF ACUTE ISCHEMIC HEART DISEASE
I70201	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70202	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70203	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70208	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70209	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY
I70211	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, RIGHT LEG

Step 2 (diagnosis of ASCVD or risk factors for CVD)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
I70212	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, LEFT LEG
I70213	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, BILATERAL LEGS
I70218	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, OTHER EXTREMITY
I70219	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, UNSPECIFIED EXTREMITY
I70221	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, RIGHT LEG
I70222	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, LEFT LEG
I70223	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, BILATERAL LEGS
I70228	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, OTHER EXTREMITY
I70229	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, UNSPECIFIED EXTREMITY
I70231	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF THIGH
I70232	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF CALF
I70233	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF ANKLE
I70234	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70235	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF FOOT
I70238	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF LOWER RIGHT LEG
I70239	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I70241	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF THIGH
I70242	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF CALF
I70243	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF ANKLE
I70244	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70245	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF FOOT
I70248	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF LOWER LEFT LEG

Step 2 (diagnosis of ASCVD or risk factors for CVD)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
I70249	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I7025	ATHEROSCLEROSIS OF NATIVE ARTERIES OF OTHER EXTREMITIES WITH ULCERATION
I70261	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, RIGHT LEG
I70262	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, LEFT LEG
I70263	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, BILATERAL LEGS
I70268	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, OTHER EXTREMITY
I70269	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, UNSPECIFIED EXTREMITY
I70291	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70292	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70293	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70298	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70299	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY

Step 3 (diagnosis of renal failure or severe hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
B251	CYTOMEGALOVIRAL HEPATITIS
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS

Step 3 (diagnosis of renal failure or severe hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS, WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS, WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED

Step 3 (diagnosis of renal failure or severe hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K760	FATTY (CHANGE OF) LIVER, NOT ELSEWHERE CLASSIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K762	CENTRAL HEMORRHAGIC NECROSIS OF LIVER
K763	INFARCTION OF LIVER
K764	PELIOSIS HEPATIS
K765	HEPATIC VENO-OCCLUSIVE DISEASE
K766	PORTAL HYPERTENSION
K767	HEPATORENAL SYNDROME
K7681	HEPATOPULMONARY SYNDROME
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE
M3214	GLOMERULAR DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS
M3215	TUBULO-INTERSTITIAL NEPHROPATHY IN SYSTEMIC LUPUS ERYTHEMATOSUS
M3504	SICCA SYNDROME WITH TUBULO-INTERSTITIAL NEPHROPATHY
N186	END STAGE RENAL DISEASE

Step 3 (history of a strong CYP3A4 or P-gp inhibitor)	
Number of claims: 1	
Look back timeframe: 30 days	
Description	GCN
ATAZANAVIR SULFATE 150MG CAP	19952
ATAZANAVIR SULFATE 200MG CAP	19953
ATAZANAVIR SULFATE 300MG CAP	97430
CLARITHROMYCIN 125 MG/5 ML SUS	11670
CLARITHROMYCIN 250 MG TABLET	48852
CLARITHROMYCIN 250 MG/5 ML SUS	11671
CLARITHROMYCIN 500 MG TABLET	48851
CLARITHROMYCIN ER 500 MG TAB	48850
CYCLOSPORINE 100 MG CAPSULE	13910

Step 3 (history of a strong CYP3A4 or P-gp inhibitor)	
Number of claims: 1	
Look back timeframe: 30 days	
Description	GCN
CYCLOSPORINE 100 MG/ML SOLN	13917
CYCLOSPORINE 25 MG CAPSULE	13911
CYCLOSPORINE MODIFIED 100 MG	13919
CYCLOSPORINE MODIFIED 25 MG	13918
CYCLOSPORINE MODIFIED 50 MG	13916
DARUNAVIR 600MG TABLET	99434
DARUNAVIR 800MG TABLET	33723
EVOTAZ 300MG-150MG TABLET	37797
GENGRAF 100MG CAPSULE	13919
GENGRAF 100MG/ML SOLUTION	13917
GENGRAF 25MG CAPSULE	13918
GENVOYA TABLET	40092
ITRACONAZOLE 100 MG CAPSULE	49101
ITRACONAZOLE 10MG/ML SOLUTION	49100
KALETRA 100-25 MG TABLET	99101
KALETRA 200-50 MG TABLET	25919
KALETRA 400-100/5 ML ORAL SOLU	31782
KETOCONAZOLE 200 MG TABLET	42590
KORLYM 300MG TABLET	31485
KRAZATI 200 MG TABLET	53379
LANSOPRAZOL-AMOXICIL-CLARITHRO	64269
LOPINAVIR-RITONAVIR 100-25MG TAB	99101
LOPINAVIR-RITONAVIR 200-50MG TAB	25919
LOPINAVIR-RITONAVIR 80-20MG/ML	31782
NEFAZODONE 100MG TABLET	16406
NEFAZODONE 150MG TABLET	16407
NEFAZODONE 200MG TABLET	16408
NEFAZODONE 250MG TABLET	16409
NEFAZODONE 50MG TABLET	16404
NEORAL 100MG GELATIN CAPSULE	13919
NEORAL 100MG/ML SOLUTION	13917
NEORAL 25MG GELATIN CAPSULE	13918
NOXAFIL 300MG POWDERMIX SUSP	49744
NOXAFIL 40MG/ML SUSPENSION	26502
NOXAFIL DR 100MG TABLET	35649

Step 3 (history of a strong CYP3A4 or P-gp inhibitor)	
Number of claims: 1	
Look back timeframe: 30 days	
Description	GCN
NUEDEXTA 20-10 MG CAPSULE	29290
OMECLAMOX-PAK COMBO PACK	32137
PAXLOVID 150-100 MG PACK (EUA)	52199
PAXLOVID 300-100 MG PACK (EUA)	51742
POSACONAZOLE 200MG/5ML SUSP	26502
POSACONAZOLE DR 100MG TABLET	35649
PREZCOBIX 800-150MG TABLET	37367
PREZISTA 100MG/ML SUSPENSION	31201
PREZISTA 150MG TABLET	23489
PREZISTA 600MG TABLET	99434
PREZISTA 75MG TABLET	16759
PREZISTA 800MG TABLET	33723
QUINIDINE GLUC ER 324 MG TABLET	01011
QUINIDINE SULFATE 200 MG TABLET	01053
QUINIDINE SULFATE 300 MG TABLET	01055
RANOLAZINE ER 1,000 MG TABLET	98733
RANOLAZINE ER 500 MG TABLET	26459
RECORLEV 150MG TABLET	51757
REYATAZ 200MG CAPSULE	19953
REYATAZ 300MG CAPSULE	97430
REYATAZ 50MG POWDER PACK	36647
RITONAVIR 100MG TABLET	28224
SANDIMMUNE 100MG CAPSULE	13910
SANDIMMUNE 100MG/ML SOLN	08220
SANDIMMUNE 25MG CAPSULE	13911
SPORANOX 10 MG/ML SOLUTION	49100
SPORANOX 100 MG CAPSULE	49101
SYMTUZA 800-150-200-10MG TAB	43968
TOLSURA 65MG CAPSULE	45848
TRANDOLAPR-VERAPAM ER 1-240 MG	32112
TRANDOLAPR-VERAPAM ER 2-180 MG	32111
TRANDOLAPR-VERAPAM ER 2-240 MG	32113
TRANDOLAPR-VERAPAM ER 4-240 MG	32114
TUKYSA 150MG TABLET	47931
TUKYSA 50MG TABLET	47929

Step 3 (history of a strong CYP3A4 or P-gp inhibitor)	
Number of claims: 1	
Look back timeframe: 30 days	
Description	GCN
TYBOST 150MG TABLET	36468
VERAPAMIL 120 MG TABLET	02341
VERAPAMIL 360 MG CAP PELLETT	03004
VERAPAMIL 40 MG TABLET	47110
VERAPAMIL 80 MG TABLET	02342
VERAPAMIL ER 120 MG CAPSULE	03003
VERAPAMIL ER 120 MG TABLET	32472
VERAPAMIL ER 180 MG CAPSULE	03001
VERAPAMIL ER 180 MG TABLET	32471
VERAPAMIL ER 240 MG CAPSULE	03002
VERAPAMIL ER 240 MG TABLET	32470
VERAPAMIL ER PM 100 MG CAPSULE	94122
VERAPAMIL ER PM 200 MG CAPSULE	94123
VERAPAMIL ER PM 300 MG CAPSULE	94124
VERELAN PM 100 MG CAP PELLETT	94122
VERELAN PM 200 MG CAP PELLETT	94123
VERELAN PM 300 MG CAP PELLETT	94124
VFEND 200MG TABLET	17498
VFEND 40MG/ML SUSPENSION	21513
VFEND 50MG TABLET	17497
VFEND IV 200 MG VIAL	17499
VIRACEPT 250 MG TABLET	40312
VIRACEPT 625 MG TABLET	19717
VORICONAZOLE 200MG TABLET	17498
VORICONAZOLE 40MG/ML	21513
VORICONAZOLE 50MG TABLET	17497
ZOKINVY 50MG CAPSULE	48901
ZOKINVY 75MG CAPSULE	48902
ZYDELIG 100 MG TABLET	36884
ZYDELIG 150MG TABLET	36885
ZYKADIA 150MG TABLET	46119



Colchicine Agents

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2023. Available at www.clinicalpharmacology.com. Accessed on December 5, 2023.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on December 5, 2023.
3. Lodoco Prescribing Information. Parsippany, NJ. AGEPHA Pharma USA, LLC. June 2023.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/26/2024	Initial publication and presentation to the DUR Board